SRI RAMACHANDRA

INSTITUTE OF HIGHER EDUCATION AND RESEARCH

(Deemed to be University)

Porur, Chennai - 600 116

REGULATIONS AND SYLLABUS

FOR

BACHELOR OF PHARMACY (B.Pharm) DEGREE PROGRAM

[Credit Based Semester System]

(Effective from the Academic year 2019–20)

Category of Courses -Bachelor of Pharmacy

SEMESTER	CORE COURSE(27)		Total Credits
	THEORY	**PRACTICAL**	
I	BP101T	BP107P	
	BP102T	BP108P	
	BP103T	BP109P	
	BP104T	BP110P	
	BP105T	BP111P	
	BP106RBT/ BP106RMT	BP112 RBT	
Total credits	**20**	**10**	**27/29$/30#**
II	BP201T	BP207P	
	BP202T	BP208P	
	BP203T	BP209P	
	BP204T	-	
	BP205T	BP210P	
	BP206T		
Total credits	**22**	**7**	**29**
III	BP301T	BP305P	
	BP302T	BP306P	
	BP303T	BP307P	
	BP304T	BP308P	
Total credits	**16**	**8**	**24**
IV	BP401T		
	BP402T	BP406P	
	BP403T	BP407P	
	BP404T	BP408P	
	BP405T	BP409P	
Total credits	**20**	**8**	**28**
V	BP501T		
	BP502T	BP506P	
	BP503T	BP507P	
	BP504T	BP508P	
	BP505T	-	
Total credits	**20**	**6**	**26**
VI	BP601T	BP607P	
	BP602T	BP608P	
	BP603T	BP609P	
	BP604T	-	
	BP605T	-	
	BP606T	-	
Total credits	**24**	**6**	**30**
VII	BP701T	BP705P	
	BP702T	-	
	BP703T	-	
	BP704T	-	
		BP705PS	
Total credits	**16**	**8**	**24**
VIII	BP801T	-	
	BP802T	-	
	BP803ET1/I,II,III, IV, V	-	
	BP804ET2/I,II,III, IV, V,VI	-	
	-	BP813PW	
Total Credits	**16**	**7**	**23**
Grand Total Credit Points			**211/213$/214#**

[$]Applicable ONLY for the students who studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course**.**

[#]Applicable ONLY for the students who studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course**.**

[$] [#]Credit points will be reflected in the final marks statement

REGULATIONS FOR BACHELOR OF PHARMACY DEGREE PROGRAM
[Credit Based Semester System]

INTRODUCTION

The Bachelor of Pharmacy degree program is a 4-year undergraduate program in pharmacy for students covering relevant topics and a research project in the key areas of Pharmacy including Pharmaceutics, Pharmacognosy, Pharmaceutical Chemistry, Pharmacology and Pharmacy Practice. The aim of this undergraduate program is to develop highly qualified professional leaders in pharmaceutical industry and health care systems enriched with excellent skills in communication, research and services.The SRI RAMACHANDRA INSTITUTE OF HIGHER EDUCATION AND RESEARCH (Deemed to be University) curriculum is aimed to provide a thorough training in the subject area through formal lectures, seminar and training programs.

PROGRAM OUTCOME

Upon completion of the B. Pharm programme, the candidate should be able to:

PO1: Demonstrate knowledge for in-depth analytical and critical thinking to identify, formulate and solve the issues related to Pharmaceutical Industry, Regulatory Agencies, Hospital Pharmacy & Community Pharmacy.

PO2: Develop an ability to solve, analyze and interpret data generated from Formulation Development, Quality Control & Quality Assurance.

PO3: Demonstrate skills to use modern pharmaceutical tools / software / equipments in drug discovery and development, analyze and solve problems in various sectors of Pharmacy profession.

PO4: Assume managerial roles in conflict management and apply interpersonal skills in working together thereby lead and function both individually and as a member of a team.

PO5: Appreciate and execute their professional roles in society as health care professionals,

employers and employees in pharma industries, regulators, researchers, educators and managers.

PO6: Adopt code of ethics in professional and social context and demonstrate exemplary professional, ethical and legal behaviors in decision making.

PO7: Apply written and oral communication skills to communicate effectively in patient care industry, academia and research.

PO8: Apply responsibilities to promote societal health and safety, upholding the trust given to the profession by the society.

PO9: Develop skills, attitude and values required for self-directed, lifelong learning and professional development.

In exercise of the powers conferred by rule 12.1 (iv) of the Memorandum of Association & Rules and clause 21 of Bye-Laws of, Porur, Chennai-600 116, the Academic Council of the University hereby makes the following Regulations:

1. SHORT TITLE AND COMMENCEMENT

These regulations may be called as “THE REGULATIONS AND SYLLABUS FOR BACHELOR OF PHARMACY DEGREE PROGRAM (CBSS) OF SRI RAMACHANDRA INSTITUTE OF HIGHER EDUCATION AND RESEARCH (Deemed to be University), PORUR, CHENNAI-600116”.

These regulations shall be deemed to have come into force from the academic year 2019- 20. These regulations are subject to such modifications as may be approved by the Academic Council from time to time.

2. ELIGIBILITY FOR ADMISSION

(a) A candidate applying for admission to the Bachelor of Pharmacy Degree Programme should have passed the HSC/CBSE/ISC or equivalent examination with the following subjects:

i. English, Physics, Chemistry, Mathematics and / or Biology or (Botany & Zoology) or equivalent PCI recognized qualification.

(b) **B. Pharm lateral entry (to third semester):**
A pass in D. Pharm. programme from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

2. 1. Age Limit for Admission

Every candidate should have completed the age of 17 years as on 31st December of the year of admission.

2. 2. Medical Fitness Certificate

A candidate shall, at the time of admission, submit to the Head of the Institution, a Certificate of Medical Fitness from an authorized Medical Officer certifying that the candidate is physically fit to undergo the academic program and does not suffer from any disability or contagious disease.

2. 3. Eligibility Certificate

Candidates who have passed any qualifying examination other than the Higher Secondary examination conducted by the Government of States concerned shall obtain by paying the prescribed fee, an Eligibility Certificate from SRI RAMACHANDRA INSTITUTE OF HIGHER EDUCATION AND RESEARCH (Deemed to be University), and produce it at the time of admission.

2. 4. Registration

A candidate admitted to the course shall register his/her name with the University by submitting application form for registration duly filled in, along with the prescribed fee, through the Head of the Institution within the stipulated date.

3. DURATION OF THE PROGRAM

The duration of the Bachelor of Pharmacy Degree Program shall be four academic years comprising eight semesters and six semesters (three academic years) for lateral entry students.

4. COMMENCEMENT OF THE PROGRAM

The program shall commence ordinarily from 1st July of the academic year.

i. Odd Semester – 1,3,5, 7	June / July – November/ December
ii. Even Semester – 2,4,6,8	November / December – April / May

5. CUT- OFF DATES FOR ADMISSION TO THE EXAMINATION

The candidates admitted from 1st July to 31st August of the academic year shall be registered to take their first semester examination, after fulfillment of the regulations concerned, in the month of November / December of that academic year (Table 8).

6. COMMENCEMENT OF THE EXAMINATIONS

There shall be two sessions of University examinations in an academic year, *viz*., April and November.The candidates admitted from 1st September to 30th September of the academic year shall be registered to take up their first semester examinations, after fulfillment of the regulations concerned, in the month of April of the next year, along with the second semester examinations.

7. MEDIUM OF INSTRUCTION

English shall be the medium of instruction for all subjects of study and examinations will be conducted only in English.

8. WORKING DAYS IN A SEMESTER

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/ December and the even semesters shall be conducted from November/December to April/May in every calendar year.

9. PROGRAM COMMITTEE

The B. Pharm. program shall have a Program Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
The composition of the Program Committee shall be as follows:
A senior teacher shall be the Chairperson; one teacher from each department handling B.Pharm courses; and four student representatives of the program (one from each academic year), nominated by the Head of the institution.

9.1. Duties of the Program Committee:

I. Periodically reviewing the progress of the classes.
II. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
III. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
IV. Communicating its recommendation to the Head of the institution on academic matters.
V. The Program Committee shall meet at least thrice in a semester preferably at the end of each sessional exam (Internal Assessment) and before the end semester exam.

10. CURRICULUM

The curriculum and the syllabus for the program shall be as prescribed from time to time by Pharmacy Council of India, New Delhi and approved by the Academic council of the University. It consists of course work, practical, industrial training, practice school and a group project.

STRUCTURE OF CURRICULUM

For UG Programs each course will be provided a structured syllabus in the following style:

Category	Credits	Syllabus units
Core Theory	4	5
Core Lab	2	10- 15 experiments
Core Project (GROUP)	7	

The program will be conducted on a credit based semester pattern as described below:

10.1. ACADEMIC WORK

A regular record of attendance both in theory and practical shall be maintained by the teaching staff of respective courses. The course of study for B. Pharm shall include semester wise theory & practical as given in Tables 9 to 16. In the VIII semester students in addition to the common theory courses shall register for any 2 electives (4 credits each) from among the ten offered (Table-17).

10.2. Submission of Practical Work Book

At the time of practical examination, each candidate shall submit to the examiners the practical workbook duly certified by the Head of the Institution as a bonafide record of work done by the candidate.

10.3. Industrial Training

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. This industrial training opportunity is offered after the Semester – VI and before the commencement of Semester – VII. Successful completion of the training is marked by submission of satisfactory report and certificate duly signed by the authority of training organization to the head of the institute at SRU.

10.4. Practice School

In the VII semester, every candidate shall undergo practice school for a period of 21 days (150 hours) evenly distributed throughout the semester and it carries 6 credits. The student shall be posted for clinical rotations/ ward round participation in the hospital settings for practice school as declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). One month before the commencement of university exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level (25 marks for CIA and 125 marks for qualifying exams with 75 for report preparation and 50 for presentation) and credits and grade point shall be awarded for the same.The marks obtained shall be sent to the office of the COE, 15 days prior to the commencement of VII semester University exam.The format is given below:

Table 2a. Evaluation of Practice School Report

Objective(s) of the work	15 Marks
Content development/Methodology	20 Marks
Collaboration & Teamwork	15 Marks
Conclusions and Outcomes	25 Marks
Total	75 Marks

Table 2b. Evaluation of Practice School Presentation

Presentation skills	20 Marks
Communication skills	10 Marks
Viva	20 Marks
Total	50 Marks

- The 75 marks assigned to the report shall be awarded to the students individually.
- 50 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.(Table 2b).
- 25 marks allotted for CIA is also evaluated by the internal expert.
- The marks will be sent to the Controller of Examinations 15 days before the commencement of University Examination.

11. CREDITS

The term credit is used to describe the quantum of syllabus for various courses in terms and hours of study. It indicates differential weightage given according to the contents and duration of the course in the curriculum design. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, For example, a course carrying one credit for lectures will have instruction of one period per week during the semester, if three hours of lecture is necessary in each week for that course, then 3 credits will be the weightage.

Illustration for Credit Allotment:

Credits will be assigned based on the lectures / laboratory work/ Practice School / Project and other form of learning in a 15weeks schedule over the duration of eight semesters.

- One credit for one hour lecture (L) and /or tutorial (T) hours per week. (1 credit = 15 hours)
- One credit for every two hours of laboratory or practical work (1 credit = 30 hours)
- One credit for three hours of clinics/project (1 credit = 45 hours)

Each course may consist of lectures / tutorial hours/ laboratory work / seminar / project work / practical training / report / viva voce. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

11.1. Minimum credit requirements

The minimum credit requirement for a four years Bachelor's programme shall be 211.The semester-wise credit distribution is given in Table: 3(as per the semester wise credits given by PCI syllabus) :

TABLE - 3: SEMESTER WISE CREDITS DISTRIBUTION

Semester	I	II	III	IV	V	VI	VII	VIII	**Total credits for the program**	Credits earned during their first Semester, as per PCI requirements for students eligible for admissions in B Pharmacy Program and not included for the CGPA	
										With Remedial Mathematics course	With Remedial Biology course
Credits	**27**	29	24	28	26	30	24	23	**211**	+2	+3

11. 2. Lateral entry

The lateral entry students shall get 52 credit points transferred from their D. Pharm program. Such students shall take up additional remedial courses as applicable in accordance with PCI.

12. GRADING SYSTEM

12.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given below

TABLE4: LETTER GRADES AND GRADE POINTS EQUIVALENT TO PERCENTAGE OF MARKS AND PERFORMANCES

Percentage of Marks Obtained	**Letter Grade**	**Grade Point**	**Performance**
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any university semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

12. 2. Computation of SGPA and CGPA:

12.2.1 The Semester Grade Point Average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester.

i. The SGPA is the ratio of sum of the product of the number of credits with the grade points scored by a student in all the courses taken by a student and the sum of the number of credits of all the courses undergone by a student, *i.e*.,

SGPA (Si) =∑(CixGi) /∑Ci

where Ci is the number of credits of the ith course and Gi is the grade point scored by the student in the ith course (as shown in Table 3 & 4).

ii. The CGPA is also calculated in the same manner taking into account all the courses undergone by a student over all the semesters of a programme, *i.e*.,

CGPA = ∑(Ci x Si) / ∑ Ci

where Si is the SGPA of the ith semester and Ci is the total number of credits in that semester (as illustrated in table 5). The SGPA and CGPA shall be rounded off to 2 decimal points and reported in the transcripts.

Illustration of Computation of SGPA and CGPA and Format for Transcripts

i. Computation of SGPA
ii. Computation of CGPA

TABLE - 5: ILLUSTRATION OF COMPUTATION OF SGPA

BACHELOR OF PHARMACY DEGREE PROGRAMME Semester I					
Category	**Course title**	**Credit Points(Ci)**	**Grade Letter**	**Grade Point(Gi)**	**Credit Point (Ci x Gi)**
BP101T	Human Anatomy and Physiology I– Theory	4	A	9	4 × 9 = 36
BP102T	Pharmaceutical Analysis I – Theory	4	B	8	4 × 8 = 32
BP103T	Pharmaceutics I – Theory	4	A	9	4 × 9 = 36
BP104T	Pharmaceutical Inorganic Chemistry – Theory	4	C	7	4 × 7 = 28
BP105T	Communication skills – Theory *	2	A	9	2 × 9 =18
BP107P	Human Anatomy and Physiology – Practical	2	B	8	2 × 8 =16
BP108P	Pharmaceutical Analysis I – Practical	2	A	9	2× 9 = 18
BP109P	Pharmaceutics I – Practical	2	C	7	2 × 7 =14
BP110P	Pharmaceutical Inorganic Chemistry – Practical	2	A	9	2 × 9 =18
BP111P	Communication skills – Practical*	1	B	8	1 × 8 = 8
	Total	**27**			**224**
BP106RBT	Remedial Biology/	2	B	8	**PASS**
BP112RBP	Remedial Biology – Practical*	1	**B**	8	**PASS**
Thus, SGPA = 224/ 27 = 8.29 (Si)					

It should be noted that, the SGPA for any semester shall **NOT** take into consideration the F and ABS grade awarded to courses in that semester and will have to be earned in subsequent appearances

TABLE – 6: ILLUSTRATION OF COMPUTATION OF SGPA AND CGPA AND FORMAT FOR TRANSCRIPTS

Semester 1	**Semester 2**	**Semester 3**	**Semester 4**
Credit: 27 SGPA: 9.74	Credit: 29 SGPA: 9.25	Credit: 24 SGPA: 9.21	Credit: 28 SGPA: 8.05
Semester 5	**Semester 6**	**Semester 7**	**Semester 8**
Credit: 26 SGPA: 9.74	Credit: 30 SGPA: 9.15	Credit: 24 SGPA: 8.21	Credit: 23 SGPA: 9.07
CGPA = $\frac{27 \times 9.74 + 29 \times 9.25 + 24 \times 9.21 + 28 \times 8.05 + 26 \times 9.74 + 30 \times 9.15 + 24 \times 8.21 + 23}{27+ 29 + 24 + 28 + 26 + 30 + 24 + 23} \times 9.07 = 9.06$			

The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s)is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.

13. EXAMINATIONS / ASSESSMENT

For the B.Pharm Program assessment will comprise of Internal Assessments (IA) and the End Semester University examination.

i. For all category of Core Theory courses offered, the assessment will comprise of Internal Assessments (IA) and the End Semester University examination (ES). For each course the total of 100% per course is determined from the IA evaluation weighted at 25% and the ES weighted at 75%.

ii. For the category of Core Lab – Practical courses offered, the assessment will comprise of Internal Assessments (IA) and the End Semester University examination (ES) weighted at 30 % and 70 % for each course.

iii. For the category of Non-University examination courses (*) offered, the assessment will comprise of Internal Assessments (IA) and the End Semester IA examination (EIA) weighted at 100% for each course.

iv. IA Marks shall be submitted to the University for each course separately by the Head of the department/ program co-ordinator 15 days prior to the commencement of the University examinations, through the Principal.

13.1. INTERNAL ASSESSMENT

(a) Internal assessment (25%) is the sum of sessional examination (15 marks for theory and 10 marks for Practical) and continuous mode of assessment (10 marks for theory and 5 marks for Practical) for all core subjects

(b) A minimum of two written internal assessment examinations shall be conducted in each subject during a semester and the average marks of these two examinations shall be taken into consideration for the award of internal marks.

(c) A minimum of two practical examinations shall be conducted in each core lab and the average marks of these two examinations shall be taken into consideration for award of internal marks in practicals.

(d) A candidate failed in any subject in the University examination shall be provided an opportunity to improve his/her sessional marks by conducting a minimum of two examinations in theory and two practicals separately.

(e) If a failed candidate does not appear for such "Improvement Examinations" for internal marks in the failed subject(s), the internal marks already secured by him/her shall be carried over for his subsequent appearance(s).

(f) The internal assessment marks shall be submitted to the University by the Principal 15 days prior to the commencement of the University examinations.

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

TABLE – 7: SCHEME FOR AWARDING INTERNAL ASSESSMENT: CONTINUOUS MODE

Theory		
Criteria	**Maximum Marks**	
	Out of 10	Out of 5
Attendance (Refer Table 8)	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher interaction	3	1.5
Total	**10**	**5**
Practical		
Attendance (Refer Table 8)	2	
Based on Practical Records, Regular viva voce, etc.	3	
Total	**5**	

TABLE – 8: GUIDELINES FOR THE ALLOTMENT OF MARKS FOR ATTENDANCE

Percentage of Attendance	Theory	Practical
95 – 100	4	2
90 – 94	3	1.5
85 – 89	2	1
80 – 84	1	0.5
Less than 80	0	0

13. 2. Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college (s). The scheme of question paper for theory and practical Sessional examinations is given below. The average marks of two Sessional exams shall be computed for internal assessment as per the requirements.

Sessional exam shall be conducted for 30 marks for theory and computed for 15 marks. Similarly, Sessional exam for practical shall be conducted for 40 marks and computed for 10 marks.

13. 3. PATTERN OF QUESTION PAPER FOR THEORY SESSIONAL EXAMINATIONS (IA)
(For subjects having University examination)

i) Question paper pattern for theory sessional examinations

I. Multiple Choice Questions (MCQs)
(Answer all the questions) = 10 x 1 = 10
I. Long Answers (Answer 1 out of 2) = 1 x 10 = 10
II. Short Answers (Answer 2 out of 3) = 2 x 5 = 10

Total = 30 marks
---

ii) Question paper pattern for practical sessional examinations

I. Synopsis = 10
II. Experiments = 25
III. Viva voce = 05

Total = 40 marks

Sessional exam for practical shall be conducted for 40 marks and computed for 10 marks.

13.4: NON-UNIVERSITY EXAMINATION COURSES

Non-University examination courses [asterix symbol (*)] the assessments are made from the IA component as well as an examination that shall be conducted by the subject experts at college level and the marks / grades shall be submitted to the Universitye.g, Communication skills, Remedial Biology / Remedial Mathematics; Computer applications etc.,

Scheme of Marks for the assessments:
The quantum of marks is based on any one of the patterns given below and as indicated in the Scheme of Curriculum and Evaluation table

Course Types	Theory 1	Theory 2	Practical	Practice School
CIA	15	25	10	25
Semester end exams	35	50	15	125
Total Marks	50	75	25	150

13.4.1. PATTERN OF QUESTION PAPER FOR NON- UNIVERSITY EXAMINATION

Theory Sessional tests: Question Paper Pattern:

I. Long Answers (Answer 1 out of 2) = 1 x 10 = 10
II. Short Answers (Answer 4 out of 6) = 4 x 5 = 20

Total = 30 marks

Sessional exam shall be conducted for 30 marks for theory and computed for 15 or 25 marks as applicable

13. 4. 2. Pattern for end semester assessments:

BACHELOR OF PHARMACY		
THEORY QUESTION PAPER PATTERN FOR NON – UNIVERSITY EXAMINATIONS (Theory Exam Assessment Pattern - SEMESTERS - I to VIII **For 50 marks** paper) (2 hours duration)		
University Examination Theory		
Section A		
Pattern & Choices	**Marks**	**Total Marks**
Essay questions 2 out of 3	2 x 10 marks	20
Total (a)		**20**
Section B		
Short notes question 6 out of 8	6 x 5 marks	30
Total (b)		**30**
Grand Total Section (a + b)		**50**

BACHELOR OF PHARMACY		
THEORY QUESTION PAPER PATTERN FOR NON-UNIVERSITY EXAMINATIONS (Theory Exam Assessment Pattern - SEMESTERS - I to VIII For **35 marks paper**) (1.5 hours duration)		
University Examination Theory		
Section A		
Pattern & Choices	**Marks**	**Total Marks**
Essay questions 1 out of 2	1x 10 marks	10
Total (a)		**10**
Section B		
Short notes question 5 out of 7	5 x 5 marks	25
Total (b)		**25**
Grand Total Section (a + b)		**35**

PRACTICAL

BACHELOR OF PHARMACY	
PRACTICAL QUESTION PAPER PATTERN FOR NON-UNIVERSITY EXAMINATIONS (Practical Exam Assessment Pattern - SEMESTERS - I to VIII **For 15 marks** paper) (1hour duration)	
University Examination Practical	
Pattern & Choices	**Total Marks**
I. Synopsis	5
II. Experiment	**5**
III. Viva voce	5
Total	**15**
Grand Total Section (I + II + III)	**15**

13.5. End semester University Examinations

The End Semester University Examinations for each theory and practical course through semesters I to VIII (Tables 9 to 16) shall be conducted by the University except for the category of Non-University examination courses [asterix symbol (*)]for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University.

13.5.1. Eligibility for Admission to Examinations

Attendance requirements:

(a) No candidate shall be permitted to appear for the University examinations, unless he/she attends the course for the prescribed period and produces the necessary certificate of attendance and satisfactory conduct from the Head of the Institution.

(b) Every candidate is required to put in a minimum of 80% of attendance both in theory and practical separately in each subject for admission to the examination.

(c) A candidate lacking in the prescribed attendance in any course in theory and /or practical shall not be permitted to appear for University end semester Examination for that course.

Internal assessment Marks:

For theory and practical courses a candidate should obtain a minimum of 40% of allotted marks (10 marks) in IA theory or practicals (6 marks) to be eligible to appear for University examination of each course in a semester.

"Candidates lacking 80% attendance and /or 40% marks in the IA component will be detained from appearing for the University end semester examination for the said courses ONLY"

13. 5. 2. PATTERN OF QUESTION PAPER FOR END SEMESTER UNIVERSITY EXAMINATION

UNIVERSITYEXAMPATTERN – THEORY

BACHELOR OF PHARMACY		
THEORY QUESTION PAPER PATTERN FOR UNIVERSITYEXAMINATIONS (Theory Exam Assessment Pattern - SEMESTER - I to VIII For 75 marks paper) (3 hours duration)		
University Examination Theory		
Section A		
Pattern & Choices	**Marks**	**Total Marks**
Essay questions 2 out of 3	2 x 10 marks	20
Total (a)		**20**
Section B		
Short notes question 7 out of 9	7x 5 marks	35
Total (b)		**35**
	Section C	
Multiple Choice Questions (MCQ) 20 No choice	20 x1 marks	20 (Time: 20 min)
Total (c)		**20**
Grand Total Section (a + b + c)		**75**

UNIVERSITY EXAM PATTERN - PRACTICAL

BACHELOR OF PHARMACY	
PRACTICALQUESTION PAPER PATTERN FOR UNIVERSITY EXAMINATIONS (Practical Exam Assessment Pattern - SEMESTERS - I to VIII For 35 marks) (4 hours duration)	
University Examination Practical	
Pattern & Choices	**Total Marks**
I. Synopsis	5
II. Experiments	25
III. Viva voce	5
Total	**35**
Grand Total Section (I + II + III)	**35**

14. CRITERIA FOR PASSING

14.1. Marks Qualifying for a Pass

A candidate shall be declared to have passed the examination if he/she obtains the following minimum qualifying marks:-

(a) 50% of marks in the University theory examinations and 50% of marks in the aggregate in theory and internal assessment taken together.

(b) 50% of marks in the University Practical examination and 50% marks in the aggregate in practical and internal assessment taken together (for internal assessment 40%minimum passing mark is necessary to attend University examinations)

(c) A candidate who has been declared as FAIL either in Theory or Practical has to reappear for the failed subject (Theory or Practical) only.

(d) 50% of marks for Project Work in University examination.

(e) 50% of marks for all courses indicated as Non- University Examination [Remedial Mathematics / Biology etc.].

A student shall complete all the training programmes before completion of the degree course.

Promotion and award of grades:

A student shall be declared PASS and eligible for getting grade in a course of B.Pharm. program if he/she secures at least 50% marks in that particular course including internal assessment. For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25marks for the total 50 including internal assessment and end semester practical examination.

14.2. CARRY-OVER OF FAILED SUBJECTS

No student shall be admitted to any examination unless he/she fulfills the norms given for attendance (80%). Academic progression rules are applicable as follows:

1. A student shall be eligible to carry forward all the courses of I, II and III semesters till the IV semester examinations. However, he/she shall not be eligible to attend the courses of V semester until all the courses of I and II semesters are successfully completed.

2. A student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of I, II, III and IV semesters are successfully completed.

3. A student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of I, II, III, IV, V and VI semesters are successfully completed.

4. A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to VIII semesters within the stipulated time period as per the norms specified under "Duration of completion of the program of study".

5. A lateral entry student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of III and IV semesters are successfully completed.

6. A lateral entry student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of III, IV, V and VI semesters are successfully completed.

7. A lateral entry student shall be eligible to get his/her CGPA upon successful completion of the courses of III to VIII semesters within the stipulated time period as per the norms specified under "Duration of completion of the program of study".

8. Any student who has given more than 4 chances for successful completion of I / III semester courses and more than 3 chances for successful completion of II / IV semester courses shall be permitted to attend V / VII semester classes ONLY during the subsequent academic year as the case may be. In simpler terms there shall NOT be any ODD BATCH for any semester.

Note: Grade AB should be considered as failed and treated as one head for deciding academic progression. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

15. END SEMESTER SUPPLEMENTARY EXAMINATIONS

If a student admitted to a course of study in this University is for any reason not able to complete the course or qualify for the degree by passing the examinations prescribed within a period comprising twice the duration prescribed in the Regulations for the concerned course, he /she will be discharged from the said course, his / her name will be taken off the rolls of the University and he / she will not be permitted to attend classes or appear for any examination conducted by the University thereafter.

TENTATIVE SCHEDULE OF END SEMESTER SUPPLEMENTARY EXAMINATIONS

Semester	Regular exams	Supplementary exams
I, III, V and VII	November / December	May / June
II, IV, VI and VIII	May / June	November / December

16. PROJECT WORK

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate to any one of the elective subjects opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. Individual allotment of candidate for project is not permissible. The project report shall be submitted in triplicate (typed & bound with not less than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students). The projects shall be evaluated as per the criteria given below.

Evaluation of Project Book:

Objective(s) of the work done		15 Marks
Methodology adopted		20 Marks
Results and Discussions		20 Marks
Conclusions and Outcomes		20 Marks
	Total	**75 Marks**

Evaluation of Presentation:

Presentation of work		25 Marks
Communication skills		20 Marks
Question and answer skills		30 Marks
	Total	**75 Marks**

Explanation: The 75 marks assigned to the project book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

The credit point assigned for extracurricular and or co-curricular activities shall be added to the Project work (6 credits for Project work and one credit for presentation or publication as a part of their project work).

17. CLASSIFICATION OF SUCCESSFUL CANDIDATES

The class shall be awarded based on the CGPA as follows:

CGPA	**Classification**	**Remarks**
≥ 7.50	First Class with Distinction	First attempt only
6.00 to 7.49	First Class	Class will be awarded only when the course is completed within the stipulated period. All others would be declared as '**PASS'**
5.00 to 5.99	Second Class	

All assessments of B. Pharm program on an absolute mark basis will be considered and passed by the respective results passing Boards in accordance with the rules of the University. Thereafter the Controller of Examinations shall convert the marks for each program to the corresponding letter grade as follows, compute the grade point average and cumulative grade point average, and prepare the grade and mark sheets. On satisfactory completion of the courses, a candidate earns credits.

18. RANKING OF CANDIDATES

The candidates who are eligible to get the B.Pharm degree in **FIRST CLASS WITH DISTINCTION** will be ranked together based on the CGPA for all the subjects of study from I to VIII Semester.The candidate passing with **FIRST CLASS** will be ranked next after those with distinction on the basis of CGPA for all the subjects of study from I to VIII Semester.

18. 1. AWARD OF RANKS

Ranks and Medals shall be awarded based on the final CGPA. However, candidates who fail in one or more courses during the B.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the B. Pharm program in minimum prescribed number of years, (four years) for the award of Ranks.

19. AWARD OF DEGREE

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

20. DURATION FOR COMPLETION OF THE PROGRAM OF STUDY

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students should pass within the said period, otherwise they have to get fresh Registration.

21. REVIEW OF ANSWER PAPERS OF FAILED CANDIDATES

As per the regulations prescribed for review of answer papers by the University.

22. MIGRATION / TRANSFER OF CANDIDATES

Application seeking Migration/Transfer of a candidate from any recognized institution to the Deemed University shall be considered subject to the regulations of the University.

23. RE-ADMISSION AFTER BREAK OF STUDY

The University regulations for readmission are applicable for a candidate seeking re-entry to a program.

a) Students admitted to a program and absenting for more than 3 months must seek readmission into the appropriate semester as per University norms.
b) The student shall follow the syllabus *in vogue* (currently approved / is being followed) for the program.
c) All re-admissions of students are subject to the approval of the Vice-Chancellor.

24. VACATION

The Head of the Institution shall declare vacation not exceeding six weeks in an academic year.

25. SCHEME OF CURRICULUM AND EVALUATION

The course of study for B. Pharm program shall include semester wise theory and practical. The scheme of curriculum and evaluation of the program for semesters I to VIII for all specializations are given in tables 9 to 16. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in the Tables.

B.PHARM Year 1 – Semester-I,
TABLE 9: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM

Course Number	Course Code	Category	Course Title		Credits (hours) / Week			Credits(C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) - Theory / Practical (a)	End Semester Examination (ESE)		Grand Total
					Lecture (L)	Tutorial(T)/ Clinical Training(CT)	Practical (P)/Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b Practical: a + c
1.	BP101T	CT	Human Anatomy and Physiology I		3	1	0	4	45	15	0	60	80	25	75	0	100
2.	BP102T	CT	Pharmaceutical Analysis		3	1	0	4	45	15	0	60	80	25	75	0	100
3.	BP103T	CT	Pharmaceutics I		3	1	0	4	45	15	0	60	80	25	75	0	100
4.	BP104T	CT	Pharmaceutical Inorganic Chemistry		3	1	0	4	45	15	0	60	80	25	75	0	100
5.	BP105T	CT	Communication Skills*		2	0	0	2	30	0	0	30	80	50 *	0	0	50
6.	BP107P	CL	Human Anatomy and Physiology I Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
7.	BP108P	CL	Pharmaceutical Analysis I Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
8.	BP109P	CL	Pharmaceutics I Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
9.	BP110P	CL	Pharmaceutical Inorganic Chemistry Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
10.	BP111P	CL	Communication Skills Practical *		0	0	2	1	0	0	30	30	80	25 *	0	0	25
11.	BP106RBT/BP106RMT	CT	Remedial Biology * # / Remedial Mathematics* $	-	2	0	0	2$ #	30	0	0	30	80	50 *	0	0	50
12.	BP112RBP	CL	Remedial Biology * #	-	0	0	2	1#	0	0	30	30	80	25 *	0	0	25
Year 1 – Semester-I			**Total**		16	4	20	30	240	60	300	600	-	310	300	140	750

* Non – University Examination (Theory - 25 marks for CIA and 35 marks for final qualifying exam; Practical – 10 marks for CIA and 15 marks for final qualifying exam)

B.PHARM Year 1 – Semester-II, 2019
TABLE 10: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title		Credits (hours) / Week			Credits(C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) - Theory / Practical (a)	End Semester Examination (ESE)		Grand Total
					Lecture (L)	Tutorial(T)/ Clinical Training(CT)	Practical (P)/Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b Practical: a + c
13.	BP201T	CT	Human Anatomy and Physiology II		3	1	0	4	45	15	0	60	80	25	75	0	100
14.	BP202T	CT	Pharmaceutical Organic Chemistry I		3	1	0	4	45	15	0	60	80	25	75	0	100
15.	BP203T	CT	Biochemistry		3	1	0	4	45	15	0	60	80	25	75	0	100
16.	BP204T	CT	Pathophysiology		3	1	0	4	45	15	0	60	80	25	75	0	100
17.	BP205T	CT	Computer Applications in Pharmacy*		3	0	0	3	45	0	0	45	80	75*	0	0	75
18.	BP206T	CT	Environmental Sciences*		3	0	0	3	45	0	0	45	80	75*	0	0	75
19.	BP207P	CL	Human Anatomy and Physiology II Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
20.	BP208P	CL	Pharmaceutical Organic Chemistry I Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
21.	BP209P	CL	Biochemistry Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
22.	BP210P	CL	Computer Applications in Pharmacy Practical*		0	0	2	1	0	0	30	30	80	25*	0	0	25
Year 1 – Semester-II			**Total**		18	4	14	29	270	60	210	540	-	320	300	105	725
* Non-University Examination (Theory - 25 marks for CIA and 50 marks for final qualifying exam; Practical – 10 marks for CIA and 15 marks for final qualifying exam)																	

B. PHARM Year 2 – Semester-III
TABLE 11: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM

Course Number	Course Code	Category	Course Title		Credits (hours) / Week			Credits(C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) - Theory / Practical (a)	End Semester Examination (ESE)		Grand Total
					Lecture (L)	Tutorial(T)/ Clinical Training(CT)	Practical (P)/Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b Practical: a + c
23.	BP301T	CT	Pharmaceutical Organic Chemistry II		3	1	0	4	45	15	0	60	80	25	75	0	100
24.	BP302T	CT	Physical Pharmaceutics I		3	1	0	4	45	15	0	60	80	25	75	0	100
25.	BP303T	CT	Pharmaceutical Microbiology		3	1	0	4	45	15	0	60	80	25	75	0	100
26.	BP304T	CT	Pharmaceutical Engineering		3	1	0	4	45	15	0	60	80	25	75	0	100
27.	BP305P	CL	Pharmaceutical Organic Chemistry II Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
28.	BP306P	CL	Physical Pharmaceutics I Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
29.	BP307P	CL	Pharmaceutical Microbiology Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
30.	BP308P	CL	Pharmaceutical Engineering Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
Year 2 – Semester-III			**Total**		12	4	16	24	180	60	240	480	-	160	300	140	600

B. PHARM Year 2 – Semester- IV
TABLE 12: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM

Course Number	Course Code	Category	Course Title		Credits (hours) / Week			Credits(C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) - Theory / Practical (a)	End Semester Examination (ESE)		Grand Total
					Lecture (L)	Tutorial(T)/ Clinical Training(CT)	Practical (P)/Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b Practical: a + c
31.	BP401T	CT	Pharmaceutical Organic Chemistry III		3	1	0	4	45	15	0	60	80	25	75	0	100
32.	BP402T	CT	Medicinal Chemistry I		3	1	0	4	45	15	0	60	80	25	75	0	100
33.	BP403T	CT	Physical Pharmaceutics II		3	1	0	4	45	15	0	60	80	25	75	0	100
34.	BP404T	CT	Pharmacology I		3	1	0	4	45	15	0	60	80	25	75	0	100
35.	BP405T	CT	Pharmacognosy and Phytochemistry I		3	1	0	4	45	15	0	60	80	25	75	0	100
36.	BP406P	CL	Medicinal Chemistry I Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
37.	BP407P	CL	Physical Pharmaceutics II Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
38.	BP408P	CL	Pharmacology I Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
39.	BP409P	CL	Pharmacognosy and Phytochemistry I Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
Year 2 – Semester- IV			**Total**		15	5	16	28	225	75	240	540	-	185	375	140	700

B. PHARM Year 3 – Semester- V
TABLE 13: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM

Course Number	Course Code	Category	Course Title		Credits (hours) / Week			Credits(C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) - Theory / Practical (a)	End Semester Examination (ESE)		Grand Total
					Lecture (L)	Tutorial(T)/ Clinical Training(CT)	Practical (P)/Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b Practical: a + c
40.	BP501T	CT	Medicinal Chemistry II		3	1	0	4	45	15	0	60	80	25	75	0	100
41.	BP502T	CT	Industrial Pharmacy I		3	1	0	4	45	15	0	60	80	25	75	0	100
42.	BP503T	CT	Pharmacology II		3	1	0	4	45	15	0	60	80	25	75	0	100
43.	BP504T	CT	Pharmacognosy and Phytochemistry II		3	1	0	4	45	15	0	60	80	25	75	0	100
44.	BP505T	CT	Pharmaceutical Jurisprudence		3	1	0	4	45	15	0	60	80	25	75	0	100
45.	BP506P	CL	Industrial Pharmacy I Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
46.	BP507P	CL	Pharmacology II Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
47.	BP508P	CL	Pharmacognosy and Phytochemistry II Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
Year 3 – Semester-V			**Total**		15	5	12	26	225	75	180	480	-	170	375	105	650

B. PHARM Year 3 – Semester- VI
TABLE 14: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM

Course Number	Course Code	Category	Course Title		Credits (hours) / Week			Credits(C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) - Theory / Practical (a)	End Semester Examination (ESE)		Grand Total
					Lecture (L)	Tutorial(T)/ Clinical Training(CT)	Practical (P)/Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b Practical: a + c
48.	BP601T	CT	Medicinal Chemistry III		3	1	0	4	45	15	0	60	80	25	75	0	100
49.	BP602T	CT	Pharmacology III		3	1	0	4	45	15	0	60	80	25	75	0	100
50.	BP603T	CT	Herbal Drug Technology		3	1	0	4	45	15	0	60	80	25	75	0	100
51.	BP604T	CT	Biopharmaceutics and Pharmacokinetics		3	1	0	4	45	15	0	60	80	25	75	0	100
52.	BP605T	CT	Pharmaceutical Biotechnology		3	1	0	4	45	15	0	60	80	25	75	0	100
53.	BP606T	CT	Quality Assurance		3	1	0	4	45	15	0	60	80	25	75	0	100
54.	BP607P	CL	Medicinal Chemistry III Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
55.	BP608P	CL	Pharmacology III Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
56.	BP609P	CL	Herbal Drug Technology Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
Year 3 – Semester- VI			**Total**		18	6	12	30	270	90	180	540	-	195	450	105	750

B. PHARM Year 4 – Semester- VII
TABLE 15: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM

Course Number	Course Code	Category	Course Title		Credits (hours) / Week			Credits(C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) - Theory / Practical (a)	End Semester Examination (ESE)		Grand Total
					Lecture (L)	Tutorial(T)/ Clinical Training(CT)	Practical (P)/Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b Practical: a + c
57.	BP701T	CT	Instrumental Methods of Analysis		3	1	0	4	45	15	0	60	80	25	75	0	100
58.	BP702T	CT	Industrial Pharmacy II		3	1	0	4	45	15	0	60	80	25	75	0	100
59.	BP703T	CT	Pharmacy Practice		3	1	0	4	45	15	0	60	80	25	75	0	100
60.	BP704T	CT	Novel Drug Delivery System		3	1	0	4	45	15	0	60	80	25	75	0	100
61.	BP705P	CL	Instrumental Methods of Analysis Practical		0	0	4	2	0	0	60	60	80	15	0	35	50
62.	BP706PS	IN	Practice School*		0	0	12	6	0	0	180	180	80	150 *	0	0	150
Year 4 – Semester- VII			**Total**		12	4	16	24	180	60	240	480	-	265	300	35	600
* Non-University Examination (25 marks for CIA and 125 marks for final qualifying exam)																	

B. PHARM Year 4 – Semester- VIII
TABLE 16: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM

Course Number	Course Code	Category	Course Title		Credits (hours) / Week			Credits(C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) - Theory / Practical (a)	End Semester Examination (ESE)		Grand Total
					Lecture (L)	Tutorial(T)/ Clinical Training(CT)	Practical (P)/Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b Practical: a + c
63.	BP801T	CT	Biostatistics and Research Methodology		3	1	0	4	45	15	0	60	80	25	75	0	100
64.	BP802T	CT	Social and Preventive Pharmacy		3	1	0	4	45	15	0	60	80	25	75	0	100
65.	BP803ET1/III,III, IV, V	CT	Elective 1 **		3	1	0	4	45	15	0	60	80	25	75	0	100
66.	BP804ET2/III,III, IV, V,VI	CT	Elective 2 **		3	1	0	4	45	15	0	60	80	25	75	0	100
67.	BP813PW	RP	Project Work***		0	0	12	7 ***	0	0	180	180	80	0	0	150	150
Year 4 – Semester-VIII			**Total**		12	4	12	23	180	60	180	420	-	100	300	150	550
GRAND TOTAL				-	118	36	118	211 213[$] 214[#]	1770	540	1770	4080	-	1705	2700	920	5325

** Electives 1 and 2 can be chosen by the candidates from the list of course titles as given in Table 17.

*** The credit point assigned for extracurricular and or co-curricular activities shall be added to the Project work (6 credits for Project work and one credit for presentation or publication as a part of their project work.

[$] Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.
[#]Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course.

a: CIA Theory & Practical (eligibility for ESE- Min. 50 % CIA marks seperaterly in theory and Practical to be submitted to the University 15 days before the ESE)

b: EST (Pass Min 50%, CIA & ESE Aggregate 50%)

c: ESP (Pass Min 50%, CIA & ESE Aggregate 50%)

Table - 17: ELECTIVES – COURSE CODE AND TITLE

S. No.	Elective code	Course title
1	BP803ET1/I	Pharma Marketing Management
2	BP803ET1/II	Pharmaceutical Regulatory Science
3	BP803ET1/III	Pharmacovigilance
4	BP803ET1/IV	Quality Control and Standardization of Herbals
5	BP803ET1/ V	Computer Aided Drug Design
6	BP804ET2/I	Cell and Molecular Biology
7	BP804ET2/II	Cosmetic Science
8	BP804ET2/III	Experimental Pharmacology (Pharmacological Screening and Methods)
P	BP804ET2/IV	Advanced Instrumentation Techniques
10	BP804ET2/V	Dietary Supplements and Nutraceuticals
11	BP804ET2/VI	Pharmaceutical Product Development

SYLLABUS
SEMESTER – I
HUMAN ANATOMY AND PHYSIOLOGY- I (BP101T)

(Theory) **45 Hours**

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives:

Upon completion of this course the student should be able to

- Explain the gross morphology and functions of various organs of the human body.
- Describe the various homeostatic mechanisms.
- Explain in detail the organization of various muscles, types of bones and joints of the human body
- Describe in detail the circulatory and peripheral nervous system
- Identify the various tissues and organs of different systems of human body.
- Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure.

Course outcome:

Upon completion of the unit the student shall be able to:

CO1: Demonstrate an understanding of the gross morphology and levels of structural organization of the listed body systems

CO2: Describe the cellular and tissue level organization of the listed organ systems

O3: Describe the basic physiological processes of the different systems of the human body

CO4: Demonstrate competence in the understanding of the regulation and co-ordination between the organ systems

Course Content

Unit I

10 hours

Introduction to human body

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

Cellular level of organization

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

Tissue level of organization

Classification of tissues, structure, location and functions of epithelial, muscular, nervous and connective tissues.

Unit II

10 hours

Integumentary system

Structure and functions of skin

Skeletal system

Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction

Joints

Structural and functional classification, types of joints movements and its articulation

Unit III **10 hours**

Body fluids and blood

Body fluids, composition and functions of blood, hemopoeisis, formation of hemoglobin, anaemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of
blood, Reticulo endothelial system.

Lymphatic system

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

Unit IV **08 hours**

Peripheral nervous system.

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system. Origin and functions of spinal and cranial nerves.

Special senses

Structure and functions of eye, ear, nose and tongue and their disorders.

Unit V **07 hours**

Cardiovascular system

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heartbeat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electro cardiogram anddisorders of heart.

HUMAN ANATOMY AND PHYSIOLOGY - I (BP107P)
(Practical)
4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practical allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject**.**

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time

10. Estimation of hemoglobin content
11. Determination of blood group.
12. Determination of erythrocyte sedimentation rate (ESR).
13. Determination of heart rate and pulse rate.
14. Recording of blood pressure.
15. Study of muscular system, cardiovascular system with the help of models, charts and specimens.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee Brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

9. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
10. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
11. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje Academic Publishers, Kolkata

PHARMACEUTICAL ANALYSIS (BP102T)

(Theory) **45 Hours**

Scope: This course deals with the fundamentals of analytical chemistry and principles of **e**lectrochemical analysis of drugs

Objectives:

Upon completion of the course student shall be able to

- Understand the principles of volumetric and electro chemical analysis
- Carryout various volumetric and electrochemical titrations
- Develop analytical skills

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain the principles of volumetric and electrochemical methods of analysis

CO2: Enumerate different techniques employed in the analysis of drug substance and products.

CO3: Demonstrate the basic laboratory skills employed during the volumetric titrations.

CO4: Perform standardization and assay using Acid base, Non-aqueous, Precipitation Complexometry, Diazotisation and Redox titration methods as per the valid procedure.

CO5: Discuss the applications of various electrochemical methods of analysis such as Conductometry, Potentiometry and Polarography in the determination of drugs and pharmaceuticals.

CO6: Explain errors and list the various methods employed to minimize errors during drug analysis.

CO7: Define accuracy, precision and their significance during the analysis of drugs and solve problems in significant figures using proper scientific rounding off rules.

Course Content

UNIT I **10 Hours**

Pharmaceutical analysis- Definition and s cope of Different techniques of analysis, Methods of expressing concentration, Primary and secondary standards. Preparation and standardization of various molar and normal solutions-Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate.

Errors: Sources of errors, types of errors, methods of minimizing errors,accuracy, precision and significant figures.

UNIT II **10 Hours**

Acid base titration: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak and very weak acids and bases, neutralization curves

Non-aqueous titration: Solvents, acidimetry and alkalimetry titration, estimation of Sodium benzoate and Ephedrine HCl.

UNITIII **10 Hours**

Precipitation titrations: Theory, Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.

Complexometric titration: Theory, Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.

Gravimetry: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.
Diazotisation titration: Basic Principles, methods and application of diazotisation titration.

UNIT IV

08 Hours

Redox titrations

Concepts of oxidation and reduction
Types of redox titrations (Principles and applications)
Ceriometry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

UNIT V

07 Hours

Electrochemical methods of analysis
Conductometry- Introduction, Conductivity cell, Conductometric titrations, applications.
Potentiometry - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
Polarography - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

PHARMACEUTICAL ANALYSIS (BP108P)
(Practical)

4 Hours / Week

Preparation and standardization of

Sodium hydroxide
Sulphuric acid
Sodium thiosulfate
Potassium permanganate
Ceric ammonium sulphate

II **Assay of the following compounds along with Standardization of Titrant**

Ammonium chloride by acid base titration
Ferrous sulphate by Ceriometry
Copper sulphate by Iodometry
Calcium gluconate by complexometry
Hydrogen peroxide by Permanganometry
Sodium benzoate by non-aqueous titration
Sodium Chloride by precipitation titration

III **Determination of Normality by electro-analytical methods**

Conductometric titration of strong acid against strong base
Conductometric titration of strong acid and weak acid against strong base
Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis.
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry.
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry.
5. John H. Kennedy, Analytical chemistry principles.
6. Indian Pharmacopoeia.
7. Pharmaceutical Analysis by Dr. A.V. Kasture and Dr. K. R. Mohadik, Vol 1 & 2.
8. Pharmaceutical titrimetric analysis (Theory & Practical) by A. A. Napolean.

PHARMACEUTICS - I (BP103T)

(Theory) **45 Hours / Week**

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives:

Upon completion of this course the student should be able to:

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

Course outcome:
Upon completion of this course the student should be able to:

CO1: Explain history of profession of pharmacy.

CO2: Identify different dosage forms displayed in laboratory.

CO3: Classify and explain pharmaceutical incompatibilities involved in pharmaceutical preparations.

CO4: Carry out various pharmaceutical calculations

CO5: Analyze, Identify and describe different types of errors related to prescription

CO6: Exhibit the knowledge of professional way of handling the prescription

CO7: Prepare various conventional dosage forms according to standard formula.

Course Content

UNIT I

10 Hours

Historical background and development of profession of pharmacy: Historyof profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.

Dosage forms: Introduction to dosage forms, classification and definitions

Prescription: Definition, Parts of prescription, handling of Prescription and Errors in prescription.

Posology: Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT II

10 Hours

Pharmaceutical calculations: Weights and measures–Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.

Powders: Definition, classification, advantages and disadvantages,Simple &compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

Liquid dosage forms: Advantages and disadvantages of liquid dosage forms.Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

UNIT III

10 Hours

Monophasic liquids: Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.

Biphasic liquids:

Suspensions: Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.

Emulsions: Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV

08 Hours

Suppositories: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.

Pharmaceutical incompatibilities: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIV – V

07 Hours

Semisolid dosage forms: Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms

PHARMACEUTICS - I (BP109P)

(Practical) **4 Hours / week**

1. Syrups
Syrup IP'66
Compound syrup of Ferrous Phosphate BPC'68

2. Elixirs
Piperazine citrate elixir
Paracetamol paediatric elixir

3. Linctus
Terpin Hydrate Linctus IP'66
Iodine Throat Paint (Mandles Paint)

4. Solutions
Strong solution of ammonium acetate
Cresol with soap solution
Lugol's solution

5. Suspensions
Calamine lotion
Magnesium Hydroxide mixture
Aluminium Hydroxide gel

6. Emulsions
Turpentine Liniment
Liquid paraffin emulsion

7. Powders and Granules
ORS powder (WHO)
Effervescent granules
Dusting powder
Divded powders

8. Suppositories
Glycero gelatin suppository
Coca butter suppository
Zinc Oxide suppository

9. Semisolids
Sulphur ointment

Non-staining-iodine ointment with methyl salicylate
Carbopal gel

10. Gargles and Mouthwashes
Iodine gargle
Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science & Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S. J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

PHARMACEUTICAL INORGANIC CHEMISTRY (BP104T)

(Theory) **45 Hours**

Scope: This subject deal with the monographs of inorganic drugs and pharmaceuticals.

Objectives: Upon completion of course student shall be able to

- Know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- Understand the medicinal and pharmaceutical importance of inorganic compounds

Course outcome:
Upon completion of the course, the student shall be able to:

CO1: Demonstrate the knowledge and skills involved in the limit test test for chloride, sulphate, iron and heavy metals in pharmaceutical substance.

CO2: Exemplify the Sources and types of impurities in pharmaceutical substances and perform the identification test and test for purity for selected pharmaceutical substances.

CO3: Enumerate the buffers used in pharmaceutical systems and correlate Buffer equations and buffer capacity.

CO4: Explain the various Electrolytes used in the replacement therapy.

CO5: Describe the general methods of preparation, assay, properties and medicinal uses of Acidifiers, Antacids, Cathartics, Antimicrobials , Expectorants, Emetics, Haematinics, Antidote and Astringents with examples.

CO6: Explain the principle of the measurement of radioactivity, properties of α, β, γ radiations, Half life, radio isotopes, storage conditions, precautions of Radiopharmaceuticals, and their pharmaceutical applications.

Course Content:

10 Hours

Impurities in pharmaceutical substances: History of Pharmacopoeia,Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

General methods of preparation, assay for the compounds superscripted with **asterisk (*),** properties and medicinal uses of inorganic compounds belonging to the following classes

UNIT II **11 Hours**

Acids, Bases and Buffers: Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.

Major extra and intracellular electrolytes: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance.

Dental products: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

UNIT III
Gastrointestinal agents **10 Hours**

Acidifiers: Ammonium chloride* and Dil. HCl

Antacid: Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate*, Aluminium hydroxide gel, Magnesium hydroxide mixture
Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite
Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT IV **08 Hours**

Miscellaneous compounds
Expectorants: Potassium iodide, Ammonium chloride*.
Emetics: Copper sulphate*, Sodium potassium tartarate
Haematinics: Ferrous sulphate*, Ferrous gluconate
Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite
Astringents: Zinc Sulphate, Potash Alum

UNIT V **06 Hours**

Radiopharmaceuticals: Radio activity, Measurement of radioactivity,Properties of α, β, γ radiations, Half-life, radio isotopes and study of radio isotopes - Sodium iodide I^{131}, Storage conditions, precautions & pharmaceutical application of radioactive substances.

Pharmaceutical aids: Bentonite, magnesium stearate, sodium carboxy methy l cellulose, purified water and water for injection.

PHARMACEUTICAL INORGANIC CHEMISTRY (BP110P)
(Practical)
4 Hours / Week

I. **Limit tests for following ions**
   a. Limit test for Chlorides and Sulphates
   b. Modified limit test for Chlorides and Sulphates
   c. Limit test for Iron
   d. Limit test for Heavy metals
   e. Limit test for Lead
   f. Limit test for Arsenic

II. **Identification test**
   a. Magnesium hydroxide
   b. Ferrous sulphate
   c. Sodium bicarbonate
   d. Calcium gluconate
   e. Copper sulphate

III. **Test for purity**
   a. Swelling power of Bentonite
   b. Neutralizing capacity of Aluminium hydroxide gel
   c. Determination of potassium iodate and iodine in potassium Iodide

IV. **Preparation of inorganic pharmaceuticals**

a. Boric acid
b. Potash alum
c. Ferrous sulphate

Recommended Books (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia

COMMUNICATION SKILLS (BP105T)

(Theory **30 Hours**

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

The course aims to help the students to

- Develop the language skills needed for a Pharmacist to function effectively in the areas of pharmaceutical operation
- Communicate effectively using Verbals and Non-Verbals
- Develop writing and speaking skills to manage effectively as a team player
- Develop on the interview skills
- Enhance various liguistical skills needed to express leadership qualities and essentials

Course outcome:
Upon completion of the course, the student shall be able to:

CO1: Identify barriers and various perpectives to communication skills

CO2: Distinguish different styles of communication, their context of usage and demonstrate proficiency in the use of spelling, grammar, punctuation and vocabulary

CO3: Manifest listening proficiency as well as of effective written communication techniques.

CO4: Show competence in planning presentations and in interview facing skills

CO5: Demonstrate group communication skills such as persuasion, negotiation, analysis, argumentation and problem solving.

Course content:

UNIT I **07 Hours**

Communication Skills: Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context

Barriers to communication: Physiological Barriers, Physical Barriers, CulturalBarriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers

Perspectives in Communication: Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

UNIT II **07 Hours**

Elements of Communication: Introduction, Face to Face Communication - Tone ofVoice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication

Communication Styles: Introduction, The Communication Styles Matrix with examplefor each - Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style.

Basic Grammar.

UNIT III **07 Hours**

Basic Listening Skills: Introduction, Self-Awareness, Active Listening, Becoming anActive Listener, Listening in Difficult Situations

Effective Written Communication: Introduction, When and When Not to Use WrittenCommunication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication

Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message (Essay writing and letter writing)

UNIT IV **05 Hours**

Interview Skills: Purpose of an interview, Do's and Dont's of an interview.

Giving Presentations: Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery.

UNIT V **04 Hours**

Group Discussion: Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

COMMUNICATION SKILLS (BP111P)
(Practical)
2 Hours / week

The following learning modules are to be conducted using Wordsworth® English language lab software*

Basic communication covering the following topics
Meeting People
Asking Questions
Making Friends
What did you do?
Do's and Dont's

Pronunciations covering the following topics
Pronunciation (Consonant Sounds)
Pronunciation and Nouns
Pronunciation (Vowel Sounds)

Advanced Learning
Listening Comprehension / Direct and Indirect Speech
Figures of Speech
Effective Communication
Writing Skills
Effective Writing
Interview Handling Skills
E-Mail etiquette
Presentation Skills

*In the absence of the above software, Clarity Software – Issues in English, Tense Busters, Connected Speech and Study skills success have been used. All these are highly interactive and authenticated version.

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011
3. Organizational Behaviour, Stephen. P. Robbins, 1stEdition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5th Edition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011

9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning India pvt. ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1st Edition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009
12. Bringing out the best in people, Aubrey Daniels, 2nd Edition, Mc Graw Hill, 1999.

REMEDIAL BIOLOGY (BP 106 RBT)

(Theory) **30 Hours**

Scope: To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

Objectives:

Upon completion of the course, the student shall be able to

- Know the classification and salient features of five kingdoms of life
- Understand the basic components of anatomy & physiology of plant
- Know understand the basic components of anatomy & physiology animal with special reference to human

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Classify and explain the salient features of five kingdoms of life

CO2: Explain the basic components of anatomy & physiology of plant

CO3: Describe the basic components of anatomy & physiology of animal kingdom with special reference to human

CO4: Demonstrate techniques of permanent slide preparation (sectioning, staining, mounting & focusing).

CO5: Differentiate monocot and dicot stem/leaf/root based on anatomical features using microscope.

CO6: Measure blood pressure of an individual using sphygmomanometer accurately.

CO7: Perform frog dissection and label the various parts of digestive system in a simulated condition.

UNIT I **07 Hours**

Living world:

Definition and characters of living organisms
Diversity in the living world
Binomial nomenclature
Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus.

Morphology of Flowering plants

Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledons.

UNIT II 07 **Hours**

Body fluids and circulation

Composition of blood, blood groups, coagulation of blood
Composition and functions of lymph
Human circulatory system
Structure of human heart and blood vessels
Cardiac cycle, cardiac output and ECG

Digestion and Absorption

Human alimentary canal and digestive glands
Role of digestive enzymes
Digestion, absorption and assimilation of digested food

Breathing and respiration

Human respiratory system
Mechanism of breathing and its regulation
Exchange of gases, transport of gases and regulation of respiration
Respiratory volumes

UNIT III **07 Hours**

Excretory products and their elimination

Modes of excretion
Human excretory system- structure and function
Urine formation
Rennin angiotensin system

Neural control and coordination

Definition and classification of nervous system
Structure of a neuron
Generation and conduction of nerve impulse
Structure of brain and spinal cord
Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

Endocrine glands and their secretions
Functions of hormones secreted by endocrine glands

Human reproduction

Parts of female reproductive system
Parts of male reproductive system
Spermatogenesis and Oogenesis

Menstrual cycle

UNIT IV **05 Hours**

Plants and mineral nutrition:
Essential mineral, macro and micronutrients
Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis
Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

UNIT V **04 Hours**

Plant respiration: Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development
Phases and rate of plant growth, Condition of growth, Introduction to plant growth regulators.

Cell - The unit of life
Structure and functions of cell and cell organelles. Cell division

Tissues
Definition, types of tissues, location and functions.
Anatomy and physiology of mammal

Text Books

1. Text book of Biology by S. B. Gokhale
2. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

1. A Text book of Biology by B.V. Sreenivasa Naidu
2. A Text book of Biology by Naidu and Murthy
3. Botany for Degree students By A.C. Dutta.
4. Outlines of Zoology by M. Ekambaranatha Ayyer and T. N. Ananthakrishnan.
5. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

REMEDIAL BIOLOGY (BP112 RBP)

(Practical)

30 Hours

1. Introduction to experiments in biology
2. Study of Microscope
Section cutting techniques
Mounting and staining
Permanent slide preparation
3. Study of cell and its inclusions
Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models

5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

1. Practical human anatomy and physiology. by S. R. Kale and R. R. Kale.
2. A Manual of pharmaceutical biology practical by S. B. Gokhale, C. K. Kokate and S. P. Shriwastava.
3. Biology practical manual according to National core curriculum, Biology forum of Karnataka.

Prof. M. J. H. Shafi.

REMEDIAL MATHEMATICS (BP106RMT)

(Theory) **30 Hours**

Scope: This is an introductory course in mathematics. This subject deal with theintroduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

Objectives:

Upon completion of the course the student shall be able to:-

- Know the theory and their application in Pharmacy
- Solve the different types of problems by applying theory
- Appreciate the important application of mathematics in Pharmacy

Course outcome:

Upon completion of the unit the student shall be able to:

CO1: Demonstrate an understanding of the basics of fractions

CO2: Solve partial fractions using instructed methods

CO3: Relate the applications of partial fractions to Chemical kinetics

CO4: Connect the significance of solving partial fractions to Pharmacokinetics

CO5: Apply logarithmic functions

CO6: Demonstrate an understanding of the characteristics of Mantissa

CO7: Show an understanding of the applications of logarithms in pharmaceutical problems

Course Content

UNIT I **06 Hours**

Partial fraction

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction, Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics

Logarithms

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

Function

Real Valued function, Classification of real valued functions,

Limits and continuity:

Introduction, Limit of a function, Definition of limit of a function ($\in -\delta$definition),

$$\lim_{x\to a}\frac{x^n-a^n}{x-a}=na^{n-1},\ \lim_{\theta\to 0}\frac{\sin\theta}{\theta}=1$$

Unit II **06 Hours**

Matrices and Determinant:

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants , Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix , Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley – Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations

UNIT III

06 Hours

Calculus

Differentiation : Introductions, Derivative of a function, Derivative of aconstant, Derivative of a product of a constant and a function , Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – **Without Proof**, Derivative of x^n*w.r.t*x, where *n* is any rational number, Derivative of e^x,, Derivative of $\log_e x$, Derivative of a^x, Derivative of trigonometric functions from first principles**(withoutProof)**, Successive Differentiation, Conditions for a function to be amaximum or a minimum at a point. Application

UNIT IV **06 Hours**

Analytical Geometry

Introduction: Signs of the Coordinates, Distance formula,

Straight Line: Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line

Integration:
Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

06 Hours

Differential Equations: Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations
Application in solving Pharmacokinetic equations

Laplace Transform: Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, Application in solving Chemical kinetics and Pharmacokinetics equations

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr. B. S. Grewal

SEMESTER – II
HUMAN ANATOMY AND PHYSIOLOGY- II (BP 201T)

(Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives:

Upon completion of this course the student should be able to:

- Describe the various parts of the brain and explain the structure and functions of central nervous system
- Describe the structure, mechanism of secretion and functions of the various organ systems/glands
- Enumerate the organs of urinary system and explain the formation of urine
- Describe the structure and functions of reproductive system
- Describe the structural organization of respiratory tract and explain the regulation of respiration
- Identify the various organ systems and list the functions of each

Course outcome:

Upon completion of the unit the student shall be able to:

CO1: Demonstrate an understanding of the gross morphology and levels of structural organization of the brain

CO2: Describe the organization of respiratory system

CO3: Describe the basic physiological processes of the digestion and excretion in human body

CO4: Demonstrate competence in the understanding of the regulation and co-ordination between the organ systems

CO5: Demonstrate competence in understanding the physiology of reproduction

Course Content

Unit I

Nervous system

10 hours

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.
Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. structure and functions
of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

Unit II

Digestive system

06 hours

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and

functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

Energetics
Formation and role of ATP, Creatinine Phosphate and BMR.

Unit III

Respiratory system **10 hours**

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration
Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

Urinary system
Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit IV **10 hours**

Endocrine system
Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

Unit V
Reproductive system **09 hours**

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

Introduction to genetics

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance.

HUMAN ANATOMY AND PHYSIOLOGY – II (BP207P)

(Practical) **4 Hours/week**

Practical physiology is complimentary to the theoretical discussions in physiology. Practical allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject**.**

1. To study the integumentary and special senses using specimen, models, etc.,
2. To study the nervous system using specimen, models, etc.,
3. To study the endocrine system using specimen, models, etc
4. To demonstrate the general neurological examination
5. To demonstrate the function of olfactory nerve

6. To examine the different types of taste.
7. To demonstrate the visual acuity
8. To demonstrate the reflex activity
9. Recording of body temperature
10. To demonstrate positive and negative feedback mechanism.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index .
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee Brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C, Guyton and John.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee Brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee Brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.
9. Basics of Medical Physiology, 3rd edition by D. Venkatesh / H. H. Sudhakar.

Reference Books:

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje, Academic Publishers Kolkata

PHARMACEUTICAL ORGANIC CHEMISTRY –I (BP202T)

(Theory) **45 Hours**

Scope: This subject deal with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions

and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

Objectives:

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds
- Identify/confirm the identification of organic compound

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Classify organic compounds and discuss its nomenclature as per IUPAC systems of nomenclature.

CO2: Define isomerism and explain its types with examples of some organic compounds.

CO3: Discuss the general methods of preparation, Physical and chemical properties of organic compounds such as Alkanes, Alkenes, Conjugated dienes, Alkyl halides, Alcohols, Carbonyl compounds (Aldehydes and ketones), Carboxylic acids and Aliphatic amines.

CO4: Explain the reaction mechanisms in addition, elimination, condensation and substitution including the factors that affect such reactions in organic compounds.

CO5: Write the structure and uses of some official organic compounds considered important in Pharmaceutical applications.

CO6: Discuss the different condensation reactions and their mechanisms in carbonyl compounds.

CO7: Identify the functional group and confirm organic compounds such as Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Alcohol and Nitro compounds by performing suitable qualitative tests under the laboratory conditions.

Course Content

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I

07 Hours

Classification, nomenclature and isomerism

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds (up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds.

UNIT II **10 Hours**

Alkanes*, Alkenes* and Conjugated dienes*

SP^3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, SP^2 hybridization in alkenes

E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation, carbenes and reactivity.

Stability of conjugated dienes, Diel's Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement.

UNIT III **10 Hours**

Alkyl halides*

SN_1 and SN_2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN_1 versus SN_2 reactions, Factors affecting SN_1 and SN_2 reactions
Structure and uses of ethyl chloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

Alcohols*- Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol,**C**hlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol.

UNIT IV **10 Hours**

Carbonyl compounds* (Aldehydes and ketones)

Nucleophilic addition, Substitution vs addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanillin, Cinnamaldehyde.

UNIT V **08 Hours**

Carboxylic acids*

Nucleophilic acyl substitution, Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester.
Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid.

Aliphatic amines* - Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine

PHARMACEUTICAL ORGANIC CHEMISTRY - I (BP208P)
(Practical)

4 Hours / week

1. Systematic qualitative analysis of unknown organic compounds like
a. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation etc.
b. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
c. Solubility test
d. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes
and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
2. Melting point/Boiling point of organic compounds
3. Identification of the unknown compound from the literature using melting point/ boiling point.
4. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
5. Minimum 5 unknown organic compounds to be analysed systematically.
6. Preparation of suitable solid derivatives from organic compounds
7. Construction of molecular models

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I. L. Finar, Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P. L. Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N. K. Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwaliah /Chatwal.
10. Organic Chemistry by Paulay Bruce
11. Organic Chemistry by Leroy. G. Wade

BIOCHEMISTRY (BP203T)

(Theory) **45 Hours**

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives: Upon completion of the course student shall able to

- Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
- Understand the metabolism of nutrient molecules in physiological and pathological conditions.
- Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Course outcome:
Upon completion of the course, the student shall be able to:

CO1: Understand the importance of metabolism of biomolecules.

CO2: Acquire chemistry and biological importance of bio macromolecules.

CO3: Perform qualitative and quantitative estimation of the bio macromolecules.

CO4: Interpretation of data emanating from a Clinical Test Lab.

CO5: Explain the physiological conditions which influence the structures and reactivities of biomolecules.

CO6: Understand the basic principles of Lipids, protein and polysaccharide structure.

CO7: Explain about Enzymes, their nomenclature, kinetics and functions.

CO8: Understand Biological Demonstrate knowledge significance of vitamins, co-enzymes and minerals

CO9: Understand the concept of catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.

CO10: Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins

Course Content

UNIT I **08 Hours**

Biomolecules

Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

Bioenergetics

Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.

Energy rich compounds; classification; biological significances of ATP and cyclic AMP

UNIT II **10 Hours**

Carbohydrate metabolism

Glycolysis – Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance

HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency, Glycogen metabolism Pathways and glycogen storage diseases (GSD), Gluconeogenesis-Pathway and its significance.
Hormonal regulation of blood glucose level and Diabetes mellitus

Biological oxidation
Electron transport chain (ETC) and its mechanism.
Oxidative phosphorylation & its mechanism and substrate level phosphorylation
Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT III **10 Hours**
Lipid metabolism

β- Oxidation of saturated fatty acid (Palmitic acid)
Formation and utilization of ketone bodies; ketoacidosis De novo synthesis of fatty acids (Palmitic acid)
Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D
Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

Amino acid metabolism

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, Urea cycle and its disorders
Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)

Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline
Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV **10 Hours**
Nucleic acid metabolism and genetic information transfer

Biosynthesis of purine and pyrimidine nucleotides.
Catabolism of purine nucleotides and Hyperuricemia and Gout disease, Organization of mammalian genome
Structure of DNA and RNA and their functions DNA replication (semi conservative model) Transcription or RNA synthesis.
Genetic code, Translation or Protein synthesis and inhibitors.

UNIT V **07 Hours**
Enzymes

Introduction, properties, nomenclature and IUB classification of enzymes Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)
Enzyme inhibitors with examples
Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation
Therapeutic and diagnostic applications of enzymes and isoenzymes, Coenzymes – Structure and biochemical functions.

BIOCHEMISTRY (BP209P)

(Practical) **4 Hours / Week**

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U. Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

PATHOPHYSIOLOGY (BP 204T)

(THEORY) **45 Hours**

Scope: Pathophysiology is the study of causes of diseases and reactions of the body tosuch disease producing causes.This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives:

Upon completion of the subject student shall be able to–

- Describe the etiology and pathogenesis of the selected disease states;
- Name the signs and symptoms of the diseases; and
- Mention the complications of the diseases.

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Discuss the causes, the pathological processes and the morphology of cell injury and describe thecellular responses including the adaptive changes.

CO2: Explain the principles, types, clinical signs and the process of inflammation and the basics of wound healing and repair.

CO3: Define, classify and differentiate disease states based on their pathological characteristics as neoplastic disease, blood disorders, metabolic, hemodynamic, infectious and vascular disorders.

CO4: Describe the etiology and explain the pathophysiology of the cardiac, respiratory, gastrointestinal, hepatobiliary, pancreatic, renal, endocrine, reproductive, musculoskeletal, and central nervous system diseases.

CO5: Elucidate the signs and symptoms of each disease state and mention their long term complications

CO6: Describe the basic principles of cancer and classify cancers, based on their pathology.

CO7: Distinguish the causative organisms, pathophysiology and the clinical manifestations of the infectious and sexually transmitted diseases

Course content

Unit I

10 Hours

Basic principles of Cell injury and Adaptation:

Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury**,** Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage)**,** Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy,

hyperplasia, Metaplasia, Dysplasia),Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death, Acidosis & Alkalosis, Electrolyte imbalance.

Basic mechanism involved in the process of inflammation and repair:

Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBCs, Mediators of inflammation, Basic principles of wound healing in the skin.

Unit II **10 Hours**

Cardiovascular System:

Hypertension, Atherosclerosis, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis).

Respiratory system: Asthma, Chronic obstructive airways diseases.
Renal system: Acute and chronic renal failure.

Unit III **10Hours**

Haematological Diseases:
Iron deficiency, megaloblastic anemia (Vit B_{12} and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia.

Endocrine system: Diabetes, thyroid diseases, disorders of sex hormones.

Nervous system: Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.

Gastrointestinal system: Peptic Ulcer, Inflammatory bowel diseases, jaundice, hepatitis (A, B, C, D, E, F) alcoholic liver disease.

Unit IV 0**8 Hours**

Disease of bones and joints: Rheumatoid arthritis, osteoporosis and gout.
Principles of cancer: Classification, etiology and pathogenesis of cancer.

Unit V 0**7 Hours**

Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis, Urinary tract infections.
Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K.; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.

4. Best, Charles Herbert, 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore;1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John. E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L.Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

1. The Journal of Pathology. ISSN: 1096-9896 (Online)
2. The American Journal of Pathology. ISSN: 0002-9440
3. Pathology. 1465-3931 (Online)
4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

COMPUTER APPLICATIONS IN PHARMACY (BP205 T)

(Theory) **45 Hrs (3 Hrs/Week)**

Scope: This subject deal with the introduction Database, Database Management system, computer applications in clinical studies and use of databases.

Objectives: Upon completion of the course the student shall be able to

- Know the various types of application of computers in pharmacy
- Know the various types of databases
- Know the various applications of databases in pharmacy

Course outcome:

Upon completion of the course the student will be able to:
CO1. Develop an HTML web page.
CO2. Create a patient record database in MS Access and handle queries on the same.
CO3. Store and Retrieve drug related information using online tools
CO4. Design a questionnaire using word processing package
CO5. Comprehend the utility of tools & databases available in genomic & proteomics

Course content

UNIT I **12 hours**

Number system:

Binary number system, Decimal number system, Octalnumber system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division

Concept of Information Systems and Software: Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project.

UNIT II **08 Hours**

Web technologies: Introduction to HTML, XML, CSS andProgramming languages, Introduction to web servers and Server Products Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT III **10 Hours**

Application of computers in Pharmacy–Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System.

UNIT IV **08 hours**

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

UNIT V 07 **hours**

Computers as data analysis in Preclinical development: Chromatographic data analysis (CDS), Laboratory Information Management System (LIMS) and Text Information Management System (TIMS).

COMPUTER APPLICATIONS IN PHARMACY (BP210P)

(Practical) **(30 Hrs 2 Hrs/Week)**

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools
4. Creating mailing labels Using Label Wizard, generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields using access.
6. Design a form in MS Access to view, add, delete and modify the patient record in the Database.

7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E. Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley - Interscience, A John Willey and Sons, INC., Publication, USA.
3. Bioinformatics (Concept, Skills and Applications) – S. C. Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002 (INDIA).
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N. Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi – 110002.

ENVIRONMENTAL SCIENCES (BP206T)

(Theory) **45 hours**

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives:

Upon completion of the course the student shall be able to**:**

- Create the awareness about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the environment.
- Motivate learner to participate in environment protection and environment improvement.
- Acquire skills to help the concerned individuals in identifying and solving environmental problems.
- Strive to attain harmony with Nature.

Course outcome:

Upon completion of the course, the student shall be able to**:**

CO1: Create the awareness about environmental problems among learners.

CO2: Impart basic knowledge about the environment and its allied problems.

CO3: Develop an attitude of concern for the environment.

CO4: Motivate learner to participate in environment protection and environment improvement.

CO5: Demonstrate skills to help the concerned individuals in identifying and solving environmental problems.

CO6: Strive to attain harmony with Nature.

Course content

Unit I **03 hours**

The Multidisciplinary nature of environmental studies

Unit II **15 hours**

Natural Resources

Renewable and non-renewable resources: Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

Unit III 05 **hours**

Ecosystems

Concept of an ecosystem. Structure and function of an ecosystem.

Unti IV **12 hours**

Introduction, types, characteristic features, structure and function of theecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries).

Unit V **10 hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford

6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico
Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

SEMESTER - III
PHARMACEUTICAL ORGANIC CHEMISTRY – II (BP301T)

(Theory) **45 hours**

Scope: This subject deal with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

Objectives:

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds,
- Prepare organic compounds

Course outcome:

Upon completion of the course the student shall be able to

CO1: Categorize the organic compound according to its nature

CO2: Identify and describe the properties of a nucleophile, electrophile and free radical

CO3: Demonstrate the skill in analyzing the chemical parameters of fat /oil

CO4: Enumerate the basic mechanism involved in electrophilic aromatic substitution reaction.

CO5: Write the structure, synthesis, reaction, and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

CO6: Discuss the acidity of phenol and basicity of aromatic amine

CO7: Explain the reactivity of benzene towards electrophilic reagents

CO8: Discuss Baeyers strain theory and its limitations, Coulson and Moffitt's modification, Sachse Mohr's theory and the chemical properties of cyclopropane and cyclobutane

CO9: Differentiate the friedel crafts alkylation and acylation reactions

Course Content

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained.To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I **10 Hours**

Benzene and its derivatives

Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule

Reactions of benzene - nitration, sulphonation, halogenation-reactivity, Friedel crafts alkylation-reactivity, limitations, Friedel crafts acylation.

Substituents, effect of substituents on reactivity and orientation of monosubstituted benzene compounds towards electrophilic substitution reaction.

Structure and uses of DDT, Saccharin, BHC and Chloramine.

UNIT II **10 Hours**

Phenols* - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols.

Aromatic Amines* - Basicity of amines, effect of substituents on basicity and synthetic uses of aryl diazonium salts.

Aromatic Acids* –Acidity, effect of substituents on acidity and important reactions of benzoic acid.

UNIT III **10 Hours**

Fats and Oils

a. Fatty acids – reactions. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT IV **08 Hours**

Polynuclear hydrocarbons: Synthesis, reactions, Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives.

UNIT V **05 Hours**

Cyclo alkanes*

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only.

Retrosynthesis: Introduction and applications **02 Hours**

PHARMACEUTICAL ORGANIC CHEMISTRY - II (BP305P)

(Practical) **04 Hrs/week**

I . Experiments involving laboratory techniques
Recrystallization
Steam distillation

II. Determination of following oil values (including standardization of reagents)
Acid value
Saponification value
Iodine value

III. Preparation of compounds

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline
- Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnamic acid from Benzaldehyde by Perkin reaction
- *P*-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I. L. Finar, Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P. L. Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N. K. Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

PHYSICAL PHARMACEUTICS- I (BP302T)

(Theory) **45 Hours**

Scope: The course deals with the various physical and physicochemical properties, andprinciples involved in dosage forms/formulations. Theory and practical components of the

subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives:

Upon the completion of the course student shall be able to

- Understand various physicochemical properties of drug molecules in the designing the dosage forms
- Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
- Demonstrate use of physicochemical properties in the formulationdevelopment and evaluation of dosage forms.

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain various physicochemical properties of drug molecules in designing the dosage forms

CO2: Demonstrate knowledge on the principles of chemical kinetics & to apply them for stability testing and determination of expiry date of formulations.

CO3: Describe the use of physicochemical properties in the formulation development and evaluation of dosage forms.

CO4: Perform preliminary formulation development aspects of various dosage forms in laboratory.

Course Content

UNIT I **10 Hours**

Solubility of drugs:

Solubility expressions, mechanisms of solute solvent interactions,ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions)

Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

UNIT II **10 Hours**

States of Matter and properties of matter: State of matter, changes in the state of matter,latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols– inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.

Physicochemical properties of drug molecules: Refractive index, optical rotation,dielectric constant, dipole moment, dissociation constant, determinations and applications

UNIT III **10 Hours**

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions, surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

UNIT IV **08 Hours**

Complexation and protein binding: Introduction, Classification of Complexation,Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.

UNIT V **07 Hours**

pH, buffers and Isotonic solutions: Sorensen's pH scale, pH determination(electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

PHYSICAL PHARMACEUTICS – I (BP306P)

(Practical) **04 Hrs/week**

1. Determination of the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl_4 and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin
2. Experimental Pharmaceutics by Eugene, Parott.
3. Tutorial Pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.

5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

PHARMACEUTICAL MICROBIOLOGY (BP303T)

(Theory) **45 hours**

Scope:
Study of all categories of microorganisims especially for the production of alcohol, antibiotics, vaccines, vitamins, enzymes etc.

Objectives:

Upon completion of the subject student shall be able to

- Understand methods of identification, cultivation and preservation of various microorganisms
- To understand the importance and implementation of sterlization in pharmaceutical processing and industry
- Learn sterility testing of pharmaceutical products.
- Carried out microbiological standardization of Pharmaceuticals.
- Understand the cell culture technology and its applications in pharmaceutical industries.

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Demonstrate basic knowledge about the anatomy, identification, growth factors and sterilization of microorganisms.

CO2: Explain sterility testing of pharmaceutical products.

CO3: Perform staining techniques of slide preparation.

CO4: Exhibit knowledge of mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect.

CO5: Carry out microbiological standardization of Pharmaceuticals.

CO6: Describe the cell culture technology and apply them in pharmaceutical industries.

CO7: Describe the principle and applications of compound as well as electron microscopy

CO8: Identify the bacterial morphology using staining techniques and acquire knowledge on the principles of biochemical tests.

Course content

Unit I

Introduction, history of microbiology, its branches, scope and its importance.
Introduction to Prokaryotes and Eukaryotes
Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).
Study of different types of phase constrast microscopy, dark field microscopy and electron microscopy.

Unit II **10 Hours**

Identification of bacteria using staining techniques (simple, Gram's &Acid fast staining) and biochemical tests (IMViC).
Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization.Evaluation of the efficiency of sterilization methods.Equipments employed in large scale sterilization. Sterility indicators.

Unit III **10 Hours**

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses.
Classification and mode of action of disinfectants. Factors influencing disinfection, antiseptics and their evaluation for bacteriostatic and bactericidal actions
Evaluation of bactericidal & Bacteriostatic. Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV **08 Hours**

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification. Principles and methods of different microbiological assay.Methods for standardization of antibiotics, vitamins and amino acids.Assessment of a new antibiotic.

Unit V **07 Hours**

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage. Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations. Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.
Application of cell cultures in pharmaceutical industry and research.

PHARMACEUTICAL MICROBIOLOGY (BP 307P)

(Practical) **04 Hrs/week**

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.

4. Staining methods-Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test : IMViCtest

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn. Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan: Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N. K. Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

PHARMACEUTICAL ENGINEERING (BP304T)

(Theory) **45 Hours**

Scope: This course is designed to impart a fundamental knowledge on the art and scienceof various unit operations used in pharmaceutical industry.

Objectives: Upon completion of the course student shall be able:

- To know various unit operations used in Pharmaceutical industries.
- To understand the material handling techniques.
- To perform various processes involved in pharmaceutical manufacturing process.
- To carry out various test to prevent environmental pollution.
- To appreciate and comprehend significance of plant lay out design for optimum use of resources.
- To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain the basic equations of Pharmaceutical engineering.

CO2: List out various units and chemical process used in Pharmaceutical industries.

CO3: Draw diagrams and sketches of different equipment used in pharmaceutical industry

CO4: Understand the concept of humidity and usage of psychrometric chart

CO5: Explain the basic principles of diffusion and mass transfer

CO6: Perform simple distillation of mixtures or crude drugs, heat exchangers and evaporators

CO7: Describe the various materials used in plant construction and preventive methods used for corrosion control in Pharmaceutical industries.

Course content

UNIT I **10 Hours**

Flow of fluids: Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.

Size Reduction: Objectives, Mechanisms & Laws governing size reduction,factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.

Size Separation: Objectives, applications & mechanism of size separation,official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

UNIT II **10 Hours**

Heat Transfer: Objectives, applications & Heat transfer mechanisms. Fourier'slaw, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

Evaporation: Objectives, applications and factors influencing evaporation,differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator.

Distillation: Basic Principles and methodology of simple distillation, flashdistillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT III **10 Hours**

Drying: Objectives, applications & mechanism of drying process, measurements& applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.

Mixing: Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquid mixing and semisolid mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles& Silverson Emulsifier.

UNIT IV

08 Hours

Filtration: Objectives, applications, Theories & Factors influencing filtration,filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.

Centrifugation: Objectives, principle & applications of Centrifugation,principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

UNIT V **07 Hours**

Materials of pharmaceutical plant construction, Corrosion and its prevention: Factors affecting during materials selected for Pharmaceutical plantconstruction, Theories of corrosion, types of corrosion and their prevention. Ferrous and nonferrous metals, inorganic and organic non-metals, basic of material handling systems.

PHARMACEUTICAL ENGINEERING (BP308P)

(Practical) **04 Hours/week**

1. Determination of radiation constant of brass, iron, unpainted and painted glass.
2. Steam distillation – To calculate the efficiency of steam distillation.
3. To determine the overall heat transfer coefficient by heat exchanger.
4. Construction of drying curves (for calcium carbonate and starch).
5. Determination of moisture content and loss on drying.
6. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
7. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
8. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
9. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.

10. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such othermajor equipment.
11. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity)
12. To study the effect of time on the Rate of Crystallization.
13. To calculate the uniformity Index for given sample by using Double Cone Blender.

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson-Latest edition.
3. Unit operation of chemical engineering – Mcabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S. Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann, Latest edition.
7. Physical pharmaceutics- C.V.S. Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial Pharmacy, S. J. Carter, Latest edition.

SEMESTER IV
PHARMACEUTICAL ORGANIC CHEMISTRY – III (BP401T)

(Theory) **45 hours**

Scope: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Objectives:

At the end of the course, the student shall be able to
- Understand the methods of preparation and properties of organic compounds
- Explain the stereo chemical aspects of organic compounds and stereo chemical reactions
- Know the medicinal uses and other applications of organic compounds

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain the method of preparation, chemical reactions and uses of heterocyclic compounds

CO2: Describe the nomenclature and classification of heterocyclic compounds

CO3: Discuss the basics of stereochemistry

CO4: Explain stereoselective and stereospecifc reactions

CO5: Reiterate the reactions of synthetic importance

Course Content
Note: To emphasize on definition, types, mechanisms, examples, uses/applications

UNIT I **10 Hours**
Stereo isomerism

Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds, Elements of symmetry, chiral and achiral molecules.

DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers.Reactions of chiral molecules.
Racemic modification and resolution of racemic mixture. Asymmetric synthesis: partial and absolute.

UNIT II **10 Hours**
Geometrical isomerism
Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)
Methods of determination of configuration of geometrical isomers.Conformational isomerism in Ethane, n-Butane and Cyclohexane.
Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.
Stereospecific and stereoselective reactions

UNIT III **10 Hours**
Heterocyclic compounds:
Nomenclature and classification, Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene.
Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene.

UNIT IV **08 Hours**
Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrazole, Imidazole, Oxazole Thiazole and Quinazoline.
Pyridine, Quinoline, Isoquinoline, Acridine and Indole.Basicity of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives.

UNIT V **07 Hours**
Reactions of synthetic importance
Metal hydride reduction ($NaBH_4$and $LiAlH_4$), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.
Oppenauer-oxidation and Dakin reaction.
Beckmanns rearrangement and Schmidt rearrangement. Claisen- Schmid condensation.

Recommended Books (Latest Editions)

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist.

MEDICINAL CHEMISTRY – I (BP402T)

(Theory) **45 hours**

Scope: This subject is designed to impart fundamental knowledge on the structure,chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives:

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship (SAR) of different class of drugs
- Write the chemical synthesis of some drugs

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Demonstrate the knowledge on chemistry of Autonomic nervous system and Central nervous system drugs with respect to their pharmacological activity

CO2 : Discuss the physiochemical properties of drugs in relation to biological action

CO3 : Discuss the principles involved in drug metabolism and the factors affecting it

CO4: Discuss the mechanism of action, metabolic pathways, adverse effect and therapeutic value of drugs acting on Autonomic nervous system and Central nervous system drugs

CO5: Interpret the Structural Activity Relationship (SAR) of different class of Autonomic nervous system and Central nervous system drugs

CO6: Write the chemical synthesis of some important medicinally active compounds of Autonomic nervous system and Central nervous system

CO7: Predict the mechanism of action for few drugs.

Course Content

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT I

10 Hours

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

Drug metabolism

Drug metabolism principles- Phase I and Phase II.
Factors affecting drug metabolism including stereo chemical aspects.

UNITII **10 Hours**

Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.
Adrenergic receptors (Alpha & Beta) and their distribution

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.
Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha adrenergic blockers:
Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol*,Metipranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT III **10 Hours**

Cholinergic neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):

Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolatehydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT IV

08 Hours

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

Barbiturates: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

Miscelleneous:

Amides & imides: Glutethmide. Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

Phenothiazeines: SAR of Phenothiazeines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Ring Analogues of Phenothiazeines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpiride.

C. Anticonvulsants: SAR of Anticonvulsants**,** mechanism of anticonvulsant action.

Barbiturates: Phenobarbitone, Methabarbital.

Hydantoins: Phenytoin*, Mephenytoin, Ethotoin.

Oxazolidine diones: Trimethadione, Paramethadione.

Succinimides: Phensuximide, Methsuximide, Ethosuximide*

Urea and monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam.

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate.

UNIT V **07 Hours**

Drugs acting on Central Nervous System

General anesthetics:

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.
Ultra - short acting barbitutrates: Methohexital sodium*, Thiamylalsodium, Thiopental sodium.
Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics
Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anileridine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepirac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

MEDICINAL CHEMISTRY – I (BP406P)

(Practical) **4 hours/week**

I. **Preparation of drugs/ intermediates**

1,3-pyrazole
1,3-oxazole
Benzimidazole
Benztriazole
2,3- diphenyl quinoxaline
Benzocaine
Phenytoin
Phenothiazine
Barbiturate

II. **Assay of drugs**

Chlorpromazine
Phenobarbitone
Atropine
Ibuprofen
Aspirin
Furosemide

III. **Determination of Partition coefficient for any two drugs**

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A. I. Vogel. 94.

PHYSICAL PHARMACEUTICS - II (BP403T)

(Theory) **45 Hours**

Scope: The course deals with the various physical and physicochemical properties, andprinciples involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives:

Upon the completion of the course student shall be able to

- Understand various physicochemical properties of drug molecules in designing the dosage forms
- Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
- Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain various physicochemical properties of drug molecules in the designing the dosage forms

CO2: Explain different chemical kinetics equations

CO3: Apply Arrhenius equations for determination of expiry date of formulations

CO4: Calculate absolute and relative viscosity of liquids

CO5: Carry out solubility behavior study

CO6: Describe the matter properties & viscosity with Newtonian flow systems and non-Newtonian flow systems.

CO7: Analise Buffer solutions and apply buffer equations

CO8: Discuss the physicochemical properties in the formulation development and evaluation of dosage forms.

CO9: Describe the fundamental and derived properties of powders

CO10: Explain the properties, stability and applications of colloidal systems.

Course Content

UNIT I **05 Hours**

Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, c oacervation, peptization & protective action.

UNIT II **10 Hours**

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature,non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain,Elastic Modulus

UNIT III **10 Hours**

Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method.

UNIT IV **10 Hours**

Micromeretics: Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.

UNIT V **10 Hours**

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basicrate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation.Accelerated stability testing in expiration dating of pharmaceutical dosage forms.Photolytic degradation and its prevention.

PHYSICAL PHARMACEUTICS- II (BP 407P)

(Practical) **4 Hrs /week**

1. Determination of particle size, particle size distribution using sieving method
2. Determination of particle size, particle size distribution using Microscopic method
3. Determination of bulk density, true density and porosity
4. Determine the angle of repose and influence of lubricant on angle of repose
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination of sedimentation volume with effect of different suspending agent
7. Determination of sedimentation volume with effect of different concentration of single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2,
3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

PHARMACOLOGY- I (BP404T)

(Theory) **45 Hours**

Scope: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

Objectives:

Upon completion of this course the student should be able to

- Understand the pharmacological actions of different categories of drugs.
- Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
- Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
- Observe the effect of drugs on animals by simulated experiments.
- Appreciate correlation of pharmacology with other bio medical sciences.

Course outcome:
Upon completion of the Course, thestudent will be able to:

CO1: Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.

CO2: Define the different classes of drugs and identify representative drugs from each class for treatment of various disease conditions.

CO3: Describe the various receptor actions.

CO4: Discuss the concepts of absorption, distribution, metabolism and excretion.

CO5: Describe the pharmacological actions of different categories of drugs.

CO6: Describe routes of administration of different classes of drugs.

CO7: Explain Neurohumoral transmission of Autonomic Nervous System and Central Nervous System.

CO8: Classify and describe the significance of Neurotransmitters of Autonomic Nervous System and Central Nervous System.

CO9: State the pharmacological actions, adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs acting on Autonomic Nervous System and Central Nervous System.

CO10: Define the major pharmacokinetic features/limitations of drugs acting on Autonomic Nervous System and Central Nervous System.

CO11: Identify the major indications (uses) of drugs acting on Autonomic Nervous System and Central Nervous System.

CO12: Describe the common mechanisms of drug interactions and their impact on drug therapy.

CO13: Demonstrate the effect of drugs on animals by simulated experiments using softwares.

CO14: Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.

CO15: Apply the basic pharmacological knowledge in the prevention of drug-drug interaction and drug abuse.

CO16: Correlate the knowledge of pharmacology with related medical sciences appropriately.

Course Content

UNIT I **08 hours**

General Pharmacology

Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists (competitive and non-competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs. Enzyme induction, enzyme inhibition, kinetics of elimination.

UNIT II **12 Hours**

General Pharmacology

Pharmacodynamics-Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors, drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action. Adverse drug reactions. Drug interactions (pharmacokinetic and pharmacodynamic)

Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNITIII **10 Hours**

Pharmacology of drugs acting on peripheral nervous system

a. Organization and function of ANS.

b. Neurohumoral transmission, co-transmission and classification of neurotransmitters. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral). Local anesthetic agents. Drugs used in myasthenia gravis and glaucoma.

UNIT IV **08 Hours**

Pharmacology of drugs acting on central nervous system

Neurohumoral transmission in the C. N. S. special emphasis on importance of various neurotransmitters like GABA, Glutamate, Glycine, serotonin, dopamine. General anesthetics and pre-anesthetics**.** Sedatives, hypnotics and centrally acting muscle relaxants.Anti-epileptics.Alcohols and disulfiram.

UNIT V **07 Hours**

Pharmacology of drugs acting on central nervous system

Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens. Drugs used in Parkinsons disease and Alzheimer's disease. CNS stimulants and nootropics.Opioid analgesics and antagonists.Drug addiction, drug abuse, tolerance and dependence.

PHARMACOLOGY- I (BP408P)

(Practical) **4Hrs/Week**

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,.Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M. M. Lippincott's Illustrated Reviews-Pharmacology
6. K. D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan,

PHARMACOGNOSY AND PHYTOCHEMISTRY- I (BP405T)

(Theory) **45 hours**

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification ofcrude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

Objectives:

Upon completion of the course, the student shall be able to

- Know the techniques in the cultivation and production of crude drugs
- Know the crude drugs, their uses and chemical nature
- Know the evaluation techniques for the herbal drugs
- Carry out the microscopic and morphological evaluation of crude drugs

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Describe the techniques in the cultivation and production of crude drugs
CO2: Enumerate about the crude drugs, chemical nature and their uses
CO3: Explain the microscopic and morphological evaluation of crude drugs
CO4: Discuss the quality control of crude drugs.
CO5: Explain the plant tissue culture
CO6: Discuss the role of Pharmacognosy in allopathy and traditional systems of medicine.

Course Content

UNIT I **10 Hours**

Introduction to Pharmacognosy:

Definition, history, scope and development of Pharmacognosy. Sources of Drugs – Plants, Animals, Minerals, Marine & Tissue culture. Introduction to organized drugs and unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum - resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs.

Quality control of Drugs of Natural Origin:

Adulteration of drugs of natural origin.Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT II **10 Hours**

Cultivation, Collection, Processing and storage of drugs of natural origin:

Cultivation and Collection of drugs of natural origin. Factors influencing cultivation of medicinal plants.

Plant hormones and their applications. Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

Brief note on endangered medicinal plants and list of endangered plants

Need for conservation. Methods of conservation - In-situ and ex-situ Conservation and Traditional Methods of Conserving Medicinal Plants. Germ plasm technique for conservation

Cryopreservation technique for conservation of Plants

Tissue Culture Techniques Used for Conservation

Genetic Conservation

Govt. policies for conserving the medicinal plants

UNIT III **07 Hours**

Plant tissue culture:

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance. Applications of plant tissue culture in pharmacognosy. Edible vaccines

UNIT IV **06Hours**

Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT V **12 Hours**

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products:

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites: General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic uses and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites:

Carbohydrates: Acacia, Agar, Tragacanth, Honey, starch

Proteins and Enzymes: Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

Lipids (Waxes, fats, fixed oils): Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

Marine Drugs: Novel medicinal agents from marine sources

Pharmaceutical aid: Kaolin, Bentonite, Talc.

PHARMACOGNOSY AND PHYTOCHEMISTRY- I (BP409P)

(Practical) **04 Hours/Week**

1. Analysis of crude drugs by chemical tests:

(i) Tragacanth
(ii) Acacia
(iii) Agar
(iv) Gelatin
(v) Starch
(vi) Honey
(vii) Castor oil

2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming index

Recommended Books: (Latest Editions)

1. W. C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co. London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J. E., Pharmacognosy, 9thEdn.,Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis.
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Mangathayaru K. Pharmacognosy: An Indian Perspective, Peason. 2013.
7. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
8. Essentials of Pharmacognosy, Dr. S. H. Ansari, IInd edition, Birla publications, New Delhi, 2007.
9. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae.
10. Anatomy of Crude Drugs by M.A. Iyengar.
11. C. S. Shah's Pharmacognosy, Ramesh K. Goyal, D. Chamundeeswari, R. Thirumalaikumaran, NeeruVasudeva and Bhoomika M. Patel. 16th edition, B. S. Shah Prakashan, Ahmedabad.

SEMESTER V
MEDICINAL CHEMISTRY – II (BP501T)

(Theory) **45 Hours**

Scope: This subject is designed to impart fundamental knowledge on the structure,chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives:

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship of different class of drugs
- Study the chemical synthesis of selected drugs

Course outcome:

Upon completion of the course the student shall be able to

CO1: Demonstrate the knowledge on chemistry of Antihistaminic,Anti-anginal,Anti-hypertensive,Anti-arrhythmic,Diuretics, Anti-hyperlipidemic, Coagulant and Anticoagulants,Drugs

acting on Endocrine system, Antidiabetic agents and Local Anesthetics drugs with respect to their pharmacological activity.

CO2: Understand the drug metabolic pathways, adverse effect and therapeutic value of Antihistaminic,Anti-anginal,Anti-hypertensive,Anti-arrhythmic,Diuretics, Anti-hyperlipidemic, Coagulant and Anticoagulants,Drugs acting on Endocrine system, Antidiabetic agents and Local Anesthetics drugs.

CO3: Demonstrate the Structural Activity Relationship of Antihistaminic, Anti-anginal, Anti-hypertensive, Anti-arrhythmic, Diuretics, Anti-hyperlipidemic, Coagulant and Anticoagulants, Drugs acting on Endocrine system, Antidiabetic agents and Local Anesthetics drugs.

CO4: Write the chemical synthesis of selected drugs of Antihistaminic,Anti-anginal,Anti-hypertensive,Anti-arrhythmic,Diuretics, Anti-hyperlipidemic, Coagulant and Anticoagulants,Drugs acting on Endocrine system, Antidiabetic agents and Local Anesthetics drugs.

Course Content.

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*).

UNIT

10 Hours

Antihistaminic agents: Histamine, receptors and their distribution in thehumanbody

H_1–antagonists: Diphen hydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride*, Meclizine hydrochloride*, Buclizine hydrochloride*, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetrizine, Levocetrazine Cromolyn sodium.

H_2-antagonists: Cimetidine*, Famotidine, Ranitidin.

Gastric Proton pump inhibitors: Omeprazole*, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil*, Floxuridine, Cytarabine, Methotrexate*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT II **10 Hours**

Anti-anginal:

i. **Vasodilators:** Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole.

ii. **Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazemhydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

1. Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

2. Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol.

3. Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide,Bosentan, Tezosentan.

UNIT III

10 Hours

1. Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.
Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,
Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.
Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.
Osmotic Diuretics: Mannitol

2. Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine andCholestipol

3. Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel

UNIT IV **08 Hours**

Drugs acting on Endocrine system
Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

UNIT V

07 Hours

Antidiabetic agents:

Insulin and its preparations
Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride, Glibenclamide
Biguanides: Metformin.
Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.
Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A. I. Vogel.
11. Principles of Medicinal chemistry by Dr. S. S. Kadam
12. Medicinal Chemistry by Ashutoskar.

INDUSTRIAL PHARMACY- I (BP502T)

(Theory) 45 Hours

Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

Objectives: Upon completion of the course the student shall be able to

- Know the various pharmaceutical dosage forms and their manufacturing techniques.
- Know various considerations in development of pharmaceutical dosage forms
- Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Define various pharmaceutical dosage forms and their manufacturing techniques.

CO2: Categorize different manufacturing techniques.

CO3: Explain various considerations in development of pharmaceutical dosage forms

CO4: Formulate solid, liquid and semisolid dosage forms

CO5: Evaluate solid, liquid and semisolid dosage forms

CO6: Work independently in different fields of a pharmaceutical industry

Course content

UNITI **07 Hours**

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significance.

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT II **10 Hours**

Tablets:

Introduction, ideal characteristics of tablets, classification of tablets.Excipients, Formulation of tablets, granulation methods, compression and processing problems.Equipments and tablet tooling.

Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

Quality control tests: In process and finished product tests.

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

UNITIII **08 Hours**
Capsules:

Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. Size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

UNIT IV **10 Hours**

Parenteral Products:
Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
Production procedure, production facilities and controls, aseptic processing
Formulation of injections, sterile powders, large volume parenterals and lyophilized products.

Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eyedrops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

UNIT V **10 Hours**

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

Packaging Materials Science: Materials used packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

INDUSTRIAL PHARMACY - I (BP506P)
(Practical)

4 Hours/week

1. Preformulation studies on paracetamol/aspirin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Quality control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (as per IP)

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Lieberman & Lachman
7. Pharmaceutics- The science of dosage form design by M. E. Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5thedition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

PHARMACOLOGY- II (BP503T)

(Theory) **45 Hours**

Scope: This subject is intended to impart the fundamental knowledge on various aspects(classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition, emphasis on the basic concepts of bioassay.

Objectives:

Upon completion of this course the student should be able to

- Understand the mechanism of drug action and its relevance in the treatment of different diseases
- Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments.
- Demonstrate the various receptor actions using isolated tissue preparation.
- Appreciate correlation of pharmacology with related medical sciences

Course outcome:

Upon completion of the Course, the student will be able to:

CO1: Explain the electrophysiology of heart and classify the drugs acting on cardiovascular system.

CO2: Describe the mechanism of action, therapeutic effects, clinical uses, side effects and contraindications of drugs acting on different systems of body like cardiovascular system, Urinary system and Endocrine system.

CO3: Classify Autacoids and explain their physiological and pathophysiological role.

CO4: Emphasise the basic concepts of bioassay.

CO5: Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments.

CO6: Explain the basic concepts in endocrine pharmacology.

CO7: Reproduce the mechanism of drug action and its relevance in the treatment of different diseases.

CO8: Correlate the preclinical data to humans.

Course Content

UNIT I

10 hours

Pharmacology of drugs acting on cardio vascular system

Introduction to hemodynamic and electrophysiology of heart.
Drugs used in congestive heart failure
Anti-hypertensive drugs.
Anti-anginal drugs.
Anti-arrhythmic drugs.

Anti-hyperlipidemic drugs.

UNITII **10 hours**

Pharmacology of drugs acting on cardio vascular system

Drug used in the therapy of shock.
Hematinics, coagulants and anticoagulants.
Fibrinolytics and anti-platelet drugs
Plasma volume expanders

Pharmacology of drugs acting on urinary system

Diuretics
Anti-diuretics.

UNIT III

10 hours

Autacoids and related drugs

Introduction to autacoids and classification
Histamine, 5-HT and their antagonists.
Prostaglandins, Thromboxanes and Leukotrienes.
Angiotensin, Bradykinin and Substance P.
Non-steroidal anti-inflammatory agents
Anti-gout drugs
Antirheumatic drugs

UNIT IV

08 hours

Pharmacology of drugs acting on endocrine system

Basic concepts in endocrine pharmacology.
Anterior Pituitary hormones- analogues and their inhibitors.
Thyroid hormones- analogues and their inhibitors.
Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
Insulin, Oral Hypoglycemic agents and glucagon.
ACTH and corticosteroids.

UNIT V **07 hours**

Pharmacology of drugs acting on endocrine system

Androgens and Anabolic steroids.
Estrogens, progesterone and oral contraceptives.
Drugs acting on the uterus.

Bioassay

a. Principles and applications of bioassay.
b. Types of bioassay
c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT.

PHARMACOLOGY- II (BP507P)

(Practical) **04 Hrs/Week**

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
6. K. D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

PHARMACOGNOSY AND PHYTOCHEMISTRY- II (BP504T)

(Theory) **45 Hours**

Scope: The main purpose of subject is to impart the students the knowledge of how thesecondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

Objectives:

Upon completion of the course, the student shall be able to

- Know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents.
- Understand the preparation and development of herbal formulation.
- Understand the herbal drug interactions to carryout isolation and identification of phytoconstituents.

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Discuss the introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of secondary metabolites:

CO2: Describe the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents

CO3: Demonstrate the preparation and development of herbal formulation

CO4: Recognise the herbal drug interactions

CO5: Carryout isolation and identification of phytoconstituents

CO6: Enumerate the basic metabolic pathways in higher plants

CO7: Explain the utilization of radioactive isotopes in the investigation of Biogenetic studies.

Course Content

UNIT I **07 Hours**

Metabolic pathways in higher plants and their determination

Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT II **14 Hours**

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium, Cinchona, ephedra

Phenylpropanoids and Flavonoids: Lignans (Quassia), Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

ridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT III **06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

a) Terpenoids: Menthol, Citral, Artemisin
b) Glycosides: Glycyrhetinic acid & Rutin
c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine
d) Resins: Podophyllotoxin, Curcumin

UNIT IV **10 Hours**

Industrial production, estimation and utilization of the following phytoconstituents:
Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT V 0**8 Hours**

Basics of Phytochemistry

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.

PHARMACOGNOSY AND PHYTOCHEMISTRY- II (BP508P)

(Practical) **04 Hours/Week**

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles

a. Caffeine - from tea dust.
b. Diosgenin from Dioscorea
c. Atropine from Belladonna
d. Sennosides from Senna

3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstitutents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv)

Aloes (v) Myrrh

Recommended Books: (Latest Editions)

1. W. C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37 th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), I st Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr. S H. Ansari, II nd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H. Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.
14. C. S. Shah's Pharmacognosy, Ramesh K. Goyal, D. Chamundeeswari, R. Thirumalaikumaran, NeeruVasudeva and Bhoomika M. Patel. 16th edition, B. S. Shah Prakashan, Ahmedabad.

PHARMACEUTICAL JURISPRUDENCE (BP505T)

(Theory) **45 Hours**

Scope: This course is designed to impart basic knowledge on importantlegislations related to the profession of pharmacy in India.

Objectives: Upon completion of the course, the student shall be able to understand:

- The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- Various Indian pharmaceutical Acts and Laws.
- The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
- The code of ethics during the pharmaceutical practice.

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain the Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.

CO2: Explain the various Indian pharmaceutical Acts and Laws

CO3: Understand the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals

CO4: Apply the code of ethics in professional practice

Course Content:

UNIT-I **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from

Import, Import under license or permit. Offences and penalties**.**

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-III **10 Hours**

Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; itsconstitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties

Medicinal and Toilet Preparation Act–1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation,

opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties.

UNIT-IV **08 Hours**

Study of Salient Features of Drugs and Magic Remedies Act and its

Rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties

Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties

National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM).

UNIT-V **07 Hours**

Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee

Code of Pharmaceutical ethics D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath

Medical Termination of Pregnancy Act

Right to Information Act

Introduction to Intellectual Property Rights (IPR)

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. 9.Bare Acts of the said laws published by Government. Reference books (Theory)

SEMESTER - VI
MEDICINAL CHEMISTRY – III (BP601T)

(Theory) **45 Hours**

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Objectives:

Upon completion of the course student shall be able to

- Understand the importance of drug design and different techniques of drug design.
- Understand the chemistry of drugs with respect to their biological activity.
- Know the metabolism, adverse effects and therapeutic value of drugs.
- Know the importance of SAR of drugs.

Course outcome:

Upon completion of the course, student shall be able to:

CO1 : Explain the basic concept and application of prodrug design.

CO2 : Write the structure and uses of different classes of drugs.

CO3 : Outline the chemical synthesis of selected drugs

CO4 : Demonstrate the principles of pharmacophore modeling and docking studies.

CO5 : Correlate the pharmacological activity with the structure

CO6 : Discuss the mechanism of action of antibiotics, antimalarial, and antitubercular drugs.

CO7: Enumerate the applications of combinatorial chemistry.

CO8 : Discuss the structure activity relationship of quinolone, quinolines and azoles.

Course Content

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*).

UNIT I **12 Hours**

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

β-Lactam antibiotics: Penicillin, Cepholosporins,β- Lactamase inhibitors,Monobactams
Aminoglycosides: Streptomycin, Neomycin, Kanamycin
Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline
Macrolide: Erythromycin Clarithromycin, Azithromycin.
Miscellaneous: Chloramphenicol*, Clindamycin.

UNIT II **08 Hours**

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine,Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovoquone.

UNIT III **10 Hours**

Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para Amino salicylic acid.*

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid,
Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT IV **08 Hours**

Antifungal agents:

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole,Oxiconazole Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide,Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*,Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT V **07 Hours**

Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.

Pharmacophore modeling and docking t echniques

Combinatorial Chemistry: Concept and applications of combinatorialchemistry: solid phase and solution phase synthesis.

MEDICINAL CHEMISTRY- III (BP607P)

(Practical) **04 Hours / week**

I.Preparation of drugs and intermediates

1. Sulphanilamide
2. 7-Hydroxy, 4-methyl coumarin
3. Chlorobutanol
4. Triphenyl imidazole
5. Tolbutamide
6. Hexamine

II.Assay of drugs

1. Isonicotinic acid hydrazide
2. Chloroquine
3. Metronidazole
4. Dapsone
5. Chlorpheniramine maleate
6. Benzyl penicillin

III. Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV. Drawing structures and reactions using chem draw®

V. Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's Extra Pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A. I. Vogel.

PHARMACOLOGY- III (BP602T)

(Theory) **45 Hours**

Scope: This subject is intended to impart the fundamental knowledge on various aspects(classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chronopharmacology.

Objectives:

Upon completion of this course the student should be able to:

- Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
- Comprehend the principles of toxicology and treatment of various poisonings and
- Appreciate correlation of pharmacology with related medical sciences.

Course outcome:

Upon completion of the Course, the student will be able to:

CO1: Explain the mechanism of action, pharmacological actions, adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs acting on Respiratory System and Gastrointestinal tract.

CO2: Discuss the general principles of Chemotherapy.

CO3: Explain the mechanism of action of chemotherapeutic agents and its relevance in the treatment of infectious diseases.

CO4: Apply the principles of toxicology and treatment of various poisonings.

CO5: Explain the principles of Immunopharmacology and its significance.

CO6: Perform the chemical tests to identify poisoning.

CO7: Explain the different methods of toxicity studies in animal models.

CO8: Demonstrate *in-vitro* and *in-vivo* preclinical evaluation processes.

CO9: Relate the knowledge of pharmacological actions of drugs to organ toxicity.

CO10: Explain the biological clock and their significance leading to chronotherapy.

CO11: Carry out the dose calculation in pharmacological experiments.

CO12: Calculate acute oral toxicity (LD50) of a drug from a given data.

CO13: Calculate pharmacokinetic parameters from a given data.

CO14: Explain the biostatistics methods in experimental pharmacology (student's t test, ANOVA, Chi square test, Wilcoxon Signed Rank test).

Course Content

UNIT I **10 hours**

Pharmacology of drugs acting on Respiratory system

a. Anti -asthmatic drugs
b. Drugs used in the management of COPD
c. Expectorants and antitussives
d. Nasal decongestants
e. Respiratory stimulants

Pharmacology of drugs acting on the Gastrointestinal Tract

a. Antiulcer agents.
b. Drugs for constipation and diarrhoea.
c. Appetite stimulants and suppressants.
d. Digestants and carminatives.

e. Emetics and anti-emetics.

UNIT II **10 hours**

Chemotherapy

a. General principles of chemotherapy.
b. Sulfonamides and cotrimoxazole.
c. Antibiotics - Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolines, tetracycline and aminoglycosides

UNIT III **10 hours**

Chemotherapy

a. Antitubercular agents
b. Antileprotic agents
c. Antifungal agents
d. Antiviral drugs
e. Anthelmintics
f. Antimalarial drugs
g. Antiamoebic agents

UNIT IV **08 hours**

Chemotherapy

a. Urinary tract infections and sexually transmitted diseases.
b. Chemotherapy of malignancy.

Immunopharmacology

a. Immunostimulants
b. Immunosuppressant
Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT V **07 hours**

Principles of toxicology

a. Definition and basic knowledge of acute, subacute and chronic toxicity.
b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
c. General principles of treatment of poisoning
d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound, lead, mercury and arsenic poisoning.

Chronopharmacology

a. Definition of rhythm and cycles.
b. Biological clock and their significance leading to chronotherapy.

PHARMACOLOGY- III (BP608P)

(Practical) **4Hrs/Week**

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.

4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology (student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

Note:Experiments are demonstrated by simulated experiments/videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K. D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R. Craig& Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan,
10. N. Udupa and P. D. Gupta, Concepts in Chronopharmacology.

HERBAL DRUG TECHNOLOGY (BP603T)

(Theory) **45 hours**

Scope: This subject gives the student the knowledge of basic understanding of herbal drugindustry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs.

Objectives:

Upon completion of this course the student should be able to:

- understand sourcing of herbal drugs from cultivation to herbal drug product
- know the WHO and ICH guidelines for evaluation of herbal drugs
- know the herbal cosmetics, natural sweeteners, nutraceuticals
- appreciate patenting of herbal drugs, GMP.

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain the raw materials as source of herbal drugs

CO2: Understand the process involved in cultivation of herbal drug to product preparation

CO3: Explain WHO and ICH guidelines for evaluation of herbal drugs

CO4: Describe the preparation and standardization of herbal formulation and herbal cosmetics

CO5: Understand the role of nutraceuticals in various ailments and the products available in the market

CO6: Describe the significance of herbs as excipients

CO7: Explain the process of patenting of herbal drugs

CO8: Recognize Herb-Drug and Herb-Food Interactions

CO9: Describe the basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

Course content

UNIT I **11 Hours**

Herbs as raw materials in the preparation of herbal formulation

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs Selection, identification and authentication of herbal materials Processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides / Bioinsecticides. Revival of traditional agricultural practices

Indian Systems of Medicine

Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy.
Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma, Taila, lepa and kasaya.

UNIT II **07 Hours**

Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market.Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.
Study of following herbs as health food: Alfalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina.

Herbal-Drug and Herb-Food Interactions:

General introduction to interaction andclassification. Study of following drugs and their possible side effects and interactions: Hypericum, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper, Ephedra, Turmeric and ginger.

UNIT III **10 Hours**

Herbal Cosmetics

Sources and description of raw materials of herbal origin used viz., fixed oils, waxes, gums, colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:

Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations:

Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT IV **10 Hours**

Evaluation of Drugs - WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:

Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT V **07 Hours**

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India. Export potential / trade of medicinal plants

Schedule T–Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

HERBAL DRUG TECHNOLOGY (BP609P)

(Practical) **04 hours/ week**

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.

6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr. S. H. Ansari
5. Pharmacognosy & Phytochemistry by V. D. Rangari
6. Pharmacopoeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
8. Mangathayaru, K. Pharmacognosy- an Indian Perspective. Pearson Publisher, India, 2013.

BIOPHARMACEUTICS AND PHARMACOKINETICS (BP604T)

(Theory) **45 Hours**

Scope: This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arised therein.

Objectives:

Upon completion of the course student shall be ableto:

- Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- Understand various pharmacokinetic parameters, their significance & applications.

Course outcome:

Upon completion of the course student shall be able to:

CO1: Explain the basic concepts in biopharmaceutics and pharmacokinetics

CO2: Discuss about the significance of pharmacokinetics principles .

CO3: Apply formulas to calculate the pharmacokinetic parameters using plasma drug concentration-time data.

CO4: Apply the concepts of bioavailability and bioequivalence of drug products and their significance.

CO5: Enumerate the basic pathways involved in metabolism of drugs including the cytochrome p-450 cycle.

CO6: Perform various pharmacokinetic parameters, their significance & applications.

CO7: Carry out the protein binding studies of drugs.

CO8: Determine the reaction *order* from *experimental* data and solve it

CO9: Analyze experimental results, differentiating between simulated and real patient data.

CO10: Identify drug - drug interactions and food - drug interactions

Course content

UNIT I **10 Hours**

Absorption; Mechanisms of drug absorption through GIT, factors influencing drugabsorption though GIT, absorption of drug from Non-per oral extra-vascular routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT II **10 Hours**

Elimination: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non-renal routes of drug excretion of drugs

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability,absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT III **10 Hours**

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non-compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_E ,t1/2,Vd,AUC,Ka, Clt and CL_R- definitions methods of eliminations, understanding of their significance and application.

UNIT IV **08 Hours**

Multicompartment models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.

UNIT V 07 Hours

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International edition. USA

4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi, Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack,
11. Publishing Company, Pennsylvania 1989.
12. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
13. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.

PHARMACEUTICAL BIOTECHNOLOGY (BP605T)

(Theory) **45 Hours**

Scope: Biotechnology has a long promise to revolutionize the biological sciences and technology. Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.

Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new
and cheaper pharmaceutical drugs.

Biotechnology has already produced transgenic crops and animals and the future promises lot more. It is basically a research-based subject.

Objectives:

Upon completion of the subject student shall be able to;

- Understand the importance of Immobilized enzymes in Pharmaceutical Industries
- Genetic engineering applications in relation to production of pharmaceuticals
- Importance of Monoclonal antibodies in Industries
- Appreciate the use of microorganisms in fermentation technology

Course outcome:

Upon completion of the subject student shall be able to:

CO1: Differentiate the organisms by its cell structure, explain the arrangement of genes and their interaction.

CO2: Explain the structure of nucleic acids, list out their types and forms

CO3: Apply principles of animal culture, media preparation in Pharmaceutical Industries

CO4: Describe the importance of Immobilized enzymes in Pharmaceutical Industries

CO5: Discuss importance of recombinant DNA technology in production of therapeutic compounds

CO6: Discuss about the genetic engineering applications in relation to production of pharmaceuticals

CO7: Describe the importance of Monoclonal antibodies in Industries.

CO8: Explain infections caused by different bacteria and viruses.

CO9: Enumerate the principles underlying various Instruments and Immunotechniques.

CO10: Describe principles underlying design of Fermentor and Fermentation Process.

CO11: Identify careers in biotechnology, and skills required for handling a job.

CO12: Develop ethics in biotechnology, including confidentiality and scientific accountability.

CO13: Describe in detail about gene cloning, hybridoma technology & DNA fingerprinting with their applications

Course content

Unit I **10 Hours**

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
Enzyme Biotechnology- Methods of enzyme immobilization and applications.
Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
Brief introduction to Protein Engineering.
Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase,
Lipase, Protease, Penicillinase.
Basic principles of genetic engineering.

Unit II **10 Hours**

Study of cloning vectors, restriction endonucleases and DNA ligase.
Recombinant DNA technology. Application of genetic engineering in medicine.
Application of r DNA technology and genetic engineering in the production of:
i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.
Brief introduction to PCR

Unit III **10 Hours**

Types of immunity- humoral immunity, cellular immunity
Structure of Immunoglobulins
Structure and Function of MHC
Hypersensitivity reactions, Immune stimulation and Immune suppressions.
General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
Storage conditions and stability of official vaccines
Hybridoma technology- Production, Purification and Applications

Unit IV **08 Hours**

Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
Genetic organization of Eukaryotes and Prokaryotes
Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
Introduction to Microbial biotransformation and applications.
Mutation: Types of mutation/mutants.

Unit V **07 Hours**

Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.

Large scale production fermenter design and its various controls.

Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,

Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.

Recommended Books (Latest edition):

1. B. R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldshy et. al.: Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

QUALITY ASSURANCE (BP606T)

(Theory) **45 Hours**

Scope: This course deals with the various aspects of quality control and qualityassurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives:

Upon completion of the course student shall be able to:

- Understand the cGMP aspects in a pharmaceutical industry
- Appreciate the importance of documentation
- Understand the scope of quality certifications applicable to pharmaceutical industries
- Understand the responsibilities of QA & QC departments

Course outcome:

Upon completion of the course student shall be able to:

CO1 : Explain the basic concepts and various terminologies used in the area of quality, quality control and quality management system.

CO2 : Identify the elements and philosophies that are part of the quality measuring process in Total Quality Management system.

CO3 : Describe elements of standards and certifications of ISO.

CO4 : Explain QbD program and tools in pharmaceutical industry.

CO5: Apply the tools of analytical methods under *QbD* in Pharmaceutical drug development.

CO6 : Illustrate the importance and scope of calibration and validation.

CO7 : Apply Good warehousing practice in pharmaceutical industry.

CO8 : Apply the importance of *documentation,* quality audit, quality review in pharmaceutical quality system.
CO9 : Explain ICH Guidelines with special emphasis on Q-series.

Course content

UNIT I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP.

Total Quality Management (TQM): Definition, elements, philosophies.

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM,with special emphasis on Q-series guidelines, ICH stability testing guidelines.

Quality by design (QbD): Definition, overview, elements of QbD program, tools
ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation: Principles and procedures

UNIT II

10 Hours

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT III **10 Hours**

Quality Control: Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities,Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT IV **08 Hours**

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.
Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT V **07 Hours**

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.

4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sedhan K G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

SEMESTER VII
INSTRUMENTAL METHODS OF ANALYSIS (BP701T)

(Theory) **45 Hours**

Scope: This subject deal with the application of instrumental methods in qualitative andquantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives:

Upon completion of the course the student shall be able to

- Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
- Understand the chromatographic separation and analysis of drugs.
- Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course outcome:

Upon completion of the course the student shall be able to

CO1 : Describe the nature and interaction of electromagnetic radiation.

CO2 : Demonstrate knowledge on fundamental principles and measurement of various spectroscopic techniques.

CO3 : Illustrate the instrumental arrangement and operations of various spectrophotometers.

CO4 : Explain the applications and usage of spectroscopic techniques in industrial environment.

CO5 : Explain the basis of Chromatography.

CO6 : Identify appropriate chromatographic technique and approach for analysis.

CO7 : Describe the technical knowledge and practical experience in the chromatographic analyses and in capillary electrophoresis.

Course Content

UNIT I **10 Hours**

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications.

NMR: Theory, chemical shift and applications.

Mass: Theory, Instrumentation and applications.

UNIT II **10 Hours**

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nephelo turbidimetry- Principle, instrumentation and applications

UNIT III
Introduction to chromatography **10 Hours**

Adsorption and partition column chromatography- Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography- Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis–Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT IV **08 Hours**

Gas chromatography- Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications.

Highperformanceliquid chromatography (HPLC) - Introduction, theory, instrumentation, advantages and applications.

UNIT V **07 Hours**

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications.
Gel chromatography- Introduction, theory, instrumentation and applications.

Affinity chromatography- Introduction, theory, instrumentation and applications.

INSTRUMENTAL METHODS OF ANALYSIS (BP705P)

(Practical) **04 Hours/Week**

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
2. Estimation of dextrose by colorimetry

3. Estimation of sulfanilamide by colorimetry
4. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
5. Assay of paracetamol by UV- Spectrophotometry
6. Estimation of quinine sulfate by fluorimetry
7. Study of quenching of fluorescence
8. Determination of sodium by flame photometry
9. Determination of potassium by flame photometry
10. Determination of chlorides and sulphates by nephelo turbidometry
11. Separation of amino acids by paper chromatography
12. Separation of sugars by thin layer chromatography
13. Separation of plant pigments by column chromatography
14. Demonstration experiment on HPLC
15. Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. Instrumental methods of chemical analysis by R. Chatwal, Himalaya publishing house.
12. Text book of pharmaceutical analysis, 3rd edition by S. Ravishankar, Rx publicatons, Thirunelveli.
13. Principles and applications of UV Visible spectroscopy by Dr. A. Rajasekaran, Rupi publications, Srivilliputhur.
14. Instrumental method of analysis by Willard, 6th edition, CBS Publishers and distributors, New Delhi.
15. Pharmaceutical analysis, Vol II, by A.V. Kasture and More, Nirali Prakasham, Pune.

INDUSTRIAL PHARMACY- II (BP702T)

(Theory) **45 hours**

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Objectives:

Upon completion of the course, the student shall be able to:

- Know the process of pilot plant and scale up of pharmaceutical dosage forms
- Understand the process of technology transfer from lab scale to commercial batch
- Know different Laws and Acts that regulate pharmaceutical industry
- Understand the approval process and regulatory requirements for drug products

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain the importance of pilot plant and scale up of pharmaceutical dosage forms.

CO2: Acquire knowledge of technology transfer from lab scale to commercial batch.

CO3: Define and describe different Laws and Acts that regulate pharmaceutical industry.

CO4: Explain the approval process and regulatory requirements for drug products.

CO5: Explain the environmental considerations in pharmaceutical facilities.

CO6: Describe technology transfer in pharmaceutical companies from research area to production.

CO7: Describe about the fundamentals of pharmaceutical industry.

CO8: Perform work related to manufacturing, packaging and evaluation of dosage form.

Course Content

UNIT I **10 Hours**

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT II **10 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer(TT):Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT III **10 Hours**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT IV **08 Hours**

Quality management systems: Quality management & Certifications: Concept ofQuality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT V **07 Hours**

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php

3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.

PHARMACY PRACTICE (BP703T)

(Theory) **45 Hours**

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Objectives:

Upon completion of the course, the student shall be able to

- Explain various drug distribution methods in a hospital
- Appreciate the pharmacy stores management and inventory control
- Monitor drug therapy of patient through medication chart review and clinical review
- Obtain medication history interview and counsel the patients
- Identify drug related problems
- Detect and assess adverse drug reactions
- Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease statesKnow pharmaceutical care services
- Do patient counselling in community pharmacy;
- Appreciate the concept of Rational drug therapy.

Course outcome

Upon completion of the course, the student shall be able to:

CO1: Define and classify hospitals, explain the organization, structure and functions of a hospital and a hospital pharmacy

CO2: Describe the roles, responsibilities and functions of a hospital pharmacist including the Pharmacy and Therapeutics Committee and in the preparation of Hospital Formulary

CO3: Demonstrate knowledge onvarious drug distribution and dispensing methodsin a hospitaland apply it in hospital pharmacy practice setting.

CO4: Demonstrate ability to prepare and implement a budget, carry out purchase and inventory control of drugs in a hospital pharmacy, organize, stock the drugs including the investigational drugs and manage a pharmacy store in practice setup.

CO5: Explain the organisation, structure and requirements for the management of a community pharmacy, exhibit professional ethics and dispense drugs rationally, including over the counter drugs along with provision of patient education in a community pharmacy.

CO6: Explain the concept of clinical pharmacy, and involve in clinical pharmacy activities including monitoring the drug therapy of patients through medication chart review and clinical review, obtaining medication history interview and promoting medication adherence in patients.

CO7: Apply knowledge and skills to interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states, and in the interpretation of the prescribed medication order to

identify drug related problems, detect and assess adverse drug reactions, and to provide patient centered pharmaceutical care services.

CO8: Explain the drug information resources and steps involved in the provision of drug information services and apply the same in practice.

CO9: Describe the significance and general guidelines for TDM testing, list the commonly monitored drugs and considerations for TDM methods.

CO10: Communicate effectively with the patients, prescribers and other healthcare professionals.

Course Content

Unit I **10 Hours**

a) Hospital and it's organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

b) Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

c) Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

d) Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

Unit II **10 Hours**

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

b) Budget preparation and implementation

c)Drug store management and inventory control

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

d) Investigational use of drugs

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

Unit III **10 Hours**

a) Community Pharmacy
Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

b) Community pharmacy management
Financial, materials, staff, and infrastructure requirements.

c) Over the counter (OTC) sales
Introduction and sale of over the counter, and Rational use of common over the counter medications.

d) Education and training program in the hospital
Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

Unit IV **8 Hours**

a) Clinical Pharmacy
Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history interview and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

b) Interpretation of Clinical Laboratory Tests
Blood chemistry, hematology, and urinalysis

c) Patient medication history interview
Need for the patient medication history interview, medication interview forms.

d) Medication adherence
Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

Unit V **7 Hours**

a) Drug information services
Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.

b) Patient counseling
Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist

c) Therapeutic drug monitoring
Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

d) Adverse drug reaction
Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug

interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

e) Prescribed medication order and communication skills

Prescribed medication order- interpretation and legal requirements, Communication skills- communication with prescribers and patients.

Recommended Books (Latest Edition):

1. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of Clinical Pharmacy Practice-essential concepts and skills,* 1st ed. Chennai: Orient Longman Private Limited; 2004.
2. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
3. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
4. Scott LT. *Basic skills in interpreting laboratory data*, 4th ed. American Society of Health System Pharmacists Inc; 2009.
5. Parmar N.S. *Health Education and Community Pharmacy,* 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN: 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharma times (Monthly magazine)

NOVEL DRUG DELIVERY SYSTEMS (BP704T)

(Theory) **45 hours**

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives:

Upon completion of the course student shall be able

- To understand various approaches for development of novel drug delivery systems.
- To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation.

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain various approaches for development of novel drug delivery systems.

CO2: Demonstrate knowledge for selection of drugs and polymers for the development of Novel drug delivery systems.

CO3: Carry out different formulation in laboratory as per formulas

CO4: Evaluate the given dosage form as per protocol.

CO5: Describe the modern techniques and characterization of vesicular drug delivery system

CO6: Discuss various approaches related to formulation development.

CO7: Describe the modern techniques and characterization of particulate drug delivery system

Course content

Unit I **10 Hours**

Controlled drug delivery systems: Introduction, terminology / definitions and rationale, advantages, disadvantages, selection of drug candidates.Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application ofpolymers in formulation of controlled release drug delivery systems.

Unit II **10 Hours**

Microencapsulation: Definition, advantages and disadvantages, microspheres / microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion /mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump

Unit III **10 Hours**

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factorsaffecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes ofdrug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers.

Unit IV **08 Hours**

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit V **07 Hours**

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome – Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

Recommended Books: (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5.S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

SEMESTER VIII
BIOSTATISTICS AND RESEARCH METHODOLOGY (BP801T)

(Theory) **45 Hours**

Scope: To understand the applications of Biostatistics in Pharmacy. This subject deal with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non-Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel**.**

Objectives:

Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems**.**

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)

CO2: Describe the various statistical techniques to solve statistical problems

CO3: Apply the statistical techniques in solving the problems

Course content

Unit I **10 Hours**

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, multiple correlation-Pharmaceutical examples

Unit II **10 Hours**

Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x= a + by, Multiple regression, standard error of regression– Pharmaceutical Examples

Probability: Definition of probability, Binomial distribution, Normal distribution,Poisson's distribution, properties – problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

Parametric test: t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One wayand Two way), Least Significance difference

Unit III **10 Hours**

Non-Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallistest, Friedman Test

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph **Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit IV

08 Hours

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regression models

Introduction to Practical components of Industrial and Clinical Trials Problems:Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Unit V **07 Hours**

Design and Analysis of experiments:

Factorial Design: Definition, 2^2, 2^3design. Advantage of factorial design **Response Surface**

Methodology: Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. New York.
2. Fundamental of Statistics – Himalaya Publishing House- S. C. Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments –Wiley Students Edition, Douglas and C. Montgomery

SOCIAL AND PREVENTIVE PHARMACY (BP802T)

(Theory) **45 hours**

Scope: The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduces a number of national health programmes. The roles of the pharmacist in these contexts are also discussed

.

Objectives:

After the successful completion of this course, the student shall be able to:

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related to health and pharmaceutical issues

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Define health and disease and explain the concepts of the causes, prevention and control of diseases

CO2: Explain the role of nutrition in health, the impact of malnutrition, socio cultural factors and hygiene on disease states and the preventive measures

CO3: Describe the general principles of prevention and control of common infectious diseases, metabolic disorders, cancer and drug or substance abuse

CO4: Demonstrate an understanding of the objectives, functioning and outcomes of the National health programs, and the role of WHO in promoting these programs

CO5: Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.

CO6: Apply critical way of thinking based on current health care development and evaluate alternative ways of solving problems related to health and pharmaceutical issues

CO7: Explain the functions of a PHC and a pharmacist in the provision of community services in rural, urban and school and promote health education in school and improvement in rural sanitation.

Course content

Unit I **10 Hours**

Concept of health and disease: Definition, concepts and evaluation of public health.Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet,Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact ofurbanization on health and disease, Poverty and health

Hygiene and health: personal hygiene and health care; avoidable habits

Unit II **10 Hours**

Preventive medicine: General principles of prevention and control of diseases such ascholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

Unit III **10Hours**

National health programs, its objectives, functioning and outcome of the following:
HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV **08 Hours**
National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

Unit V **07 Hours**

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

Recommended Books (Latest edition)*:*

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy
3. Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
4. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications

5. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D,
6. Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
7. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
8. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland.

ELECTIVES
PHARMA MARKETING MANAGEMENT (BP803ET1/I)

(Theory) **45 Hours**

Scope: The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Objective: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Course outcome:

Upon completion of the subject student shall be able to:
CO1: Explain the marketing concepts and techniques
CO2: Apply the marketing concepts in the pharmaceutical industry.

Course content
Unit I **10 Hours**

Marketing:
Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market:

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist.Analyzing the Market;Role of market research.

Unit II **08Hours**
Product decision:

Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III **07 Hours**

Promotion:

Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

Unit IV **10 Hours**

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V **10 Hours**

Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt: Global Perspective, IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

PHARMACEUTICAL REGULATORY SCIENCE (BP803ET1/II)

(Theory) **45Hours**

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia,UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Objectives:

Upon completion of the subject student shall be able to;

- Know about the process of drug discovery and development
- Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- Know the regulatory approval process and their registration in Indian and international markets

Course outcome:

Upon completion of the subject, student shall be able to:

CO1: Define the difference between brand, generic and substitute drugs.

CO2: Discuss the process of drug discovery and development

CO3: List out different regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals

CO4: Acquire Knowledge on the regulatory approval process and their registration in Indian and international markets

CO5: Explain WHO and ICH guidelines in regulations of pharmaceutical products

Course content:

Unit I **10 Hours**

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II **10 Hours**

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III **10 Hours**

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research.

Unit IV **08 Hours**

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee – formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance – safety monitoring in clinical trials

Unit V **07 Hours**

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

PHARMACOVIGILANCE (BP803ET1 / III)

(Theory) **45 hours**

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- The importance of Drug Safety Monitoring
- History and development of pharmacovigilance
- National and international scenario of pharmacovigilance
- Dictionaries, coding and terminologies used in pharmacovigilance
- Detection of new adverse drug reactions and their assessment
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in pharmacovigilance
- Methods to generate safety data during pre clinical, clinical and post approval phases of drugs life cycle
- Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
- Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
- ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
- CIOMS requirements for ADR reporting
- Writing case narratives of adverse events and their quality.

Course outcome:

Upon completion of the course, the student shall be able to,

CO1: Define pharmacovigilance and explain the history, development and the national and international scenario of pharmacovigilance.

CO2: Describe the significance of drug safety monitoring, and state the International standards for classification of diseases and drugs, the dictionaries, coding and terminologies used in pharmacovigilance.

CO3: Classify adverse drug reactions, identify, detect and assess the adverse drug reactions using appropriate scales and their documentation.

CO4: Explain the procedures involved in adverse drug reaction reporting and communication in pharmacovigilance.

CO5: Describe the methods to generate safety data during pre clinical, clinical and post approval phases of drugs life cycle and vaccine safety surveillance.

CO6: Perform drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation

CO7: Explain the ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning, CIOMS requirements for ADR reporting, Pharmacovigilance Program of India (PvPI) and CDSCO, Schedule Y requirement for ADR reporting in India.

Course Content

Unit I

10 Hours

Introduction to Pharmacovigilance

History and development of Pharmacovigilance
Importance of safety monitoring of Medicine
WHO international drug monitoring programme
Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

Definitions and classification of ADRs
Detection and reporting
Methods in Causality assessment
Severity and seriousness assessment
Predictability and preventability assessment
Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

Terminologies of adverse medication related events
Regulatory terminologies

Unit II **10 hours**

Drug and disease classification

Anatomical, therapeutic and chemical classification of drugs
International classification of diseases
Daily defined doses
International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

WHO adverse reaction terminologies
MedDRA and Standardised MedDRA queries
WHO drug dictionary
Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

Basic drug information resources
Specialised resources for ADRs

Establishing pharmacovigilance programme

Establishing in a hospital
Establishment & operation of drug safety department in industry
Contract Research Organisations (CROs)
Establishing a national programme

Unit III **10 Hours**

Vaccine safety surveillance

Vaccine Pharmacovigilance
Vaccination failure
Adverse events following immunization

Pharmacovigilance methods

Passive surveillance – Spontaneous reports and case series
Stimulated reporting
Active surveillance – Sentinel sites, drug event monitoring and registries
Comparative observational studies – Cross sectional study, case control study and cohort study
Targeted clinical investigations

Communication in pharmacovigilance
Effective communication in Pharmacovigilance
Communication in Drug Safety Crisis management
Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV 0**8 Hours**

Safety data generation
Pre clinical phase
Clinical phase
Post approval phase (Post Marketing Surveilance)

ICH Guidelines for Pharmacovigilance

Organization and objectives of ICH
Expedited reporting
Individual case safety reports
Periodic safety update reports
Post approval expedited reporting
Pharmacovigilance planning
Good clinical practice in pharmacovigilance studies

Unit V 0**7 hours**

Pharmacogenomics of adverse drug reactions

Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

Paediatrics
Pregnancy and lactation
Geriatrics

CIOMS

CIOMS Working Groups
CIOMS Form

CDSCO (India) and Pharmacovigilance

D&C Act and Schedule Y
Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z by Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones& Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

QUALITY CONTROL AND STANDARDIZATION OF HERBALS (BP803ET1 / IV)

(Theory) **45 hours**

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Objectives:

Upon completion of the subject student shall be able to;

- Know WHO guidelines for quality control of herbal drugs
- Know Quality assurance in herbal drug industry
- Know the regulatory approval process and their registration in Indian and international markets
- Appreciate EU and ICH guidelines for quality control of herbal drugs

At the end of the course, the student will be able to:

CO1: Describe the WHO guidelines for quality control of herbal drugs

CO2: Describe the Quality assurance in herbal drug industry

CO3: Recognize the regulatory approval process and their registration in Indian and international markets

CO4: Describe EU and ICH guidelines for quality control of herbal drugs

CO5: Explain cGMP, GAP and GLP in traditional system of medicines
Course outcome:

Course Content

Unit I **10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use

Unit II **10 hours**

Quality assurance in herbal drug industry: cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.

Unit III **10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV **08 hours**

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

Unit V **07 hours**

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangachari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
4. Aggarwal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.

9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10.WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11.WHO. Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12.WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

COMPUTER AIDED DRUG DESIGN (BP803ET1/ V)

(Theory) **45 Hours**

Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Objectives:

Upon completion of the course, the student shall be able to understand

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

Course outcome:

Upon completion of the course, the student shall be able to:
CO1: Design and discover lead molecules
CO2: Elucidate the role of drug design in drug discovery process
CO3: Explain the concept of QSAR and docking
CO4: Discuss the various strategies to develop new drug like molecules.
CO5: Design new drug molecules using molecular modeling software

Course Content

UNIT I **10 Hours**

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies.

UNIT II **10 Hours**

Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT III **10 Hours**

Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. *Denovo* drug design.

UNIT IV **08 Hours**

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT V **07 Hours**

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro Ikovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

CELL AND MOLECULAR BIOLOGY (BP804ET2/I)

(Theory) **45 Hours**

Scope:

Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell

function. This is done both on a microscopic and molecular level. Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.

Objectives:

Upon completion of the subject student shall be able to;

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

Course outcome:

Upon completion of the Course, the student will be able to:

CO1: Summarize cell, cell cycle and molecular biology history.

CO2: Summarize cellular functioning and composition.

CO3: Describe the chemical foundations of cell biology.

CO4: Summarize the DNA properties of cell biology.

CO5: Describe protein structure and function.

CO6: Describe cellular membrane structure and function.

CO7: Describe basic molecular genetic mechanisms.

Course content

Unit I **10 Hours**

Cell and Molecular Biology: Definitions theory and basics and Applications.
Cell and Molecular Biology: History and Summation.
Properties of cells and cell membrane.

Prokaryotic versus Eukaryotic
Cellular Reproduction
Chemical Foundations – an Introduction and Reactions (Types)

Unit II **10 Hours**

DNA and the Flow of Molecular Information

DNA Functioning
DNA and RNA
Types of RNA
Transcription and Translation

Unit III **10 Hours**

Proteins :Definitions, Amino Acid structure, Protein Structure
Regularities in Protein Pathways
Cellular Processes
Positive Control and significance of Protein Synthesis

Unit IV **08 Hours**

Science of Genetics
Transgenics and Genomic Analysis
Cell Cycle analysis
Mitosis and Meiosis
Cellular Activities and Checkpoints

Unit V **07 Hours**

Cell Signals: Introduction
Receptors for Cell Signals
Signaling Pathways: Overview
Misregulation of Signaling Pathways
Protein-Kinases: Functioning

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N. K. Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
13. RA Goldshy et. al.: Kuby Immunology.
14. Molecular biology of the Cell by Alberts.B, Bray.D, Lewis.J, Raff M, Roberts .K, Watson. JD, 3rd Edition

15. Molecular cell biology by Lodish. H, Baltimore.D, Berk.A et al 5thEdition.

COSMETIC SCIENCE (BP804ET2/II)

(Theory) **45 Hours**

Scope:

This course is designed to impart the fundamental knowledge on the cosmetic excipients, formulation and evaluation of various cosmetic and cosmeceutical products and cosmetic problems.

Objectives:

Upon completion of the course the student shall be able to

- Know the various cosmeceutical excipients used in the formulation.
- Formulate the skin care, oral care and hair care products.
- Know various principles of cosmetic evaluation.
- Know the cosmetic problems associated with hair, skin and scalp.

Course outcome:

Upon completion of the course, the students shall be able to:

CO1: Discuss the Key and role of ingredients used in cosmetics

CO2: Describe Current technologies in the market.

CO3: Explain US FDA cosmetic and drug regulations

CO4: Exhibit familiarity with relevant governmental regulations (primarily US) which will help confirm product compliance.

C**O5**: Categorize ingredients used in cosmetics.

CO6: Develop cosmetic and personal care products

CO7: Formulate cosmetics to meet desired product attributes using an understanding of the physical and chemical basis of these formulations.

Course content

UNIT I **10Hours**

Classification of cosmetic and cosmeceutical products
Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums**.**

UNIT II **10 Hours**

Principles of formulation and building blocks of skin care products:
Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages.Application of these products in formulation of cosmeceuticals.

Antiperspirants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products:
Conditioning shampoo, Hair conditioner, anti-dandruff shampoo. Hair oils.
Chemistry and formulation of Para-phylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT III **10 Hours**
Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics: Skin Care: Aloe and turmeric Hair care: Henna and amla. Oral care: Neem and clove .
Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste**.**

UNIT IV **08 Hours**.
Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties Soaps,and syndet bars. Evolution and skin benefits.

UNIT V **07 Hours**
Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.
Antiperspirants and Deodorants- Actives and mechanism of action

References

1. Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2. Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3. Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

EXPERIMENTAL PHARMACOLOGY (BP804ET2/III)
(PHARMACOLOGICAL SCREENING METHODS)

(Theory) **45 Hours**

Scope: This subject is designed to impart the basic knowledge of preclinical studies inexperimental animals including design, conduct and interpretations of results.

Objectives

Upon completion of the course the student shall be able to,

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and research methodology
- Design and execute a research hypothesis independently

Course outcome:

Upon completion of the Course, the student will be able to:

CO1: Impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

CO2: Describe the various CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals.

CO3: Appreciate the applications of various commonly used laboratory animals.

CO4: Demonstrate the various screening methods used in preclinical research.

CO5: Explain the techniques of blood collection, common routes of drug administration and euthanasia techniques in laboratory animals.

CO6: Appreciate and demonstrate the importance of biostatistics and research methodology.

CO7: Design and execute a research hypothesis independently.

Course content

UNIT I **08 Hours**

Laboratory Animals:

Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals.Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.

UNIT II **10 hours**

Preclinical screening models

a.Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.

Study of screening animal models for

Diuretics, nootropics, anti-Parkinson's, antiasthmatics,

Preclinical screening models: for CNS activity- analgesic,antipyretic,anti- inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease

Unit III **11 Hours**

Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.

Unit IV

11 Hours

Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants. Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.

UNIT V **5 Hours**

Research methodology and Bio-statistics

Selection of research topic, review of literature, research hypothesis and study design. Pre-clinical data analysis and interpretation using Students't' test and One-way ANOVA. Graphical representation of data

References

1. Fundamentals of experimental Pharmacology-by M. N. Ghosh
2. Hand book of Experimental Pharmacology-S. K. Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PS. Sundar Rao and J Richard

ADVANCED INSTRUMENTATION TECHNIQUES (BP804ET2/IV)

(Theory) **45 Hours**

Scope: This subject deal with the application of instrumental methods in qualitative andquantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives:

Upon completion of the course the student shall be able to

- Understand the advanced instruments used and its applications in drug analysis
- Understand the chromatographic separation and analysis of drugs.
- Understand the calibration of various analytical instruments
- Know analysis of drugs using various analytical instruments.

Course outcome:
Upon completion of the course, the student shall be able to:

CO1: Explain the working principle of advanced instruments and their applications in drug analysis

CO2: Explain the chromatographic separation and analysis of drugs.

CO3: Explain the calibration of various analytical instruments

CO4: Perform analysis of drugs using various analytical instruments.

Course Content

UNIT I **10 Hours**

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT II **10 Hours**

Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC).

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT III **10 Hours**

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments: Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

UNIT IV **08 Hours**

Radio immuno assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay.

Extraction techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction.

UNIT V **07 Hours**

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. Instrumental method of analysis by Willard, 6th edition, CBS Publishers and Distributors, New Delhi.
12. Pharmaceutical process vailidation by Ira. R. Berry & Robert A. Nash
13. Validation in Pharmaceutical Industry by P.P. Sharma
14. QA Manual by D.H. Shah

DIETARY SUPPLEMENTS AND NUTRACEUTICALS (BP804ET2/V)

(Theory) **45 hours**

Scope:

This subject cover foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

Objective:

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:

- Understand the need of supplements by the different group of people to maintain healthy life.
- Understand the outcome of deficiencies in dietary supplements.
- Appreciate the components in dietary supplements and the application.
- Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Describe the need of supplements by the different group of people to maintain healthy life.

CO2: Explain the concepts behind the applications of dietary supplements

CO3: Describe the outcome of deficiencies in dietary supplements.

CO4: List the components in dietary supplements and their application.

CO5: Recognize the regulatory and commercial aspects of dietary supplements including health claims.

Course Content

UNIT I **07 hours**

Definitions of Functional foods, Nutraceuticals and Dietary supplements.Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e.
weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.

Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II **15 hours**

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following
Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin
Sulfides: Diallyl sulfides, Allyl trisulfide.
Polyphenolics: Reservetrol
Flavonoids- Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones
Prebiotics / Probiotics: Fructo oligosaccharides, Lacto bacillum
Phyto estrogens: Isoflavones, daidzein, Geebustin, lignans
Tocopherols

Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT III **07 hours**

Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.Dietary fibres and complex carbohydrates as functional food ingredients.

UNIT IV **10 hours**

Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders.Free radicals theory of ageing.

Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin

Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
Functional foods for chronic disease prevention

UNIT V **06 hours**

Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.

Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK.HACCP and GMPs on Food Safety. Adulteration of
foods.Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

References:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K. T Agusti and P. Faizal: BS Publication. Advanced Nutritional Therapies by Cooper. K.A., (1996).
3. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
4. Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2nd Edn., Avery Publishing Group, NY (1997).
5. G. Gibson and C. Williams Editors 2000 Functional foods Woodhead Publ. Co. London.
6. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York. 182

7. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs)and Shelf Life Testing in *Essentials of FunctionalFoods* M.K. Sachmidl and T.P. Labuza eds. Aspen
Press.182

8. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition).
9. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. 8th edition. Lea and Febiger.

Pharmaceutical Product Development (BP804ET2/VI)

(Theory) **45 Hours**

Scope:

- This course is designed to impart the fundamental knowledge on the various pharmaceutical excipients, Preformulation studies on product development, optimization techniques and quality control tests for packaging materials for various pharmaceutical products.

Objectives:

Upon completion of the course the student shall be able to

- Know the various pharmaceutical excipients.
- Know the Preformulation studies and stability assessment for various pharmaceutical products.
- Know the various optimization techniques for pharmaceutical product development.
- Carry out quality control tests for packaging materials for various pharmaceutical products.

Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Develop the various pharmaceutical dosage forms and their manufacturing techniques.

CO2: Explain various considerations in development of pharmaceutical dosage forms

CO3: Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality.

Course content

Unit I **10 Hours**

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

Unit II **10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories, Solvents and solubilizers, Cyclodextrins and their applications Non - ionic surfactants and their applications, Polyethylene glycols and sorbitols, Suspending and emulsifying agents, Semi solid excipients.

Unit III **10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories, Tablet and capsule excipients, Directly compressible vehicles, Coat

materials, Excipients in parenteral and aerosols products, Excipients for formulation of NDDS, Selection and application of excipients in pharmaceutical formulations with specific industrial applications.

Unit IV **08 Hours**

Optimization techniques in pharmaceutical product development.A study of various optimization techniques for pharmaceutical product development with specific examples.Optimization by factorial designs and their applications.A study of QbD and its application in pharmaceutical product development.

Unit V **07 Hours**

Selection and quality control testing of packaging materials for pharmaceutical product development-regulatory considerations.

Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition, Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop K Khar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt. Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K. Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B. Popovich,
Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton,3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman and Joseph B. Schwartz
11. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Libermann.

Advanced Review Articles related to the topics.

SRI RAMACHANDRA

INSTITUTE OF HIGHER EDUCATION AND RESEARCH

(Deemed to be University)

Porur, Chennai - 600 116

REGULATIONS AND SYLLABUS FOR

Pharm. D. (Doctor of Pharmacy) Degree Course

(Effective from the Academic year 2019–20)

Regulations for the Pharm. D. (Doctor of Pharmacy) Degree Course

INTRODUCTION

Pharm.D. (Doctor of Pharmacy) is a professional doctoral degree program which was officially introduced by the Pharmacy Council of India, New Delhi, in India in the year 2008 to make Pharmacy education on par with international standards. It is a 6 years (5 years academic program + 1 year internship) long course. The course is integrated with didactic learning of regular and clinical pharmacy subjects and an experiential learning in clinical pharmacy practice settings .The students are trained in clinical pharmacy, pharmacy practice and pharmaceutical care. At the end of the course, students gain knowledge and skills in treatment of diseases, selection and therapeutic usage of drugs, monitoring of patients for safe and effective use of drugs etc.

The numerous and diverse career options available to Pharm.D. students are in patient care settings as Hospital / Clinical Pharmacists in hospital settings; in Clinical research as Clinical Research Associates and Coordinators; in Pharmacovigilance sectors as Drug Safety Associates; in Drug Regulatory Affairs; in Pharmaceutical Industry towards Research & Development of new drugs; into Medical writing and Data Management; Into Health Insurance sectors; into Academics; as pharma marketing executives; and as Drug Inspectors in Government service. Pharm.D. graduates also have a greater scope for Practice of Pharmacy in hospital and community pharmacy settings in foreign countries as the degree is well recognized and accepted by the board of Pharmacy education of various countries. Pharm D graduates can be successful entrepreneurs through establishing their own community pharmacies and clinical research organizations.

The SRI RAMACHANDRA INSTITUTE OF HIGHER EDUCATION AND RESEARCH (Deemed to be University) curriculum is aimed to provide a thorough training in the subject area through formal lectures, seminar and training programs.

PROGRAMME OUTCOMES:

Upon completion of the Pharm. D. programme, the candidate will be able to:

PO1: Demonstrate knowledge and skills to integrate and apply the principles of basic medical sciences, pharmaceutical sciences, pharmacology and pharmacotherapeutics in disease management and health promotion.

PO2: Implement the concepts of pharmacoepidemiology, pharmacoeconomics and therapeutic drug monitoring in the promotion of rational drug use in a patient care setting.

PO3: Apply critical thinking and problem solving skills to analyze, evaluate and provide solutions for real-world problems.

PO4: Adopt suitable team behavior in achieving shared goals and leadership virtues in planning and advocating changes to create new prospects in pharmacy-related work environments.

PO5: Enact his/her role as a competent pharmacist in devising and implementing evidence based individualized pharmaceutical care in a healthcare setting.

PO6: Apply the principles of research in the pursuit of their career in drug discovery and development, Pharmacovigilance, Regulatory and data management.

PO7: Demonstrate professional mastery in identifying social determinants of health and exhibit accountability in improving health and wellness of the society through safe and appropriate medication use.

PO8: Adopt exemplary professional and ethical behavior towards patient privacy and autonomy, respect and integrity of the teammates and the society, adhering to the laws and regulations governing pharmacy practice.

PO9: Apply effective communication and writing skills in the presentations, report preparations, documentations and productive interactions with patients, health care professionals, colleagues and the public.

PO10: Effectively utilize information and technology, modern tools and software in appropriate areas to optimize outcomes in patient care, academia and research.

PO11: Exhibit Inquisitiveness for incessant self-directed life-long learning to attain self-development and success of the profession.

In exercise of the powers conferred by rule 12.1 (iv) of the Memorandum of Association & Rules and clause 21 of Bye-Laws of *Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai-600 116,* the Academic Council of the University hereby makes the following Regulations:

1. SHORT TITLE AND COMMENCEMENT

These regulations may be called "THE REGULATIONS AND SYLLABUS FOR THE PHARM. D. (DOCTOR OF PHARMACY) DEGREE PROGRAM OF SRI RAMACHANDRA INSTITUTE OF HIGHER EDUCATION AND RESEARCH (Deemed to be University), Porur, Chennai-600116".

These regulations shall be deemed to have come into force from the academic year **2019-2020**. These regulations are subject to such modifications as may be approved by the Academic Senate from time to time.

2. ELIGIBILITY FOR ADMISSION

A candidate desiring to join the six year program leading to the Pharm. D. Degree should have passed the HSC/CBSE/ISC or equivalent examination

(i) A pass in 10+2 examination with Physics and Chemistry as compulsory subjects along with either Mathematics or Biology (Botany and Zoology); or

(ii) A pass in D. Pharm. program from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act; or

(iii) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

(iv) Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

3. AGE LIMIT FOR ADMISSION

Every candidate should have completed the age of 17 years as on 31st December of the year of admission.

4. ELIGIBILITY CERTIFICATE

Candidates who have passed any qualifying examination other than the Higher Secondary Course examination conducted by the Government of Tamil Nadu shall obtain an Eligibility Certificate from Sri Ramachandra Institute of Higher Education and Research (Deemed to be University) and produce it at the time of admission.

5. REGISTRATION

A candidate admitted to the course shall register his/her name with the University by submitting an application form for registration duly filled in, along with the prescribed fee, through the Head of the Institution within the stipulated date.

6. DURATION OF THE PROGRAM

The duration of the Pharm. D. Degree program shall be six academic years (five years of study and one year of internship).

7. COMMENCEMENT OF THE PROGRAM

The program shall commence ordinarily from 1st July of the academic year.

8. COMMENCEMENT OF THE EXAMINATIONS

There shall be a session of University examination in an academic year, viz., April and a supplementary examination in November.

9. CUT-OFF DATES FOR ADMISSION TO THE EXAMINATION

Candidates admitted from 1st July to 30th September of the academic year concerned will be registered to take up their 1st year examination, after fulfillment of requirements of the regulations, in April session of the next academic year.

The candidates admitted from 1st October to 31st December of the academic year shall be registered to take up their first year examination, after fulfilment of the requirements of the regulations in November session of the next year.

10. MEDIUM OF INSTRUCTION

English shall be the medium of instruction for all subjects of study and examinations will be conducted only in English.

11. WORKING DAYS IN AN ACADEMIC YEAR

Each academic year shall consist of not less than 200 working days.

12. ATTENDANCE REQUIRED FOR ADMISSION TO EXAMINATIONS

(a) No candidate shall be permitted to appear for the University examinations, unless he/she attends the program for the prescribed period and produces the necessary certificate of attendance and satisfactory conduct from the Head of the Institution.

(b) Every candidate is required to put in a minimum of 80% of attendance both in theory and practical separately in each subject for admission to the examination.

(c) A candidate lacking in the prescribed attendance in any subject in theory and /or practical shall not be admitted to the entire examination.

13. CONDONATION OF LACK OF ATTENDANCE

(a) Discretionary power of condonation of shortage of attendance up to a maximum of 10% of minimum attendance prescribed for admission to the examination rests with the Vice-Chancellor. A candidate lacking in attendance should submit an application in the prescribed form remitting

the prescribed fee, 15 days prior to the commencement of the theory examination to the University through the Head of the Institution.

(b) The Head of the Department and the Head of the Institution should satisfy themselves on the reasonableness of the candidate's request while forwarding the application of the candidate to the Controller of Examinations who would obtain the Vice-Chancellor's approval for admission to the examination. No application shall be considered if it is not forwarded through proper channel.

(c) The Head of the Institution, while recommending and forwarding the application for condonation should take into consideration the following circumstances:-

(i) Any illness afflicting the candidate:- In this case, the candidate should have submitted to the Head of the Institution, a medical certificate from a registered medical practitioner of Sri Ramachandra Institute of Higher Education and Research (Deemed to be University) soon after returning to the institution after treatment.

(ii) Any unforeseen tragedy in the family:- The parent/guardian should have given in writing the details for the ward's absence to the Head of the Institution.

(iii) Participation in N.C.C/N.S.S and other co-curricular activities representing the Institution or University:- A certificate issued by the officer-in-charge of the student activities concerned certifying the participation of the student in the event which necessitated the student's absence duly endorsed by the Head of the Institution should be enclosed.

14. CURRICULUM

The curriculum and the syllabus for the program shall be as prescribed by the Academic Senate of the University and as may be modified from time to time.

15. EXAMINATIONS AND ASSESSMENTS

15.1. COTINUOUS INTERNAL ASSESSMENT

Award of internal assessment marks and maintenance of records.—

(a) A regular record of both theory and practical class work and examinations conducted, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted for internal assessment.

(b) There shall be at least three periodic sessional examinations during each academic year for theory, conducted for 35 marks, and a model examination conducted for 70 marks (in the pattern as that of the University Examination), an average of best two computed for 20 marks, 5 marks for attendance and 5 marks for assignments and a total of 30 marks as continuous internal assessment for Theory.

(c) Two practical sessional examinations shall be conducted for each subject and the average of the two shall be computed for 20 marks, added with 5 marks for attendance and 5 marks for record totaling to 30 marks for practical internal assessment of each subject.

(d) A candidate failed in any subject in the University examination shall be provided an opportunity to improve his/her internal assessment marks by conducting a minimum of two examinations in theory and two practical exams separately.

(e) If a failed candidate does not appear for such "Improvement Examinations" for internal marks in the failed subject(s), the internal marks already secured by him/her shall be carried over for his subsequent appearance(s).

(f) The internal marks list shall be submitted to the University by the Principal 15 days prior to the commencement of the University examinations.

15. 1.a. SCHEME FOR AWARDING INTERNAL ASSESSMENT: CONTINUOUS MODE

Criteria	
Theory	**Maximum Marks**
Sessional examination	20
Assignment	5
Attendance	5
Total	**30**
Practical	
Sessional Practical	20
Attendance	5
Record	5
Total	**30**

15. 1. b. GUIDELINES FOR THE ALLOTMENT OF MARKS FOR ATTENDANCE

Percentage of Attendance	Theory	Practical
100	**5**	**5**
95 – 99	4	4
90 – 94	3	3
85 – 89	2	2
80 – 84	1	1
Less than 80	0	0

15.2. PATTERN OF QUESTION PAPER FOR THEORY SESSIONAL EXAMINATIONS (IA)
(For subjects having Practical component)

(Answer all the questions)

I. Multiple Choice Questions (MCQs)	=	10 x 1 = 10
II. Long Answers	=	1 x 10 = 10
III. Short Answers	=	3 x 5 = 15

Total	=	35 marks
		---

16. END SEMESTER EXAMINATIONS

The End Semester University Examinations for each theory and practical course through Years I to V shall be conducted by the University covering the entire syllabus except for the courses with asterix symbol (*) for which examinations shall be conducted internally by two subject experts at the University level and the marks shall be submitted to the university

PATTERN OF QUESTION PAPER FOR UNIVERSITY EXAMINATION

THEORY QUESTION PAPER PATTERN FOR UNIVERSITY EXAMINATIONS (Theory Exam Assessment Pattern for subjects with Practical – Year I to V) (3 hours duration)		
University Examination Theory		
Section A		
Pattern & Choices	**Marks**	**Total Marks**

Essay questions 2 out of 3	2 x 10 marks	20
Total (a)		**20**
	Section B	
Short notes question 6 out of 8	6x 5 marks	30
Total (b)		**30**
	Section C	
Multiple Choice Questions (MCQ) 20 No choice	20 x1 marks	20 (Time: 20 min)
Total (c)		**20**
Grand Total Section (a + b + c)		**70**

THEORY QUESTION PAPER PATTERN FOR UNIVERSITY EXAMINATIONS (Theory Exam Assessment Pattern for subjects without Practical – Year I to V) (3 hours duration)		
University Examination Theory		
Section A		
Pattern & Choices	**Marks**	**Total Marks**
Essay questions 2 out of 3	2 x 15 marks	30
Total (a)		**30**
Section B		
Short notes question 8 out of 10	8x 5 marks	40
Total (b)		**40**
Grand Total Section (a + b)		**70**

PRACTICAL QUESTION PAPER PATTERN FOR UNIVERSITY EXAMINATIONS (Practical Exam Assessment Pattern - Year I to V) (3 hours duration)	
University Examination Practical	
Pattern & Choices	**Total Marks**
I. Synopsis	15
II. Major Experiments	25
III. Minor Experiments	15
IV. Viva voce	15
Grand Total Section (I + II + III+ IV)	**70**

16.1 SUBMISSION OF PRACTICAL WORK BOOK

At the time of practical examination, each candidate shall submit to the examiners the practical workbook duly certified by the Head of the Institution as a bonafide record of work done by the candidate.

17. MARKS QUALIFYING FOR A PASS

A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including internal marks (40% in theory internal examinations being the minimum requirement for eligibility to University examination) and at least 50% marks in each of the practical examinations including internal marks (40 % in practical Internal examination being the minimum requirement for eligibility to University examination).

18. CARRY-OVER OF FAILED SUBJECTS

The candidates are permitted to carryover the 2 failed subjects from first year to second year.

After completion of second year and before entering third year, students should have completed all first year subjects. However, they are permitted to carry over 2 failed subjects of second year.

After completion of third year and before entering fourth year, students should have completed all second year subjects. However, they are permitted to carry over 2 failed subjects of third year.

After completion of fourth year and before entering fifth year, students should have completed all third year subjects. However, they are permitted to carry over 2 failed subjects of fourth year.

After completion of fifth year, students are permitted to enter into sixth year only after passing all the subjects in fourth and fifth year.

A student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.

19. CLASSIFICATION OF SUCCESSFUL CANDIDATES

A successful candidate

(i) Who secures not less than 75% in the aggregate marks shall be declared to have secured '**FIRST CLASS WITH DISTINCTION'** provided he/she passes the whole examination in the FIRST ATTEMPT;

(ii) Who secures not less than 60% in the aggregate marks and completes the course within the stipulated course period shall be declared to have passed the examinations in the **'FIRST CLASS'**;

(iii) Who secures above 50% and less than 60% in the aggregate marks and completes the course within the stipulated course period shall be declared to have passed the examinations in the **'SECOND CLASS'**; and

(iv) All other successful candidates shall be declared to have **PASSED** the examinations

20. MIGRATION / TRANSFER OF CANDIDATES

Application seeking Migration/Transfer of a candidate from any recognized institution to the University shall be considered subject to the condition that:

1. there must be vacancy in the particular year of study;
2. the applicant should satisfy norms prescribed by Pharmacy Council of India;
3. transfer shall be effective only at the beginning of an academic year; and
4. Approval of the Vice-Chancellor shall be obtained.

21. RE-ADMISSION AFTER BREAK OF STUDY

(a) Candidates having a break of study of five years and above from the date of admission and more than two spells of break will not be considered for re-admission.

(b) The five years period of break of study shall be calculated from the date of first admission of the candidate to the course inclusive of all the subsequent spells of break of studies.

(c) Candidates having break of study shall be considered for re-admission provided that they are not subjected to any disciplinary action and no charges are pending or contemplated against them.

(d) All re-admissions of candidates are subject to the approval of the Vice-Chancellor.

(e) The candidates having a break of study below 6 months shall apply for re-admission in the prescribed form and remitting the stipulated fee for condonation to the Registrar of the University. The candidates may be re-admitted in the corresponding course of study at the commencement of the session and shall undergo a minimum period of study of 3 months and after fulfilment of the regulations of this University be admitted for the examination. The candidates shall be granted exemption in the subjects they have already passed.

(f) The candidates having a break of study of 6 months and above but less than one year shall apply for re-admission in the prescribed form and remitting the stipulated fee for condonation to the Registrar of the University. The candidates may be re-admitted in corresponding course of study at the commencement of the session and shall undergo a minimum period of study of 3 months and after fulfilment of the regulations of this University be admitted for the examination. The candidate shall be granted exemption in the subjects they have already passed.

(g) A candidate having a break of study one year and above but less than three years shall apply for re-admission in the prescribed form and remitting the stipulated fee for condonation to the Registrar of the University. The candidates may be re-admitted in the corresponding course of study at the commencement of the session and shall undergo a minimum period of study of 6 months and after fulfilment of the regulations of the University be admitted for the examination. The candidate shall be granted exemption only in the I Pharm.D. courses they have already passed.

(h) The candidates having a break of study of 3 years but less than 5 years shall apply for re-admission in the prescribed form and remitting the stipulated fee for condonation to the of the University. The candidates may be permitted to re-join the course the beginning of the I Pharm.D. / II Pharm.D. course, as the case may be, with the condition that these candidates will have to undergo the prescribed period of study from the I Pharm.D. or from II Pharm.D. course and will not be granted any exemption in any subject they have already passed. They shall subscribe to the regulations of this University.

22. DISCHARGE FROM THE PROGRAM

If a student admitted to a program of study in this deemed University is for any reason not able to complete the program or qualify for the degree by passing the examinations prescribed within a period comprising twice the duration prescribed in the Regulations for the concerned program, he/she will be discharged from the said program, his/her name will be taken off the rolls of the Deemed University and he/she will not be permitted to attend classes or appear for any examination conducted by the Deemed University thereafter.

23. VACATION

The Head of the Institution shall declare vacation not exceeding six weeks in an academic year.

24. SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

PHARM. D. (YEAR I) [P02] SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019																
Course Number	Course Code	Category	Course Title	Result in Group (RG)	Hours / Week			Hours/ year (Hours/week x 30 weeks)				Attendance (%)	Continuous Internal assessment (CIA) – Theory / Practical (a)	University Examination (EYE)		Grand Total
					Lecture (L)	24Tutorial (T)	Practical (P)	Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 100
1	PPD19CT101	CT	Human Anatomy and Physiology	A	3	1	0	90	30	0	120	80	30	70	0	100
2	PPD19CT102	CT	Pharmaceutics	B	2	1	0	60	30	0	90	80	30	70	0	100
3	PPD19CT103	CT	Medicinal Biochemistry	C	3	1	0	90	30	0	120	80	30	70	0	100
4	PPD19CT104	CT	Pharmaceutical Organic Chemistry	D	3	1	0	90	30	0	120	80	30	70	0	100
5	PPD19CT105	CT	Pharmaceutical Inorganic Chemistry	E	2	1	0	60	30	0	90	80	30	70	0	100
6	PPD19CL106	CL	Human Anatomy and Physiology Practical	A	0	0	3	0	0	90	90	80	30	0	70	100
7	PPD19CL107	CL	Pharmaceutics Practical	B	0	0	3	0	0	90	90	80	30	0	70	100
8	PPD19CL108	CL	Medicinal Biochemistry Practical	C	0	0	3	0	0	90	90	80	30	0	70	100
9	PPD19CL109	CL	Pharmaceutical Organic Chemistry Practical	D	0	0	3	0	0	90	90	80	30	0	70	100
10	PPD19CL110	CL	Pharmaceutical Inorganic Chemistry Practical	E	0	0	3	0	0	90	90	80	30	0	70	100
Total					**13**	**5**	**15**	**390**	**150**	**450**	**990**	**-**	**300**	**350**	**350**	**1000**
11	PPD19CT111	CT	Remedial Mathematics *		3	1	0	90	30	0	120	80	100	0	0	100
12	PPD19CT112	CT	Remedial Biology*	F	3	1	0	90	30	0	120	80	100	0	0	100
13	PPD19CL113	CL	Remedial Biology Practical *	F	0	0	3	0	0	90	90	80	100	0	0	100

PHARM. D. (YEAR II) [P02] SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019																
Course Number	Course Code	Category	Course Title	Result in Group (RG)	Hours / Week			Hours/ year (Hours/week x 30 weeks)				Attendance (%)	Continuous Internal assessment (CIA) – Theory / Practical (a)	University Examination (EYE)		Grand Total
					Lecture (L)	Tutorial (T)	Practical (P)	Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 100
14	PPD19CT201	CT	Pathophysiology	-	3	1	0	90	30	0	120	80	30	70	0	100
15	PPD19CT202	CT	Pharmaceutical Microbiology	G	3	1	0	90	30	0	120	80	30	70	0	100
16	PPD19CT203	CT	Pharmacognosy & Phytopharmaceuticals	H	3	1	0	90	30	0	120	80	30	70	0	100
17	PPD19CT204	CT	Pharmacology - I	-	3	1	0	90	30	0	120	80	30	70	0	100
18	PPD19CT205	CT	Community Pharmacy	-	2	1	0	60	30	0	90	80	30	70	0	100
19	PPD19CT206	CT	Pharmacotherapeutics – I	J	3	1	0	90	30	0	120	80	100	0	0	100
20	PPD19CL207	CL	Pharmaceutical Microbiology Practical	G	0	0	3	0	0	90	90	80	30	0	70	100
21	PPD19CL208	CL	Pharmacognosy & Phytopharmaceuticals Practical	H	0	0	3	0	0	90	90	80	30	0	70	100
22	PPD19CL209	CL	Pharmacotherapeutics – I Practical	J	0	0	3	0	0	90	90	80	100	0	0	100
Total					**17**	**6**	**9**	**510**	**180**	**270**	**960**	**-**	**410**	**350**	**140**	**900**

PHARM. D. (YEAR III) [P02] SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019																
Course Number	Course Code	Category	Course Title	Result in Group (RG)	Hours / Week			Hours/ year (Hours/week x 30 weeks)				Attendance (%)	Continuous Internal assessment (CIA) – Theory / Practical (a)	University Examination (EYE)		Grand Total
					Lecture (L)	Tutorial (T)	Practical (P)	Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 100
23	PPD19CT301	CT	Pharmacology - II	K	3	1	0	90	30	0	120	80	30	70	0	100
24	PPD19CT302	CT	Pharmaceutical Analysis	L	3	1	0	90	30	0	120	80	30	70	0	100
25	PPD19CT303	CT	Pharmacotherapeutics - II	M	3	1	0	90	30	0	120	80	30	70	0	100
26	PPD19CT304	CT	Pharmaceutical Jurisprudence		2	0	0	60	0	0	60	80	30	70	0	100
27	PPD19CT305	CT	Medicinal Chemistry	N	3	1	0	90	30	0	120	80	30	70	0	100
28	PPD19CT306	CT	Pharmaceutical Formulations	O	2	1	0	60	30	0	90	80	30	70	0	100
29	PPD19CL307	CL	Pharmacology – II Practical	K	0	0	3	0	0	90	90	80	30	0	70	100
30	PPD19CL308	CL	Pharmaceutical Analysis Practical	L	0	0	3	0	0	90	90	80	30	0	70	100
31	PPD19CL309	CL	Pharmacotherapeutics – II Practical	M	0	0	3	0	0	90	90	80	30	0	70	100
32	PPD19CL310	CL	Medicinal Chemistry Practical	N	0	0	3	0	0	90	90	80	30	0	70	100
33	PPD19CL311	CL	Pharmaceutical Formulations Practical	O	0	0	3	0	0	90	90	80	30	0	70	100
Total					**16**	**5**	**15**	**480**	**150**	**450**	**1080**	**-**	**330**	**420**	**350**	**1100**

PHARM. D. (YEAR IV) [P02]
SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Result in Group (RG)	Hours / Week			Hours/ year (Hours/week x 30 weeks)				Attendance (%)	Continuous Internal assessment (CIA) – Theory / Practical (a)	University Examination (EYE)		Grand Total
					Lecture (L)	Tutorial (T)	Practical (P)	Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 100
34	PPD19CT401	CT	Pharmacotherapeutics - III	P	3	1	0	90	30	0	120	80	30	70	0	100
35	PPD19CT402	CT	Hospital Pharmacy	Q	2	1	0	60	30	0	90	80	30	70	0	100
36	PPD19CT403	CT	Clinical Pharmacy	R	3	1	0	90	30	0	120	80	30	70	0	100
37	PPD19CT404	CT	Biostatistics & Research Methodology		2	1	0	60	30	0	90	80	30	70	0	100
38	PPD19CT405	CT	Biopharmaceutics & Pharmacokinetics	S	3	1	0	90	30	0	120	80	30	70	0	100
39	PPD19CT406	CT	Clinical Toxicology		2	1	0	60	30	0	90	80	30	70	0	100
40	PPD19CL407	CL	Pharmacotherapeutics – III Practical	P	0	0	3	0	0	90	90	80	30	0	70	100
41	PPD19CL408	CL	Hospital Pharmacy Practical	Q	0	0	3	0	0	90	90	80	30	0	70	100
42	PPD19CL409	CL	Clinical Pharmacy Practical	R	0	0	3	0	0	90	90	80	30	0	70	100
43	PPD19CL410	CL	Biopharmaceutics & Pharmacokinetics Practical	S	0	0	3	0	0	90	90	80	30	0	70	100
Total					**15**	**6**	**12**	**450**	**180**	**360**	**990**	**-**	**300**	**420**	**280**	**1000**

PHARM. D. (YEAR V) [P02]
SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Result in Group (RG)	Hours / Week			Hours/ year (Hours/week x 30 weeks)				Attendance (%)	Continuous Internal assessment (CIA) – Theory / Practical (a)	University Examination (EYE)		Grand Total
					Lecture (L)	Tutorial (T)/ Seminar (S)	Practical (P)	Lecture	Tutorial / Seminar	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 100
44	PPD19CT501	CT	Clinical Research	-	3	1	0	90	30	0	120	80	30	70	0	100
45	PPD19CT502	CT	Pharmacoepidemiology and Pharmacoeconomics	-	3	1	0	90	30	0	120	80	30	70	0	100
46	PPD19CT503	CT	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	-	2	1	0	60	30	0	90	80	30	70	0	100
47	PPD19IN504	IN	Clerkship[$] (20 weeks)	-	0	1	24	0	30	480	510	80	30	0	70	100
48	PPD19RP505	RP	Project work (Six Months)**	-	0	0	20	0	0	400	400	80	0	0	100**	100**
Total					**8**	**4**	**44**	**240**	**120**	**880**	**1240**	**-**	**120**	**210**	**170**	**500**
GRAND TOTAL (without Remedial Biology or Mathematics)					**69**	**26**	**95**	**2070**	**780**	**2410**	**5260**	**-**	**1460**	**1750**	**1290**	**4500**
GRAND TOTAL (with Remedial Biology)					**72**	**27**	**98**	**2160**	**810**	**2500**	**5470**	**-**	**1660**	**1750**	**1290**	**4700**
GRAND TOTAL (with Remedial Mathematics)					**72**	**27**	**95**	**2160**	**810**	**2410**	**5380**	**-**	**1560**	**1750**	**1290**	**4600**

a: CIA Theory & Practical [Eligibility for appearance for End Year Examination (EYE) - 80% attendance]

b: EYT (Pass Min 50%; CIA + EYE Aggregate - 50%)

c: EYP (Pass Min 50%, CIA + EYP Aggregate - 50%)

RG – For courses wherein Theory and Lab are assessed jointly (RG), the passing minimum (50%) for the theory exams and practical exams have to be obtained separately, in order to be declared passed in the individual courses.

*- OPTIONAL COURSES INDICATES AS ASSESSED INTERNALLY (100 % IA); ADDITIONALLY EARNED COURSES

** Project work: 30 marks for Viva voce; 70 marks for Thesis work

[$] Clerkship - Attending ward rounds on daily basis.

25. COURSE CONTENT
FIRST YEAR
1.1. HUMAN ANATOMY & PHYSIOLOGY (PPD19CT101)
(THEORY)

1. **Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.

2. **Course outcomes:**
   Upon completion of the course the student shall be able to:

   CO1: Describe the structure (gross and histology) and functions of various organs of the human body

   CO2: Describe the various homeostatic mechanisms and their imbalances of various systems

   CO3: Identify the various tissues and organs of the different systems of the human body

   CO4: Perform the hematological tests and also record blood pressure, heart rate, pulse and respiratory volumes

   CO5: Explain coordinated working pattern of different organs of each system

   CO6: Explain the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

3. **Course materials:**
   Text books
   a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology. Publisher Harper Collins College, New York.
   b. Wilson, K.J.W. Ross and Wilson's Foundations of anatomy and physiology.
      Publisher: Churchill Livingstone, Edinburg.

   Reference books
   a. Guyton Arthur, C. Physiology of human body. Publisher: Holt Saunders.
   b. Chatterjee, C.C. Human Physiology. Volume 1&11. Publisher: Medical Allied Agency, Calcutta.
   c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
   d. Gray's anatomy. Publisher: Churchill Livingstone, London.

4. **Lecture wise program :**
   Topics

1 **Scope of anatomy and physiology,** basic terminologies used in this subject (Description of the body as such planes and terminologies)

2 **Structure of cell** – its components and their functions.

3 **Elementary tissues** of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics

4 a) Osseous system - structure, composition and functions of the
b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

5 Haemopoetic System

a) Composition and functions of blood
b) Haemopoesis and disorders of blood components (definition of disorder)
c) Blood groups
d) Clotting factors and mechanism
e) Platelets and disorders of coagulation

6 Lymph

a) Lymph and lymphatic system, composition, formation and circulation.
b) Spleen: structure and functions, Disorders
c) Disorders of lymphatic system (definition only)

7 Cardiovascular system

a) Anatomy and functions of heart
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
c) Electrocardiogram (ECG)
d) Cardiac cycle and heart sounds
e) Blood pressure – its maintenance and regulation
f) Definition of the following disorders

Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

8 Respiratory system

a) Anatomy of respiratory organs and functions
b) Mechanism / physiology of respiration and regulation of respiration
c) Transport of respiratory gases
d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

9 Digestive system

a) Anatomy and physiology of GIT
b) Anatomy and functions of accessory glands of GIT
c) Digestion and absorption
d) Disorders of GIT (definitions only)

10 Nervous system

a) Definition and classification of nervous system

b) Anatomy, physiology and functional areas of cerebrum
c) Anatomy and physiology of cerebellum
d) Anatomy and physiology of mid brain
e) Thalamus, hypothalamus and Basal Ganglia
f) Spinal card: Structure & reflexes – mono-poly-planter
g) Cranial nerves – names and functions
h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

11 Urinary system

a) Anatomy and physiology of urinary system
b) Formation of urine
c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
d) Clearance tests and micturition

12 Endocrine system

a) Pituitary gland
b) Adrenal gland
c) Thyroid and Parathyroid glands
d) Pancreas and gonads

13 Reproductive system

a) Male and female reproductive system
b) Their hormones – Physiology of menstruation
c) Spermatogenesis & Oogenesis
d) Sex determination (genetic basis)
e) Pregnancy and maintenance and parturition
f) Contraceptive devices

14 Sense organs

a) Eye
b) Ear
c) Skin
d) Tongue & Nose

15 Skeletal muscles

a) Histology
b) Physiology of Muscle contraction
c) Physiological properties of skeletal muscle and their disorders (definitions)

16 Sports physiology

a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
c) Drugs and athletics

1.6. HUMAN ANATOMY & PHYSIOLOGY (PPD19CL106)

(PRACTICAL)

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book (100 pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

1. Study of tissues of human body
   (a) Epithelial tissue.
   (b) Muscular tissue.

2. Study of tissues of human body
   (a) Connective tissue.
   (b) Nervous tissue.

3. Study of appliances used in hematological experiments.

4. Determination of W.B.C. count of blood.

5. Determination of R.B.C. count of blood.

6. Determination of differential count of blood.

7. Determination of
   (a) Erythrocyte Sedimentation Rate.
   (b) Hemoglobin content of Blood.
   (c) Bleeding time & Clotting time.

8. Determination of
   (a) Blood Pressure.
   (b) Blood group.

9. Study of various systems with the help of charts, models & specimens
   (a) Skeleton system part I-axial skeleton.
   (b) Skeleton system part II- appendicular skeleton.
   (c) Cardiovascular system.
   (d) Respiratory system.
   (e) Digestive system.
   (f) Urinary system.
   (g) Nervous system.
   (h) Special senses.
   (i) Reproductive system.

10. Study of different family planning appliances.

11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastroenemius sciatic nerve preparation.
14. To record simple summation curve using gastroenemius sciatic nerve preparation.
15. To record simple effect of temperature using gastroenemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastroenemius sciatic nerve preparation.
17. To record simple fatigue curve using gastroenemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1. 2. PHARMACEUTICS (PPD19CT102) (THEORY)

1. **Scope and objectives:** This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.

2. **Course outcomes:**
   Upon the completion of the course the student should be able to:

   CO1: Exhibit knowledge of different types of dosage forms

   CO2: Demonstrate knowledge of and confidence with the pharmacist's role in health care system

   CO3: Analyze, Identify and describe different types of errors related to prescription

   CO4: Review and appropriately interpret medical product orders for patients.

   CO5: Apply mathematical formulas and carry out different pharmaceutical calculation involved in pharmaceutics

   CO6: Prepare different types of dosage forms

CO7: Provide relevant information to the patients in an organized, logical fashion appropriate for the clinical situation in terms of dispensing, packing and labeling.

3. Course materials: Text books

a. Cooper and Gunn's Dispensing for pharmacy students.
b. A text book Professional Pharmacy by N. K. Jain and S. N. Sharma.

Reference books

a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
b. Remington's Pharmaceutical Sciences.
c. Register of General Pharmacy by Cooper and Gunn.
d. General Pharmacy by M. L. Schroff.

4. Lecture wise programme: Topics

1 a. Introduction to dosage forms - classification and definitions

b. Prescription: definition, parts and handling

c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.

2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.

3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.

4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.

5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.

6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavors with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.

8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.

9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.

10 Pharmaceutical calculations.

11. Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.

12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

1. 7. PHARMACEUTICS (PPD19CL107) (PRACTICAL)

List of Experiments:

1. Syrups

a. Simple Syrup I.P
b. Syrup of Ephedrine Hcl NF
c. Syrup Vasaka IP
d. Syrup of ferrous Phosphate IP
e. Orange Syrup

2. Elixir

a. Piperizine citrate elixir BP
b. Cascara elixir BPC
c. Paracetamol elixir BPC

3. Linctus

a. Simple Linctus BPC
b. Pediatric simple Linctus BPC

4. Solutions

a. Solution of cresol with soap IP
b. Strong solution of ferric chloride BPC
c. Aqueous Iodine Solution IP
d. Strong solution of Iodine IP
e. Strong solution of ammonium acetate IP

5. Liniments

a. Liniment of turpentine IP*
b. Liniment of camphor IP

6. Suspensions*

a. Calamine lotion
b. Magnesium Hydroxide mixture BP

7. Emulsions*

a. Cod liver oil emulsion
b. Liquid paraffin emulsion

8. Powders

a. Eutectic powder
b. Explosive powder
c. Dusting powder

d. Insufflations

9. Suppositories

a. Boric acid suppositories
b. Chloral suppositories

10. Incompatibilities

a. Mixtures with Physical
b. Chemical & Therapeutic incompatibilities

* Colourless bottles are required for dispensing, Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1. 3. MEDICINAL BIOCHEMISTRY (PPD19CT103) (THEORY)

1. Scope and Objectives: Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases. The objective of the present course is providing biochemical facts and the principles to the students of pharmacy.

2. Course outcomes:

Upon completion of the subject, the student shall be able to:

CO1: Explain the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases

CO2: Describe the metabolic process of biomolecules in health and illness (metabolic disorders);

CO3: Explain the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism

CO4: Explain the biochemical principles of organ function tests of kidney, liver and endocrine gland

CO5: Perform the qualitative analysis and quantitative estimation of biomolecules in the body fluids.

3. Course materials

Text books (Theory)

a. Harpers review of biochemistry - Martin

b. Text book of biochemistry – D. Satyanarayana

c. Text book of clinical chemistry- Alex Kaplan & Laverve L.Szabo

Reference books (Theory)

a. Principles of biochemistry - Lehninger

b. Text book of biochemistry - Ramarao

c. Practical Biochemistry-David T. Plummer.

d. Practical Biochemistry-Pattabhiraman.

3. Lecture wise programme:

Topics

1. **Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
2. **Enzymes**: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.
3. **Carbohydrate metabolism**: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose and Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.
4. **Lipid metabolism:** Oxidation of saturated (□-oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).
5. **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation.
6. **Protein and amino acid metabolism:** protein turn over; nitrogen balance;

   Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphyria, jaundice. Metabolic disorder of Amino acids.
7. **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.
8. **Introduction to clinical chemistry:** Cell; composition; malfunction; Roll of the clinical chemistry laboratory.
9. **The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-

   a. Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)

b. Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)

c. Urine concentration test

d. Urinary tract calculi. (stones)

10. **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.

    a. Test for hepatic dysfunction-Bile pigments metabolism.

    b. Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.

    c. Dye tests of excretory function.

    d. Tests based upon abnormalities of serum proteins.

11. **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.

12. **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases. Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)

13. **Electrolytes:** Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

1. 8. MEDICINAL BIOCHEMISTRY (PPD19CL108) (PRACTICAL)

Title of the Experiments:

1 Qualitative analysis of normal constituents of urine.*
2 Qualitative analysis of abnormal constituents of urine.*
3 Quantitative estimation of urine sugar by Benedict’s reagent method.**
4 Quantitative estimation of urine chlorides by Volhard's method.**
5 Quantitative estimation of urine creatinine by Jaffe’s method.**
6 Quantitative estimation of urine calcium by precipitation method.**
7 Quantitative estimation of serum cholesterol by Libermann Burchard’s method.**
8 Preparation of Folin Wu filtrate from blood.*
9 Quantitative estimation of blood creatinine.**
10 Quantitative estimation of blood sugar Folin-Wu tube method.**
11 Estimation of SGOT in serum.**
12 Estimation of SGPT in serum.**
13 Estimation of Urea in Serum.**
14 Estimation of Proteins in Serum.**
15 Determination of serum bilirubin**

16 Determination of Glucose by means of Glucose oxidase.**

17 Enzymatic hydrolysis of Glycogen/Starch by Amylases.**

18 Study of factors affecting Enzyme activity. (pH & Temp.)**

19 Preparation of standard buffer solutions and its pH measurements (any two)*

20 Experiment on lipid profile tests**

21 Determination of sodium, calcium and potassium in serum.**

** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1. 4. PHARMACEUTICAL ORGANIC CHEMISTRY (PPD19CT104) (THEORY)

1. Scope and objectives: This course is designed to impart a very good knowledge about. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds; some important physical properties of organic compounds; Free radical/ nucleophyllic [alkyl/ acyl/ aryl] /electrophyllic substitution, free radical/ nucleophyllic / electrophyllic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds; Some named organic reactions with mechanisms; and Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

3. Course outcomes:

Upon completion of the course, the student will be able to:

CO1: Enumerate systematic IUPAC nomenclature of organic compounds having a poly functional group**.**

CO2: Relate intermolecular forces with the physical properties of the molecule

CO3: Explain the mechanisms involved in nucleophilic aliphatic and aromatic substitution reaction

CO4: Demonstrate knowledge on substitution reaction, nucleophilic, free radical addition reaction and oxidation/reduction reactions

CO5: Discuss the mechanism involved electrophilic aromatic substitution reaction and its orientation

CO6: Depict the structure, assay methods and uses of specified pharmaceutical organic compounds

3. Course materials:

Text books

a. T. R. Morrison and R. Boyd - Organic chemistry,
b. Bentley and Driver-Text book of Pharmaceutical chemistry
c. I. L. Finar- Organic chemistry, the fundamentals of chemistry

Reference books

a. Organic chemistry – J. M. Cram and D. J. Cram
b. Organic chemistry- Brown
c. Advanced organic chemistry- Jerry March, Wiley
d. Organic chemistry- Cram and Hammered, Pine Hendrickson

4. Lecture wise programme: Topics

1. **Structures and Physical properties:**
   a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
   b. Acids and bases, Lowry Bronsted and Lewis theories
   c. Isomerism
2. Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides and Cycloalkanes.
3. **Free radicals chain reactions of alkane:** Mechanism, relative reactivity and stability

4. Alicyclic compounds: Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.

5. Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN_2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

6. Dehydro halogenation of alkyl halides: 1, 2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and

reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.

7. Electrophilic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, Markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophilic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals addition, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.

8. Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

9. Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilization of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilization of allyl cation, hyper conjugation,nucleophilic substitution in allylic substrate, SN2 nucleophilic substitution in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.

10. Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, Friedel craft alkylation, Friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical.

11. Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of carboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

12. Mechanism of aldol condensation, Claisen condensation, Cannizzaro reaction, crossed aldol condensation, crossed Cannizzaro reaction, benzoin condensation, Perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.

13. Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer-tieman's reactions.

14. Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.

15. Oxidation reduction reaction.

16. Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihyrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid,

aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

1.9. PHARMACEUTICAL ORGANIC CHEMISTRY (PPD19CL109) (PRACTICAL)

Title of the Experiments:

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesized):

1. Acetanilde / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-napthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chloro benzoic acid from O-chlorotoluene
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitro compounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.5. PHARMACEUTICAL INORGANIC CHEMISTRY (PPD19CT105) (THEORY)

1. **Scope and objectives:** This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.

2. **Course outcomes:**

Upon completion of the course student shall be able to:

CO1: Perform limit test of chloride, sulphate, iron and heavy metals in a given sample

CO2: Identify inorganic compounds present in pharmaceutical formulations and explain its therapeutic values

CO3: Explain the principles of various assay methods

CO4: Perform monograph analysis of inorganic compounds

CO5: Discuss the role and usage of medicinal gases in therapy

CO6: Explain acid, base and buffer concepts with examples and determine pH of unknown solution

3. **Course materials:**

Text books

a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya

b. A. H. Beckett and J. B. Stenlake's Practical Pharmaceutical chemistry Vol-I & Vol-II

c. Inorganic Pharmaceutical Chemistry III-Edition P. Gundu Rao

Reference books

a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal

b. Pharmaceutical Inorganic chemistry by Dr. B. G. Nagavi

c. Analytical chemistry principles by John H. Kennedy

d. d. I.P.1985 and 1996, Govt. of India, Ministry of health

4. **Lecture wise programme: Topics**

1. Errors

Errors in quantitative analysis, classification of errors, concept of accuracy and precision, treatment of analytical results.

2. Volumetric analysis

Principle of volumetric analysis, different methods of analysis, different methods for expressing concentrations of solutions, primary and secondary standards.

3. Acid-base titrations

Acid- base concepts, relative strength of acids and bases, law of mass action, common ion effect, ionic product of water, Henderson-Hasselbalch equation, buffer solutions, theory of indicators, neutralization curves, choice of indicators, mixed and universal indicators.

4. Redox titrations

Concepts of oxidation–reduction reactions, redox reactions, theory of redox titrations, redox indicators, iodometry and iodimetry, titrations involving cerric sulphate, potassium iodate, potassium bromate, potassium permanganate, titanous chloride.

5. Non aqueous titration

Theoretical basis, types of solvents, preparations and standardization of titrant solutions, titration of weak acid, weak bases and indicators. standardization of perchloric acid, lithium and sodium methoxide, tetra butyl ammonium hydroxide.

6. Precipitation titrations

Introduction, types of precipitation titrations, end point detection.

7. Complexometric titrations

Introduction, principle, types of titrations, endpoint detection.

8. Theory of Indicators

9. Gravimetry - Basic concepts, Precipitation techniques, co-precipitation, post–precipitation, various steps involved in gravimetric analysis, pharmaceutical applications.

10. Limit tests

Definition, importance, general procedure for limit test for chlorides, sulphates, iron, arsenic, lead and heavy metals.

11. Medicinal Gases

Preparation and uses of the following Oxygen, Carbon dioxide, Helium, Nitrogen and Nitrous Oxide.

Method of preparation, assay, storage conditions and uses of inorganic compounds listed in I.P belonging to the following categories.

12. Acidifiers

Dilute hydrochloric acid, Sodium phosphate, Ammonium chloride.

13. Antacids

Classification, Qualities of an ideal antacid, side effects, advantages, combination therapy, acid neutralizing capacity, Sodium bicarbonate, Potassium citrate, Aluminium hydroxide gel, Dried aluminium hydroxide gel, Magnesium hydroxide, Light and heavy magnesium trisilicate, light and heavy magnesium carbonate, Calcium carbonate, Magaldrate and Bismuth carbonate.

14. Cathartics

Magnesium hydroxide, Magnesium sulphate, Magnesium carbonate and Sodium phosphate.

15. Electrolyte replenisher

Electrolytes used for replacement therapy: Sodium chloride, Potassium chloride, Calcium chloride, Calcium gluconate, Electrolytes used in the acid-base therapy: Sodium acetate, Potassium acetate, Sodium bicarbonate, Potassium bicarbonate, Sodium citrate, Sodium lactate, Ammonium chloride. Electrolyte combination therapy, Compound sodium chloride solution, Sodium chloride injection and Oral rehydration salt.

16. Essential Trace elements

Definition, Physiological role of Iron, Copper, Zinc, Chromium, Manganese, Molybdenum, Selenium, Sulphur and Iodine.

17. Antimicrobials

Hydrogen Peroxide, Potassium Permanganate, Chlorinated Lime, Iodine, Boric Acid, Silver Nitrate, Selenium Sulphide.

18. Pharmaceutical Aids: Sodium bisulphite, sodium meta bisulphite, bentonite, magnesium stearate, zinc stearate, aluminium sulphate, sodium carboxy methyl cellulose, purified water, water for injection and sterile water for injection.

19. Dental products

Anti-caries Agents: Role of Fluorides as anti-caries agents, Sodium fluoride.

Dentifrices: Calcium carbonate, dibasic calcium phosphate, Zinc chloride.

20. Miscellaneous compounds.

Sclerosing agents: Hypertonic saline, Sodium tetra decyl sulphate.

Expectorants: Potassium citrate and Potassium iodide.

Sedative: Potassium bromide.

Antidotes: Sodium nitrite, Sodium thiosulphate and Charcoal

Respiratory stimulant: Ammonium carbonate.

21. Radiopharmaceuticals.

Introduction, measurement of radioactivity, clinical applications and dosage, hazards and precautions.

1.10. PHARMACEUTICAL INORGANIC CHEMISTRY (PPD19CL110) (PRACTICAL)

Title of the Experiments:

1. **Limit test (6 exercises)**
   a. Limit test for chlorides
   b. Limit test for sulphates
   c. Limit test for iron
   d. Limit test for heavy metals
   e. Limit test for arsenic
   f. Modified limit tests for chlorides and sulphates
2. **Assays (10 exercises)**
   a. Ammonium chloride- Acid-base titration
   b. Ferrous sulphate- Cerimetry
   c. Copper sulphate- Iodometry
   d. Calcilugluconate- Complexometry
   e. Hydrogen peroxide – Permanganometry
   f. Sodium benzoate – Nonaqueous titration

g. Sodium chloride – Modified Volhard's method
h. Assay of KI – KIO_3 titration
i. Gravimetric estimation of barium as barium sulphate
j. Sodium antimony gluconate or antimony potassium tartarate

3. Estimation of mixture (Any two exercises)

a. Sodium hydroxide and sodium carbonate
b. Boric acid and Borax
c. Oxalic acid and sodium oxalate

4. Test for identity (Any three exercises)

a. Sodium bicarbonate
b. Barium sulphate
c. Ferrous sulphate
d. Potassium chloride

5. Test for purity (Any two exercises)

a. Swelling power in Bentonite
b. Acid neutralising capacity in aluminium hydroxide gel
c. Ammonium salts in potash alum
d. Adsorption power heavy Kaolin
e. Presence of Iodates in KI

6. Preparations (Any two exercises)

a. Boric acids
b. Potash alum
c. Calcium lactate
d. Magnesium sulphate

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment1&2	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.11. REMEDIAL MATHEMATICS (PPD19CT111)
(THEORY)

1. **Scope and objectives**: This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, Laplace transform.

2. **Course outcomes:**
   Upon completion of the course the student shall be able to: –

   CO1: Explain trigonometry, analytical geometry, matrices, determinant, integration, differential equation, laplace transform and their applications
   CO2: Solve the problems of different types by applying theory

   CO3: Explain the important applications of mathematics in pharmacy.

3. **Course materials:**
   Text books
   a. Differential calculus by Shanti Narayan
   b. Text book of Mathematics for second year pre-university by Prof. B. M. Sreenivas

   Reference books
   a. Integral calculus by Shanthi Narayan
   b. Engineering mathematics by B. S. Grewal
   c. Trigonometry Part-I By S. L. Loney

4. Lecture wise programme: Topics

1 **Algebra :** Determinants, Matrices

2 **Trigonometry :** Sides and angles of a triangle, solution of triangles

3 **Analytical Geometry :**Points, Straight line, circle, parabola

4 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables

5 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.

6 **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.

7 **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

1.12. REMEDIAL BIOLOGY (PPD19CT112)
(THEORY)

1. **Scope and objectives**: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduced to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. **Course outcomes:**

Upon completion of this course, the student shall be able to:

CO1: Explain the various components of plant/animal cell

CO2: Describe the morphology of various plant parts and their modifications

CO3: Explain the physiology of plants

CO4: Describe the salient taxonomical characters of Leguminosae / Umbelliferae / Solanaceae / Lilliaceae / Zingiberaceae / Rubiaceae

CO5: Summarize various plant/animal tissue system and their functions

CO6: Describe the anatomy and physiology of various systems (respiratory/circulatory/reproductive/nervous system) of frog.

CO7: Explain the general characteristics of Pisces/Reptiles/Aves and the general organization of mammals

CO8: Identify the morphology of root/leaf/fruits/seeds and their modifications

CO9: Demonstrate the preparation of permanent slide using microtome

CO10: Perform frog dissection and label the various parts of digestive system in a simulated condition.

3. **Course materials:**

Text books

a. Text book of Biology by S. B. Gokhale

b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference books

a. A Text book of Biology by B.V. Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students by A. C. Dutta.
d. Outlines of Zoology by M. Ekambaranatha Ayyer and T.N. Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S. B. Gokhale and C. K. Kokate.

4. Lecture wise programme: Topic

PART – A

1 Introduction
2 General organization of plants and its inclusions
3 Plant tissues
4 Plant kingdom and its classification
5 Morphology of plants
6 Root, Stem, Leaf and Its modifications

7 Inflorescence and Pollination of flowers
8 Morphology of fruits and seeds
9 Plant physiology
10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zingiberaceae, Rubiaceae
11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

1 Study of Animal cell
2 Study animal tissues
3 Detailed study of frog
4 Study of Pisces, Reptiles, Aves
5 General organization of mammals
6 Study of poisonous animals

1.13. REMEDIAL BIOLOGY (PPD19CL113) (PRACTICAL)

Title of the Experiment:

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

SECOND YEAR

2.1. PATHOPHYSIOLOGY (PPD19CT201)
(THEORY)

1. **Scope and Objective:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.

2. Course outcomes:

Upon completion of the subject, the student shall be able to:

CO1: Discuss the causes, the pathological processes and the morphology of cell injury, the immunological and metabolic changes, and describe the cellular responses including the adaptive changes.

CO2: Explain the principles, types, clinical signs and the process of inflammation and the basics of wound healing and repair.

CO3: Define, classify and differentiate disease states based on their pathological characteristics as neoplastic disease, auto immune, metabolic, hemodynamic, infectious, blood and vascular disorders.

CO4: Describe the etiology and explain the pathophysiology of the cardiac, respiratory, gastrointestinal, hepatobiliary, pancreatic, renal, endocrine, neurological, psychiatric diseases and shock.

CO5: Elucidate the signs and symptoms of each disease state and mention their long term complications.

CO6: Explain the role of radiation exposure, environmental factors, Protein energy malnutrition, vitamin deficiencies, obesity and starvation in the pathogenesis of a disease state.

CO7: Describe the basic principles of cancer and classify cancer based on their pathology.

CO8: Distinguish the causative organisms, pathophysiology and the clinical manifestations of the infectious and sexually transmitted diseases.

3. Course materials:

Text books (Theory)-

a. Pathologic basis of disease by- Cotran, Kumar, Robbins
b. Text book of Pathology- Harsh Mohan
c. Text book of Pathology- Y.M. Bhinde

Reference books (Theory)

a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication
b. Essentials of Pathophysiology- Concepts of altered health states, Textbook by Carol Mattson Porth, Fourth Edition, Wolters Kluwer Publication.

4. Detailed syllabus and lecture wise schedule:

1 Basic principles of cell injury and Adaptation

a) Causes, Pathogenesis and morphology of cell injury

b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases

2 **Inflammation**

a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation

b) Repairs of wounds in the skin, factors influencing healing of wounds

3 **Diseases of Immunity**

a) Introduction to T and B cells

b) MHC proteins or transplantation antigens

c) Immune tolerance

- Hypersensitivity

  Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs

- Autoimmunity

  Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.

- Acquired immune deficiency syndrome (AIDS)
  Amyloidosis

4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.

5 Types of shock, mechanisms, stages and management

6 Biological effects of radiation

7 Environmental and nutritional diseases

i) Air pollution and smoking- SO_2,NO, NO_2, and CO

ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.

8 Pathophysiology of common diseases

a. Parkinsonism
b. Schizophrenia
c. Depression and mania
d. Hypertension,
e. Stroke (ischaemic and hemorrhage)
f. Angina, CCF, Atherosclerosis, Myocardial infarction
g. Diabetes Mellitus
h. Peptic ulcer and inflammatory bowel diseases
i. Cirrhosis and Alcoholic liver diseases
j. Acute and chronic renal failure

k. Asthma and chronic obstructive airway diseases

9 Infectious diseases :

Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

4. Assignments :

1 Chemical Mediators of inflammation
2 Drug Hypersensitivity
3 Cigarette smoking & its ill effects
4 Biological effects of Radiation
5 Etiology and hazards of obesity
6 Complications of diabetes
7 Diagnosis of cancer
8 Disorders of vitamins
9 Methods in Pathology-Laboratory values of clinical significance
10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

2.2 PHARMACEUTICAL MICROBIOLOGY (PPD19CT202) (THEORY)

1. Scope and Objective: Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. It also discusses on sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. Course outcomes:

Upon completion of the subject, the student shall be able to:

CO1: Demonstrate basic knowledge about the anatomy, identification, growth factors and sterilization of microorganisms.

CO2: Exhibit knowledge of mode of transmission of disease causing microorganisms and symptoms of infectious diseases.

CO3: Employ different methods/ techniques of cultivation, isolation, identification and staining of the microorganisms in the laboratory.

CO4: Explain the procedures of identification of infectious diseases and apply it in performing the diagnostic tests

CO5: Perform behavioral characteristics and motility of microorganisms.

3. Course materials:

Text books (Theory)

a. Vanitha Kale and Kishor Bhusari — Applied Microbiology ‖ Himalaya Publishing house Mumbai.
b. Mary Louis Turgeon — Immunology and Serology in Laboratory Medicines‖ 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
c. Harsh Mohan, — Text book of Pathology‖ 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

a. Prescot L.M., Jarley G.P Klein D.A —Microbiology, 2nd- edition Mc Graw Hill Company Inc
b. Rawlins E.A. Bentley's Text Book of Pharmaceutics, Bailliere Tindals 24-28 London 1988
c. Forbisher — Fundamentals of Microbiology, Philadelphia W.B. Saunders.
d. Prescott L.M. Jarley G.P., Klein. D.A. — Microbiology, 2nd edition WMC Brown Publishers, Oxford. 1993
e. War Roitt, Jonathan Brostoff, David Male, — Immunology, 3rd edition 1996, Mosby-year book Europe Ltd, London.
f. Pharmacopoeia of India, Govt of India, 1996.

4. Detailed syllabus and lecture wise schedule:

Title of the topic

1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.

2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.

3 Nutritional requirements, growth and cultivation of bacteria and virus.
Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.

4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.

5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations. Brief information on Validation.

6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, virucidal activities, evaluation of preservatives in pharmaceutical preparations.

7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity (active and passive) . Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.

8 Diagnostic tests: Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantoux Peripheral smear. Study of malarial parasite.

9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of
Penicillin, Streptomycin and vitamin B_2 and B_{12}. Standardization of vaccines and sera.

10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

2.7. PHARMACEUTICAL MICROBIOLOGY (PPD19CL207) (PRACTICAL)

Title of the Experiments:

1 Study of apparatus used in experimental microbiology*.
2 Sterilization of glass ware's. Preparation of media and sterilisation.*
3 Staining techniques – Simple staining ; Gram's staining ; Negative staining**
4 Study of motility characters*.
5 Enumeration of micro-organisms (Total and Viable)*
6 Study of the methods of isolation of pure culture.*
7 Bio chemical testing for the identification of micro*-organisms.
8 Cultural sensitivity testing for some micro-organisms.*
9 Sterility testing for powders and liquids.*
10 Determination of minimum inhibitory concentration.*
11 Microbiological assay of antibiotics by cup plate method.*
12 Microbiological assay of vitamins by Turbidometric method**
13 Determination of RWC.**
14 Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

1 Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasteurization) and microbial laboratories (other sterilization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
   a. Report of recent microbial techniques developed in diagnosing some common diseases.
   b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.3. PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PPD19CT203) (THEORY)

1. **Scope and objectives:** This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

2. **Course outcomes:**

Upon completion of the course, the student shall be able to:

CO1: Explain the basic principles of cultivation, collection and storage of crude drugs

CO2: Identify the source, active constituents and uses of crude drugs

CO3: Demonstrate knowledge of the uses of primary and secondary metabolites of the plant.

3. **Course materials:**

Text books

a. Pharmacognosy by G.E. Trease & W. C. Evans.

b. Pharmacognosy by C. K. Kokate, Gokhale & A. C. Purohit.

c. S. Shah's Pharmacognosy, Ramesh K. Goyal, D. Chamundeeswari, R. Thirumalaikumaran, Neeru Vasudeva and Bhoomika M. Patel. 16th edition, B. S. Shah Prakashan, Ahmedabad.

d. Mangathayaru K. Pharmacognosy: An Indian Perspective, Pearson. 2013

Reference books

a. Pharmacognosy by Brady &Tyler. E.
b. Pharmacognosy by T. E. Wallis.
c. Pharmacognosy by C.S. Shah & Qadry.
d. Pharmacognosy by M.A. Iyengar.

4. Lecture wise programme: Topics

1 Introduction, Definition, history and scope of Pharmacognosy.
2 Wild and cultivated sources of drugs
3 Classification of crude drugs.
4 Cultivation, collection, processing and storage of crude drugs.
5 Detailed method of cultivation of crude drugs.
6 Study of cell wall constituents and cell inclusions.
7 Different methods of adulteration of crude drugs.
8 Microscopical and powder Microscopical study of crude drugs mentioned in the Practical
9 Study of natural pesticides.
10 Detailed study of various cell constituents.
11 Carbohydrates and related products: Detailed study carbohydrates containing drugs.(Acacia, Agar, Tragacanth, Honey, Starch, Guargum, Pectin, Sodium Alginate, Isapgol, Carrageenan, Sterculia)
12 Definition sources, method of extraction, chemistry and method of analysis of lipids (Wool fat, Bees wax)
13 Detailed study of fixed oils (Castor oil, Cod liver oil, Shark liver oil, Chaulmoogra oil, Arachis oil).
14 Definition, classification, chemistry and method of analysis of protein (Gelatin)
15 Study of plants fibers used in surgical dressings and related products.

2.8. PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PPD19CL208) (PRACTICAL)

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

1 Introduction of Pharmacognosy laboratory and experiments.
2 Study of cell wall constituents and cell inclusions.
3 Macro, powder and microscopic study of Datura.
4 Macro, powder and microscopic study of Senna.
5 Macro, powder and microscopic study of Cassia. Cinnamon.
6 Macro, powder and microscopic study of Cinchona.
7 Macro, powder and microscopic study of Ephedra.
8 Macro, powder and microscopic study of Quassia.
9 Macro, powder and microscopic study of Clove

10 Macro, powder and microscopic study of Fennel.
11 Macro, powder and microscopic study of Coriander.
12 Macro, powder and microscopic study of Isapgol.
13 Macro, powder and microscopic study of Nux vomica.
14 Macro, powder and microscopic study of Rauwolfia.
15 Macro, powder and microscopic study of Liquorice.
16 Macro, powder and microscopic study of Ginger.
17 Macro, powder and microscopic study of Podophyllum.
18 Determination of Iodine value.
19 Determination of Saponification value and unsaponifiable matter.
20 Determination of ester value.
21 Determination of Acid value.
22 Chemical tests for Acacia.
23 Chemical tests for Tragacanth.
24 Chemical tests for Agar.
25 Chemical tests for Starch.
26 Chemical tests for Lipids.(castor oil, sesame oil, shark liver oil, bees wax)
27 Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

2.4. PHARMACOLOGY – I (PPD19CT204) (THEORY)

1. **Scope and Objective:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

2. **Course outcomes:**

Upon completion of the course, the student will be able to:

CO1: Explain the pharmacological aspects of drugs acting on Autonomic nervous system, Central nervous system, Cardiovascular system, Respiratory system.

CO2: Explain the basic concepts in endocrine pharmacology.

CO3: Discuss the Pathophysiological role of Autocoids.

CO4: Describe the importance of pharmacology subject as a basis of therapeutics and correlate and apply the knowledge therapeutically.

CO5: Explain the effects of drugs in animal using simulator software.

3. Course materials:

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.

b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.

c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory) (Author, Title, Edition, Publication Place, Publisher, Publication Year)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed,1996. Publisher Mc Graw Hill, Pergamon press.

b. Craig, C.R. & Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown. Co

c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.

d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Text books (Practical):

a. Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill Livingstone.

b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill Livingstone.

c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.

d. Ian Kitchen. Textbook of *in-vitro* practical pharmacology. Latest edition, Publisher: Black well Scientific.

4. Detailed syllabus and lecture wise schedule: Title of the topic

1. **General Pharmacology**
   a) Introduction, definitions and scope of pharmacology
   b) Routes of administration of drugs

c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
d) Pharmacodynamics
e) Factors modifying drug effects
f) Drug toxicity - acute, sub- acute and chronic toxicity.
g) Pre-clinical evaluations
h) Drug interactions

Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, therapeutic uses, interactions and dose and route of administration.

2. **Pharmacology of drugs acting on ANS**

a) Adrenergic and antiadrenergic drugs
b) Cholinergic and anticholinergic drugs
c) Neuromuscular blockers
d) Mydriatics and miotics
e) Drugs used in Myasthenia gravis
f) Drugs used in Parkinsonism

3. **Pharmacology of drugs acting on cardiovascular system**

a) Antihypertensives
b) Anti-anginal drugs
c) Anti-arrhythmic drugs
d) Drugs used for therapy of Congestive Heart Failure
e) Drugs used for hyperlipidaemias

4. **Pharmacology of drugs acting on Central Nervous System**

a) General anesthetics
b) Sedatives and hypnotics
c) Anticonvulsants
d) Analgesic and anti-inflammatory agents
e) Psychotropic drugs
f) Alcohol and methyl alcohol
g) CNS stimulants and cognition enhancers
h) Pharmacology of local anaesthetics

5. **Pharmacology of Drugs acting on Respiratory tract**

a) Bronchodilators
b) Mucolytics
c) Expectorants
d) Antitussives
e) Nasal Decongestants

6. **Pharmacology of Hormones and Hormone antagonists**

a) Thyroid and Antithyroid drugs
b) Insulin, Insulin analogues and oral hypoglycemic agents
c) Sex hormones and oral contraceptives
d) Oxytocin and other stimulants and relaxants

7. **Pharmacology of autocoids and their antagonists**

   a) Histamines and Antihistaminics

   b) 5-Hydroxytryptamine and its antagonists

   c) Lipid derived autocoids and platelet activating factor

2. 5. COMMUNITY PHARMACY (PPD19CT205) (THEORY)

1. Scope and Objective: In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.

2. Course outcome:

Upon completion of the course, the student shall be able to:

CO1: Describe the scope, roles and responsibilities of the community pharmacist and the management of a community pharmacy

CO2: List out the uses of Computers and health care software in a community pharmacy

CO3: Describe the general steps involved in creating a patient centered pharmaceutical care plan, and identify the medications related problems in the prescription.

CO4: Define and categorize methods of purchase and inventory control in community pharmacy settings.

CO5: Perform the different methods of inventory analysis in community pharmacy settings.

CO6: Identify symptoms of minor ailments and provide appropriate medications including over the counter medicines and participate in prevention programs of communicable diseases.

CO7: Demonstrate professional ethics in educating patients through counseling, providing health screening services to public and promoting safe and appropriate medication use throughout society.

3. Course materials:

Text Books:

a. Health Education and Community Pharmacy by N. S. Parmar.

b. WHO consultative group report.

c. Drug store & Business management by Mohammed Ali & Jyoti.

d. Handbook For Community Pharmacists by Atmaram Pawar, Career Publications

Reference books:

a. Handbook of pharmacy – Health care. Edt. Robin J Harman. The Pharmaceutical press.

b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipment like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

4. Lecture wise programme: Topics

1. Definition, scope, of community pharmacy; Roles and responsibilities of Community pharmacist

2. Community Pharmacy Management

i. Selection of site, Space layout, and design
ii. Staff, Materials- coding, stocking
iii. Legal requirements
iv. Maintenance of various registers
v. Use of Computers: Business and health care soft wares

3. Prescriptions – parts of prescription, legality & identification of medication related problems like drug interactions.

4. Inventory control in community pharmacy
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock

5. Pharmaceutical care
Definition and Principles of Pharmaceutical care.

6. Patient counseling
Definition, outcomes, various stages, barriers, Strategies to overcome barriers
Patient information leaflets- content, design, & layouts, advisory labels

7. Patient medication adherence

Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.

8. Health screening services
Definition, importance, methods for screening, Blood pressure/ blood sugar/ lung function and Cholesterol testing

9. OTC Medication- Definition, OTC medication list & Counselling

10. Health Education

WHO Definition of health and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.

Commonly occurring Communicable Diseases, causative agents,

Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS

Balance diet, and treatment & prevention of deficiency disorders
Family planning – role of pharmacist

11. **Responding to symptoms of minor ailments** Relevant pathophysiology, common drug therapy to Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea and constipation), Pyrexia, Opthalmic symptoms, worm infestations.

12. **Essential Drugs concept and Rational Drug Therapy - Role of community pharmacist**

13. **Code of ethics for community pharmacists**

2. 6. PHARMACOTHERAPEUTICS - I (PPD19CT206) (THEORY)

1. **Scope and Objective:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Course outcomes:**

Upon completion of this subject, the students will be able to–

CO1: Describe the etiology, pathophysiology, clinical manifestations, complications, diagnosis and management of selected cardiovascular, respiratory, endocrine and ophthalmological diseases.

CO2: Understand the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

CO3: Develop clinical skills to prepare individualized therapeutic plans based on diagnosis and provide patient – centered pharmaceutical care by applying the evidence based medicine

CO4: Discuss the clinical controversies in Drug therapy of the selected disease states with reference to the latest available evidence.

CO5: Demonstrate knowledge on general prescribing guidelines for special populations and the significance of rational drug therapy.

CO6: Continue to develop patient case based assessment skills in a clinical setting and communication skills through patient education and interaction with the healthcare team.

3. Course materials:

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

a. Pathologic basis of disease - Robins SL, W. B. Saunders publication.

b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.

c. Pharmacotherapeutics for Advanced Practice: A Practical Approach by Virginia Poole Arcangelo, Third Edition, Lippincott Williams and Wilkins Publications

d. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.

e. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA

f. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

g. Relevant review articles from recent medical and pharmaceutical literature.

4. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

1. **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias, Electrophysiology of heart and Arrhythmias

2. **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

   Endocrine system: Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis

3. **General prescribing guidelines for**
   a. Paediatric patients
   b. Geriatric patients
   c. Pregnancy and breast feeding

4. **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial

5. **Introduction to rational drug use**

   Definition, Role of pharmacist, Essential drug concept, Rational drug formulations

2. 9. PHARMACOTHERAPEUTICS – I (PPD19CL209) (PRACTICAL)

Hospital postings in various departments for a period of not less than fifty hours, designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

THIRD YEAR

3.1 PHARMACOLOGY – II (PPD19CT301) (THEORY)

1. **Scope and Objective:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autocoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

2. **Course outcomes:**

Upon completion of the course, the student will be able to:

CO1: Explain the pharmacological aspects of drugs acting on blood and blood forming agents, renal system.

CO2: Discuss the Pharmacology of immunosuppressants and stimulants.

CO3: Enumerate the structure and function of the components of the cell and cell cycle.

CO4: Describe the Principles of Animal toxicology.

CO5: Discuss the flow of genetic information.

CO6: Describe the organization and elucidation of genetic code.

CO7: Explain the basic principles of transcription and Translation.

CO8: Describe the genetic elements that control gene expression.

CO9: Enumerate altered gene functions.

CO10: Explain the principles, processes and applications of gene transfer technology.

3. Course materials:

Text books (Theory)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.

b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.

c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.

b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.

c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.

d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

e. Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.

f. Molecular Cell Biology by Lodish, H., Baltimore, D., Berk, A et al., 5th edition.

h. Molecular Biology by Turner PC, McLennan AG, Bates AD and White MRH. 2nd edition.

i. Genes VIII by Lewin, B., (2004)

j. Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)

K. Recombinant DNA by Watson, JD. Gilman, M., et al., (1996)

L. Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical):

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill Livingstone.

b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill Llivingstone.

c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.

d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

4. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Pharmacology of drugs acting on blood and blood forming agents**

   a) Anticoagulants
   b) Thrombolytics and antiplatelet agents
   c) Haemopoietics and plasma expanders

2. **Pharmacology of drugs acting on Renal System**

   a) Diuretics
   b) Antidiuretics

3. **Chemotherapy**

   a) Introduction
   b) Sulfonamides and co-trimoxazole
   c) Penicillins and Cephalosporins
   d) Tetracyclines and Chloramphenicol
   e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
   f) Quinolines and Fluroquinolines
   g) Antifungal antibiotics
   h) Antiviral agents
   i) Chemotherapy of tuberculosis and leprosy
   j) Chemotherapy of Malaria
   k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
   l) Pharmacology of Anthelmintic drugs
   m) Chemotherapy of cancer (Neoplasms)

4 **Immunopharmacology**

   Pharmacology of immunosuppressants and stimulants

5. **Principles of Animal toxicology**

   Acute, sub-acute and chronic toxicity

6. **The dynamic cell: The structures and functions of the components of the cell**

a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies

b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.

c) DNA replication: General, bacterial and eukaryotic DNA replication.

d) The cell cycle: Restriction point, cell cycle regulators and modifiers.

e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors).

The Gene: Genome structure and function:

a) Gene structure: Organization and elucidation of genetic code.

b) Gene expression: Expression systems (pro and eukaryotic),genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.

c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.
Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events

Altered gene functions: Mutations, deletions, amplifications, LOH, translocations, trinucleotide repeats and other genetic abnormalities.

Oncogenes and tumor suppressor genes.
The gene sequencing, mapping and cloning of human disease genes.
Introduction to gene therapy and targeting.

Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

3.7. PHARMACOLOGY – II (PPD19CL307) (PRACTICAL)

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.

8. To record the dose response curve of histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea -pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:

    a) Analgesic property of drug using analgesiometer.
    b) Anti-inflammatory effect of drugs using rat-paw edema method.
    c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
    d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
    e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
    f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3. 2. PHARMACEUTICAL ANALYSIS (PPD19CT302) (THEORY)

1. Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Describe the interaction of matter with EMR and its application in drug analysis

CO2: Discuss the Chromatographic separation and analysis of drugs using various advanced instrumental techniques

CO3: Outline the principles and instrumentation of spectroscopic techniques in analysis of drugs.

CO4: Relate the qualitative and quantitative analysis of drugs using various instrumental techniques.

CO5: Clarify the Good laboratory practices followed in industries

CO6: Outline the various QA and QC techniques in industries.

CO7: Analyze the different drug substances using instrumental techniques.

CO8: Explain the ISO standards for Good laboratory practice in industries.

2. Course materials:

Reference Books:

a. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.

b. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.

c. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.

d. Undergraduate Instrumental Analysis by James. E., CBS Publishers.

e. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.

f. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.

g. Text Book of Chemical Analysis, by A.I. Vogel, ELBS with Macmillan press, Hampshire.

h. Textbook of Pharm. Analysis by K. A. Connors, John Wiley & Sons, New York, Brisbane, Singapore.

i. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.

j. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.

k. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.

l. How to practice GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.

m. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.

n. TLC by Stahl, Spring Verlay.

o. Text Book of Pharm. Chemistry by Chatten, CBS Publications.

p. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.

q. I.P.-1996, The Controller of Publications, New Delhi.

r. BPC- Dept. of Health, U.K. for HMSO.

s. USP - Mack Publishing Co., Easton, PA.

t. The Extra Pharmacopoeia – The Pharm. Press, London.

3. Detailed syllabus and lecture wise schedule: Title of the topic

1. **Quality Assurance:**

    a. Introduction, sources of quality variation, control of quality variation.

b. Concept of statistical quality control.

c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.

d. GLP, ISO 9000.

e. Total quality management, quality review and documentation.

f. ICH- international conference for harmonization-guidelines.

g. Regulatory control.

2. **Chromatography:**

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

a. **Column Chromatography**: Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.

b. **TLC**: Introduction, principle, techniques, R_f value and applications.

c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.

d. **Ion-exchange chromatography**: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.

e. **HPLC**: Introduction, theory, instrumentation, and applications.

f. **HPTLC**: Introduction, theory, instrumentation, and applications.

g. **Gas Chromatography**: Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors-
Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.

h. **Electrophoresis**: Principles of separation, equipment for paper and gel electrophoresis, and application.

i. **Gel filtration** and **affinity chromatography**: Introduction, technique, applications.

3. **Electrometric Methods:**

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

a. **Potentiometry**: Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.

b. **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications.

c. **Polarography**: Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.

d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. **Spectroscopy:**

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a. **Absorption Spectroscopy:**

Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, bathochromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

- **Infrared Spectroscopy**: Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectro-meter – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors– Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.

c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.

d. **Atomic Emission Spectroscopy**: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.

e. **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications.

f. **Mass Spectroscopy**: (**Introduction only**) – Fragmentation, types of ions produced mass spectrum and applications.

g. **Polarimetry: (Introduction only**) – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.

h. **X-RAY Diffraction: (Introduction only**) – Theory, reciprocal lattice concept, diffraction patterns and applications.

i. **Thermal Analysis**: Introduction, instrumentation, applications, and DSC and DTA.

3.8. PHARMACEUTICAL ANALYSIS (PPD19CL308) (PRACTICAL)

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of an acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nephelo-turbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.3. PHARMACOTHERAPEUTICS – II (PPD19CT303) (THEORY)

1. **Scope and Objective:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly

therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. Course outcomes:

Upon completion of the subject, the student shall be able to:

CO1: Explain the pathogenesis of surgical site infections, their risk factors and the pharmacotherapy of surgical infections

CO2: Describe the etiology, pathophysiology, clinical manifestations, complications, diagnosis and management of selected renal, musculo-skeletal, dermatological, infectious diseases and cancers.

CO3: Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s).

CO4: Discuss the pharmacotherapy and clinical controversies in drug therapy of the selected disease states with reference to the latest available evidence.

CO5: Develop clinical skills to prepare individualized therapeutic plans based on diagnosis and provide patient – centered pharmaceutical care by applying the evidence based medicine.

CO6: Develop skills to identify drug related problems in the patient medication orders through critical analysis of the prescription in alignment with the diagnosis, manifestations and investigations and provide necessary intervention.

CO7: Continue to develop patient case based assessment skills in a clinical setting and communication skills through patient education and interaction with the healthcare team.

3. Course materials:

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

a. Pathologic basis of disease - Robins SL, W. B. Saunders publication

b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication

c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication

d. Pharmacotherapeutics for Advanced Practice: A Practical Approach by Virginia Poole Arcangelo, Third Edition, Lippincott Williams and Wilkins Publications

e. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda –Kimble MA

f. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

g. Relevant review articles from recent medical and pharmaceutical literature.

4. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

Title of the topic

1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhea and Syphillis

2. **Musculoskeletal disorders**

   Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.

3. **Renal system**

   Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

4. **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy induced nausea and emesis

5. **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3. 9. PHARMACOTHERAPEUTICS – II (PPD19CL309) (PRACTICAL)

Hospital postings in various departments for a period of not less than fifty hours, designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.

6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	End Year Examination
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.4 PHARMACEUTICAL JURISPRUDENCE (PPD19CT304) (THEORY)

1. **Scope and Objective:** This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.

2. **Course outcomes:**

Upon completion of the subject, the student shall be able to:

CO1: Practice Professional ethics

CO2: Explain the various concepts of the pharmaceutical legislation in India

CO3: Explain the rules and regulations framed and amendments made under drugs and cosmetics act 1940

CO4: Explain the Drug policy, DPCO, Patent and design act

CO5: Demonstrate the labeling requirements and packaging guidelines for drugs and cosmetics

CO6: Explain the concepts of Dangerous Drugs Act and Excise duties Act

CO7: Summarize the rules and regulations framed and amendments made under pharmacy act 1948 and other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

3. Course materials:

Text books (Theory)

Mithal B M. Textbook of Forensic Pharmacy. Calcutta: National; 1988.

Reference books (Theory)

a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh Prakashan; 1995.
c. Reports of the Pharmaceutical enquiry Committee

d. I.D.M.A., Mumbai. DPCO 1995

e. Various reports of Amendments.

f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.

g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

4. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Pharmaceutical Legislations –** A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cosmetics Act, 1940, and its rules 1945.**

   Objectives, Legal definition, Study of Schedule's with reference to Schedule B,

   C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.

   Sales, Import, labeling and packaging of Drugs and Cosmetics Provisions Relating to Indigenous Systems.

   Constitution and Functions of DTAB, DCC, CDL. Qualification and duties –Govt. analyst and Drugs Inspector.
4. **Pharmacy Act –1948**.

   Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955**.

   Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory,

   Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**. Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Current).**
10. **Prevention of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

3. 5. MEDICINAL CHEMISTRY (PPD19CT305) (THEORY)

1. Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Discuss the importance of drug design and different techniques of drug design.

CO2: Elaborate QSAR parameters.

CO3: Predict the physicochemical properties based on their structure using computer software.

CO4: Describe the concept and application of prodrugs.

CO5: Classify drugs based on their chemical structure.

CO6: Outline the chemical synthesis of selected drugs

CO7: Relate the chemistry of drugs with their biological activity.

CO8: Explain the mechanism of action, adverse effects and therapeutic value of selected drugs of synthetic origin.

2. Course materials:

Reference Books:

a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.

b. William. O. Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.

c. Burgers, Medicinal Chemistry, M.E. Welly Med. Chemistry M.E. Walffed John Willey and Sons, Wiley-interscience Publication, New York, Toranto.

d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.

e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.

f. Current Index of Medical Specialties (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.

g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.

h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.

i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

3. Detailed syllabus and lecture wise schedule: Title of the topic

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), pro drug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

   A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

   Anti-infective agents

   a) Local anti-infective agents

   b) Preservatives

   c) Antifungal agents

   d) Urinary tract anti-infectives

   e) Antitubercular agents

   f) Antiviral agents and Anti AIDS agents

   g) Antiprotozoal agents

   h) Anthelmintics

   i) Antiscabies and Antipedicular agents

2. Sulphonamides and sulphones

3. Antimalarials
4. Antibiotics
5. Antineoplastic agents
6. Cardiovascular agents
    a) Antihypertensive agents
    b) Antianginal agents and vasodilators
    c) Antiarrhythmic agents
    d) Antihyperlipidemic agents
    e) Coagulants and Anticoagulants
    f) Endocrine
8. Hypoglycemic agents
9. Thyroid and Antithyroid agents
10. Diuretics
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids

3.10. MEDICINAL CHEMISTRY (PPD19CT310) (PRACTICAL)

Title of the Experiments:

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

3.6. PHARMACEUTICAL FORMULATIONS (PPD19CT306) (THEORY)

1. **Scope and Objective:** Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.

2. Course outcomes:

Upon completion of the subject, the student shall be able to:

CO1: Exhibit knowledge and apply the principle involved in formulation of various pharmaceutical dosage forms

CO2: Prepare and evaluate various pharmaceutical dosage forms in a laboratory scale

CO3: Describe the applications of excipients involved in formulations

CO4: Outline the uses of various dosage forms in the clinical practice setting.

CO5: Respond to the inquiries from patients and/or healthcare professionals related to medication use.

3. Course materials:
Text books (Theory)

a. Pharmaceutical dosage forms, Vol, I,II and III by Lachman
b. Rowlings Text book of Pharmaceutics
c. Tutorial Pharmacy – Cooper &Gun

Reference books (Theory)

a. Remington's Pharmaceutical Sciences
b. USP/BP/IP

4. Detailed syllabus and lecture wise schedule: Title of the topic

1. Pharmaceutical dosage form- concept and classification
2. **Tablets**: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
3. **Capsules**; Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
4. **Liquid orals**: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
6. **Ophthalmic preparations (Semi – Solids)**: Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular

3. 11. PHARMACEUTICAL FORMULATIONS (PPD19CL311) (PRACTICAL)

List of Experiments:

1. Manufacture of Tablets

- **a.** Ordinary compressed tablet-wet granulation
- **b.** Tablets prepared by direct compression.
- **c.** Soluble tablet.
- **d.** Chewable tablet.

2. Formulation and filling of hard gelatin capsules

3. Manufacture of parenterals

- **a.** Ascorbic acid injection
- **b.** Calcium gluconate injection
- **c.** Sodium chloride infusion.
- **d.** Dextrose and Sodium chloride injection/ infusion.

4. Evaluation of Pharmaceutical formulations (QC tests)

- **a.** Tablets
- **b.** Capsules
- **c.** Injections

5. Formulation of two liquid oral preparations and evaluation by assay

- **a.** Solution: Paracetamol Syrup
- **b.** Antacid suspensions- Aluminum hydroxide gel

6. Formulation of semisolids and evaluation by assay

- **a.** Salicyclic acid and benzoic acid ointment
- **b.** Gel formulation Diclofenac gel

7. Cosmetic preparations

- **a.** Lipsticks
- **b.** Cold cream and vanishing cream
- **c.** Clear liquid shampoo
- **d.** Tooth paste and tooth powders.

8. Tablet coating (demonstration)

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

FOURTH YEAR

4. 1. PHARMACOTHERAPEUTICS – III (PPD19CT401) (THEORY)

1. **Scope and Objective:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Course outcomes:**

Upon completion of the course, the student shall be able to:

CO1: Describe the etiology, pathophysiology, clinical manifestations, complications, diagnosis and management of selected gastro intestinal, hematological. Psychiatric, nervous system diseases, pain and pain pathways, neuralgias and headache.

CO2: Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effects).

CO3: Discuss the pharmacotherapy and clinical controversies in drug therapy of the selected disease states with reference to the latest available evidence.

CO4: Demonstrate skills to initiate individualized drug therapy applying evidence based medicine and the anticipated therapeutic goals by patient – centered therapeutic intervention.

CO5: Demonstrate skills to identify drug related problems in the patient medication orders through critical analysis of the prescription in alignment with the diagnosis, manifestations and investigations and provide necessary intervention.

CO6: Demonstrate skills for patient case based assessment in a clinical setting and communication skills through patient education and interaction with the healthcare team.

3. Course materials:

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

a. Pathologic basis of disease - Robins SL, W. B. Saunders publication

b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication

c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication

d. Pharmacotherapeutics for Advanced Practice: A Practical Approach by Virginia Poole Arcangelo, Third Edition, Lippincott Williams and Wilkins Publications

e. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda -Kimble MA

f. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

g. Relevant review articles from recent medical and pharmaceutical literature.

4. Detailed syllabus and lecture wise schedule: Title of the topic

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

1. **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
2. **Hematological system:** Anemias, Venous thromboembolism, Drug induced blood disorders.
3. **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
4. **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
5. **Pain management including Pain pathways, neuralgias, headaches.**
6. **Evidence Based Medicine**

4.7. PHARMACOTHERAPEUTICS – III (PPD19CL407) (PRACTICAL)

Practical:

Hospital postings for a period of not less than 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15

Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.2. HOSPITAL PHARMACY (PPD19CT402) (THEORY)

1. Scope and Objective: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.

2. Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Define and classify hospitals, explain the organization, structure and functions of a hospital and a hospital pharmacy.

CO2: Describe the roles, responsibilities and functions of a hospital pharmacist including the Pharmacy and Therapeutics Committee, in the preparation of Hospital Formulary and hospital drug policies.

CO3: Demonstrate knowledge on various drug distribution and dispensing methods, handling of radiopharmaceuticals and controlled substances in a hospital and apply it in the hospital pharmacy practice setting.

CO4: Develop the professional practice management skills and demonstrate code of ethics in the hospital pharmacies.

CO5: Demonstrate ability to prepare and implement a budget, carry out purchase and inventory control of drugs in a hospital pharmacy, organize, stock the drugs including the investigational drugs and manage a pharmacy store in practice setup.

CO6: Provide unbiased drug information to the doctors and other healthcare professionals.

CO7: Demonstrate knowledge on the manufacturing practices of various formulations in a hospital set up.

CO8: Develop aptitude for continuous education, training and professional development of self and of the fellow health care team.

3. Course materials:
Text books: (latest editions)

a. Hospital pharmacy by William .E. Hassan

b. A text book of Hospital Pharmacy by S.H. Merchant & Dr. J.S. Qadry. Revised by R. K. Goyal & R.K. Parikh

References:

a. WHO consultative group report.

b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.

c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

4. Lecture wise programme: Topics

1 Hospital - its organization and functions

2 Hospital pharmacy- Organization and management

a) Organizational structure-Staff, Infrastructure & work load statistics

b) Management of materials and finance

c) Roles & responsibilities of hospital pharmacist

3 The Budget – Preparation and implementation

4 Hospital drug policy

a) Pharmacy and Therapeutic committee (PTC)
b) Hospital formulary
c) Hospital committees
- Infection committee
- Research and ethical committee

d) Developing therapeutic guidelines
e) Hospital pharmacy communication - Newsletter

5 Hospital pharmacy services

a) Procurement & warehousing of drugs and Pharmaceuticals
b) Inventory control
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
c) Drug distribution in the hospital
i) Individual prescription method
ii) Floor stock method
iii) Unit dose drug distribution method
d) Distribution of Narcotic and other controlled substances
e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

a) Sterile formulations – large and small volume parenterals
b) Manufacture of Ointments, Liquids, and creams
c) Manufacturing of Tablets, granules, capsules, and powders
d) Total parenteral nutrition

7 Continuing professional development programs
Education and training

8 Radio Pharmaceuticals – Handling and packaging

9 Professional Relations and practices of hospital pharmacist

4. 8. HOSPITAL PHARMACY (PPD19CL408) (PRACTICAL)

Title of the Experiments:

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15

Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.3. CLINICAL PHARMACY (PPD19CT403) (THEORY)

1. Scope and Objective: This course is designed to impart knowledge and skills on clinical pharmacy practice activities in a patient care setting like interpretation of lab results, monitor drug therapy of patients, obtain medication history interview and counsel the patients; identify and resolve drug related problems and provide drug information.

2. Course outcomes:

Upon completion of the subject, the student shall be able to:

CO1: Explain the concept of clinical pharmacy, and involve in clinical pharmacy activities including monitoring the drug therapy of patients through medication chart review and clinical review, obtaining medication history interview and promoting medication adherence in patients.

CO2: Apply knowledge and skills to interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states.

CO3: Interpret prescribed medication order to identify and resolve drug related problems, detect and assess adverse drug reactions, and to provide patient centered pharmaceutical care services.

CO4: Explain the drug information resources and steps involved in the provision of drug information services and apply the same in practice.

CO5: Retrieve, analyze, interpret and formulate drug or medical information.

CO6: Demonstrate communication skills in interacting effectively with the patients, prescribers and other healthcare professionals.

3. Course materials:

Text books (Theory)

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.

b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.

c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.

d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr. G. Parthasarathi etal, Orient Longman Pvt. Ltd. ISSBN8125026

References

a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.

b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

4. Detailed syllabus and lecture wise schedule:
Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
   a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
   b. Ward round participation
   c. Adverse drug reaction management
   d. Drug information and poisons information
   e. Medication history
   f. Patient counseling
   g. Drug utilization evaluation (DUE) and review (DUR)
   h. Quality assurance of clinical pharmacy services
3. **Patient data analysis**

   The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
   a. Hematological, Liver function, Renal function, thyroid function tests
   b. Tests associated with cardiac disorders
   c. Fluid and electrolyte balance
   d. Microbiological culture sensitivity tests
   e. Pulmonary Function Tests
5. **Drug & Poison information**
   a. Introduction to drug information resources available
   b. Systematic approach in answering DI queries
   c. Critical evaluation of drug information and literature
   d. Preparation of written and verbal reports
   e. Establishing a Drug Information Centre
   f. Poisons information- organization & information resources
6. **Pharmacovigilance**
   a. Scope, definition and aims of pharmacovigilance
   b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]

c. Reporting, evaluation, monitoring, preventing & management of ADRs
d. Role of pharmacist in management of ADR.

7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4. 9. CLINICAL PHARMACY (PPD19CL409) (PRACTICAL)

Title of the Experiments:

Students are expected to perform 15 practical experiments in the following areas covering the topics dealt in theory class.

a. Answering drug information questions (4 Nos)
b. Patient medication counselling (4 Nos)
c. Case studies related to laboratory investigations (4 Nos)
d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15
Major Experiment	10	25

Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.4. BIOSTATISTICS AND RESEARCH METHODOLOGY (PPD19CT404) (THEORY)

1. Course outcomes:

Upon completion of the subject, the student shall be able to:

CO1: Explain various study designs, settings, and databases that are useful in the evaluation of clinical interventions and effectively design and conduct human experiments.

CO2: Demonstrate an understanding of the fundamental concepts of biostatistics.

CO3: Identify the basis, concepts, determinant, incidence and prevalence of diseases in human populations.

CO4: Develop a hypothesis, select an appropriate study design, and collect, analyze and interpret data to test the hypothesis with appropriate statistical tests

CO5: Explain the methods of sampling and sample size determination and apply the same in designing of health research in a clinical setting

CO6: Explain the significance and applications of computers in the profession of Pharmacy

CO7: Demonstrate knowledge and skills on the functioning and application of statistical software in healthcare research

2. Course materials:

Reference books:

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. New York.

b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

c. Methods in Biostatistics for Medical Students & Research workers by B.K Mahajan;Jaypee;7th Edition

d. Fundamental of Statistics – Himalaya Publishing House- S. C. Guptha

e. Research Methodology – Methods and Techniques by C.R. Kothari.

3. Detailed syllabus and lecture wise schedule

1 **Research Methodology**

a) Types of clinical study designs:
Case studies, observational studies, interventional studies,

b) Designing the methodology

c) Sample size determination and Power of a study

Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study

d) Report writing and presentation of data

2 **Biostatistics**

2.1 a) Introduction

b) Types of data distribution

c) Measures describing the central tendency distributions- average, median, mode

d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 **Data graphics**

Construction and labeling of graphs, histogram, pie charts, scatter plots, semi logarthimic plots

2.3 **Basics of testing hypothesis**

a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.

b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)

c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)

d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient.

e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 **Statistical methods in epidemiology**

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy Computerizing the
Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy
Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval

4.5. BIOPHARMACEUTICS AND PHARMACOKINETICS (PPD19CT405) (THEORY)

1. Course outcomes:

Upon completion of the subject, the student shall be able to:

CO1: Explain the principle involved in ADME of drugs and list various factors influencing the ADME process

CO2: Describe the various pharmacokinetic and pharmacodynamic parameters

CO3: Explain the pharmacokinetic considerations of potent drugs.

CO4: Discuss about the various compartment modeling of drugs

CO5: Explain non-linearity of drugs

CO6: Explain the Non-compartmental analysis of drugs

CO7: Construct and analyze plasma drug concentration/time profile curve for the given data

CO8: Apply the various regulations related to developing BA -BE study protocol for the new drug molecule.

CO9: Optimize the dosage regimen for individual patients on the basis of pharmacokinetic principles.

CO10: Determine the bioavailability of drugs based on the clinical data.

2. Course materials:

References:

a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi

b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.

c. Pharmacokinetics: By Milo Gibaldi Donald, R. Marcel Dekker Inc.

d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.

e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari

f. Biopharmaceutics; By Swarbrick

g. Biopharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi

h. Clinical cal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozer, Lea and Febiger, Philadelphia, 1995.

i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.

j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari, Marcel Dekker Inn, New York and Basel, 1987.

k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

3. Detailed syllabus and lecture wise schedule: Topics

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
   a. Absorption of drugs from gastrointestinal tract.
   b. Drug Distribution.
   c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
   a. Mathematical model
   b. Drug levels in blood.
   c. Pharmacokinetic model
   d. Compartment models
   e. Pharmacokinetic study.
3. One compartment open model.
   a. Intravenous Injection (Bolus)
   b. Intravenous infusion.
4. Multicompartment models.
   a. Two compartment open model.
   b. IV bolus, IV infusion and oral administration
5. Multiple – Dosage Regimens.
   a. Repetitive Intravenous injections – One Compartment Open Model
   b. Repetitive Extravascular dosing – One Compartment Open model c. Multiple Dose Regimen – Two Compartment Open Model
6. Nonlinear Pharmacokinetics.
   a. Introduction
   b. Factors causing Non-linearity.
   c. Michaelis-menton method of estimating parameters.
7. Noncompartmental Pharmacokinetics.
   a. Statistical Moment Theory.
   b. MRT for various compartment models.
   c. Physiological Pharmacokinetic model.
8. Bioavailability and Bioequivalence.
   a. Introduction.
   b. Bioavailability study protocol.
   c. Methods of Assessment of Bioavailability

4.10. BIOPHARMACEUTICS AND PHARMACOKINETICS (PPD19CL410) (PRACTICAL)

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of Ka, Ke, $t_1/2$, Cmax, AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxozole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

Scheme of Practical Examination:

	Sessionals	**End Year Examination**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.6. CLINICAL TOXICOLOGY (PPD19CT406) (THEORY)

1. Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Explain the general principles involved in the management of poisoning.

CO2: List out the antidotes for various toxic substances.

CO3: Discuss the various methods of gut decontamination.

CO4: Describe the elimination enhancement techniques for different poisons.

CO5: Explain the principles involved in toxicokinetics

CO6: Differentiate various symptoms and management for acute and chronic poisoning.

CO7: List the differences between venomous and non-venomous snakes, their species and their toxins and cite examples for venomous and non-venomous snakes.

CO8: Explain the complications and management of venomous snakebite.

CO9: Discuss the envenomation techniques of stings and arthropod bites.

CO10: List the substances with abuse potential and explain the manifestations and management of substances of abuse.

CO11: Apply the general toxicology principles and treatment guidelines for specific toxic substances in history, assessment, and therapy considerations associated with the management of a toxic exposure.

2. Course materials:

References:

a. Matthew J Ellenhorn. Ellen Horns Medical Toxicology – Diagnosis and Treatment of Poisoning. Second edition. Williams and Willkins publication, London.

b. V V Pillay. Handbook of Forensic Medicine and Toxicology. Thirteenth edition 2003 Paras Publication, Hyderabad

3. Detailed syllabus and lecture wise schedule: Topics

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
    a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
    b) Opiates overdose.
    c) Antidepressants
    d) Barbiturates and benzodiazepines.
    e) Alcohol: ethanol, methanol.
    f) Paracetamol and salicylates.

g) Non-steroidal anti-inflammatory drugs.

h) Hydrocarbons: Petroleum products and PEG.

i) Caustics: inorganic acids and alkali.

j) Radiation poisoning

8. Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper

9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.

10. Plants poisoning. Mushrooms, Mycotoxins.

11. Food poisonings

12. Envenomation – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

a) CNS stimulants :amphetamine
b) Opioids
c) CNS depressants
d) Hallucinogens: LSD
e) Cannabis group
f) Tobacco

FIFTH YEAR
5.1. CLINICAL RESEARCH (PPD19CT501)
(THEORY)

1. Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Describe the principles involved in the new drug development process

CO2: Explain various phases involved in the clinical trials and the roles and responsibilities of a clinical trial personnel

CO3: Demonstrate knowledge on the good clinical practice and the regulatory requirements for the conduct of clinical trial.

CO4: Describe the ethical guidelines, the roles and responsibilities of an IRB/IEC.

CO5: Demonstrate knowledge and skills required for designing of clinical study documents.

CO6: Explain the significance of safety monitoring, reporting and data management in clinical trials.

CO7: Demonstrate skills for design, conduct, analysis and reporting of a clinical trial in a trial setting.

2. Course materials:

References :

a. Bert Spilker. Guide to Clinical Trials. 8. Sandy Weinberg. Guidebook For Drug Regulatory Submissions. A John Wiley & Sons, inc.,2009 .

b. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

c. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

d. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

e. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

f. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

g. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

h. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

3. Detailed syllabus and lecture wise schedule: Topics

1. Drug development process:

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organization (CDSCO) guidelines
6. Challenges in the implementation of guidelines

7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
    a. Sponsor
    b. Investigators
    c. Clinical research associate
    d. Auditors
    e. Contract research coordinators
    f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

5. 2. PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (PPD19CT502) (THEORY)

1. Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Define and explain the concept of pharmacoepidemiology, different pharmacoepidemiological study methods and their applications.

CO2: Demonstrate skills in the design, conduct and interpretation of Pharmacoepidemiological studies in a clinical or a community setting.

CO3: Explain the concepts of risk and measures of outcome and their applications in Pharmacoepidemiology.

CO4: Identify and determine relevant cost and consequences associated with pharmacy products and services.

CO5: Explain the Pharmacoeconomic decision analysis methods, its significance and applications.

CO6: Describe various Pharmacoeconomic methods and perform Pharmacoeconomic analysis in clinical study settings.

3. Course materials:

References :

a. Textbook of Pharmacoepidemiology, 2nd Edition by Brian L. Strom, Stephen E. Kimmel, Sean Hennessy. Wiley Blackwell Publications.

b. Pharmacoepidemiology And Therapeutic Risk Management, 1st Edition by Abraham G. Hartzema, Hugh H. Tilson, K. Arnold Chan. Harvey Whitney Books

c. Pharmacoepidemiology and Pharmacoeconomics Concepts and Practice by Prof. KG. Revikumar, Pharma Med Press

d. Essentials of Pharmacoeconomics by Karen L. Rascati, Wolters Kluwer India Pvt. Ltd.; First edition.

e. Pharmacoeconomics: From Theory to Practice, 1st Edition, by Renee J. G. Arnold. CRC Press

3. Detailed syllabus and lecture wise schedule: Topics

1. Pharmacoepidemiology :

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology
Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies
Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. Pharmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations
Role in formulary management decisions

Pharmacoeconomic evaluation
Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. **Applications of Pharmacoeconomics**
   Software and case studies

5. 3. CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY) (PPD19CT503)

1. Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Describe pharmacokinetic parameters and its application in drug dosing

CO2: Apply pharmacokinetic principles to analyze and interpret Drug Interactions in a clinical setting.

CO3: Calculate drug dosing for various populations such as pediatrics, geriatrics, pregnant women and in disease conditions.

CO4: Identify and resolve drug dose problems based on pharmacokinetic and pharmacodynamic considerations.

CO5: Explain the pharmacokinetic considerations and the significance of Therapeutic drug monitoring of potent drugs.

CO6: Demonstrate skills to design and implement pharmacokinetic services such as intravenous to Oral conversion of dosage regimens and therapeutic drug monitoring of potent drugs.

CO7: Explain the concept of population pharmacokinetics and apply the same in analysis of a clinical data.

CO8: Describe the impact of genetic polymorphism in pharmacokinetics and dynamics of drugs.

2. Course materials:

References:

a. Concepts in Clinical Pharmacokinetics By Joseph T. Dipiro. 5th Edition

b. Biopharmaceutics and Clinical Pharmacokinetics: An Introduction, Fourth Edition, by Robert T. Notari, Marcel Deckker.

c. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications by Malcolm Rowland, Thomas N. Tozer, Wolters Kluwer Health/Lippincott William & Wilkins

3. Detailed syllabus and lecture wise schedule: Topics

1. **Introduction to Clinical pharmacokinetics.**
2. **Design of dosage regimens:**

Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

3. Pharmacokinetics of Drug Interaction:

a. Pharmacokinetic drug interactions

b. Inhibition and Induction of Drug metabolism

c. Inhibition of Biliary Excretion.

4. Therapeutic Drug monitoring:

a. Introduction

b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).

c. Indications for TDM. Protocol for TDM.

d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.

e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

5. Dosage adjustment in Renal and hepatic Disease.

a. Renal impairment
b. Pharmacokinetic considerations
c. General approach for dosage adjustment in Renal disease.
d. Measurement of Glomerular Filtration rate and creatinine clearance.
e. Dosage adjustment for uremic patients.
f. Extracorporeal removal of drugs.
g. Effect of Hepatic disease on pharmacokinetics.

6. Population Pharmacokinetics.

a. Introduction to Bayesian Theory.
b. Adaptive method or Dosing with feedback.
c. Analysis of Population pharmacokinetic Data.

7. Pharmacogenetics

a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.

b. Genetic Polymorphism in Drug Transport and Drug Targets.

c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

5.4. CLERKSHIP (PPD19IN504)

In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon. Each student shall submit a log book of clerkship activities in a prescribed format, duly certified by the preceptor

and duly attested by the Head of the Department or Institution at the time of the University examination.

Continuous Internal Assessment (CIA):

CIA is conducted for 30 marks in the following format:
Log Book - 5 marks
Attendance - 5 marks
Synopsis – 10 marks
Presentation - 10 marks
(Students can be asked to make a presentation of their Clerkship activities which shall be evaluated by an internal examiner)

The University examination shall be conducted by an external and an internal examiner duly appointed by the University. The student shall be evaluated in the following format:
Synopsis – 20 marks

Oral presentation- 50 marks (Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed).

5.5. PROJECT WORK (PPD19RP505)

1. To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.

2. Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

3. Objectives of project work.— The main objectives of the project work is to—
   (i) Show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner
   (ii) Develop the students in data collection, analysis and reporting and interpretation skills.

4. Methodology.— To complete the project work following methodology shall be adopted, namely:—
   (i) Students shall work in groups of not less than *two* and not more than *four* under an authorized teacher
   (ii) Project topic shall be approved by the Head of the Department or Head of the Institution
   (iii) Project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilization reviews, Pharmacoepidemiology, Pharmacovigilance or Pharmacoeconomics
   (iv) Project work shall be approved by the institutional ethics committee
   (v) Student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work

(vi) Two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

5. Reporting.—

(1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorized teacher, Head of the Department as well as by the Head of the Institution

(2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorized teacher with font size 14.

(i) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

6. Evaluation.— The following methodology shall be adopted for evaluating the project work—

(i) Project work shall be evaluated by internal and external examiners.

(ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).

(iii) Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items: **Marks**

a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)

(v) Final evaluation of project work shall be done on the following items: **Marks**

a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

5.5. PROJECT WORK (PPD19RP505)
Title Page

TITLE

Project submitted to

Sri Ramachandra Institute of Higher Education and Research
(Deemed to be University)
Porur, Chennai – 600 116

in Partial Fulfillment of the requirement for the degree examination of

V year, Pharm. D. (Doctor of Pharmacy)

Submitted by

Name of the Candidates (in capitals) Registration Number

Faculty of Pharmacy
Sri Ramachandra Institute of Higher Education and Research
(Deemed to be University)
Porur, Chennai – 600 116

Under the guidance of

Guide Name in capitals with full details

Institutional guide Clinical guide

Month & Year

Bonafide Certificate page

Sri Ramachandra Institute of Higher Education and Research
(Deemed to be University)
Porur, Chennai – 600 116, INDIA

BONAFIDE CERTIFICATE

This is to certify that the Project work entitled "TITLE IN BOLD AND CAPITALS" is based on the bonafide work done by students' Name in capitals, (Registration No) V year, Pharm. D. (Doctor of Pharmacy) during the academic year……...

Date :
Place :

Principal
Faculty of Pharmacy
Sri Ramachandra
Institute of Higher Education and Research
(Deemed to be University)
Porur, Chennai – 600 116.

Certificate Page

CERTIFICATE

This is to certify that this Project work entitled “TITLE IN BOLD AND CAPITALS” is a bonafide work done by students’ Name in Capital, (Registration No), under our guidance and is being submitted for the Pharm. D. (Doctor of Pharmacy) V year University examination during the academic year ……...

Clinical Guide

Institutional Guide

Date :

Place :

Declaration Page

DECLARATION

We hereby declare that this Project work entitled "----------" (in capital and bold) submitted by us, in partial fulfillment of the requirements for the degree of Pharm. D. (Doctor of Pharmacy) V year, is the result of our original and independent research work carried out under the guidance of Institutional guide & Clinical Guide to Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai – 600 116, during the academic year …….

Date : Reg. No: Signature of the Candidates

Place :

Evaluated by :

Date of the Examination :

Signature of the Internal Examiner :

Signature of the Interdepartmental/Clinical Examiner :

Signature of the External Examiner :

Project Report Format

Project report should be presented under the following subtitles.

1. Content Page
2. Introduction
3. Literature Review
4. Aim and Objective
5. Methodology
6. Results
7. Discussion
8. Conclusion
9. References
10. Appendices

SIXTH YEAR

6.1. Internship

Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently. Every student has to undergo one year internship as per the regulations.

1) Specific Objectives:

i) To provide patient care in cooperation with patients, prescribers, and other members of an inter-professional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.

ii) To manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.

iii) To promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an inter-professional team of health care providers.

iv) To demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.

v) To develop leadership qualities to function effectively as a member of the health care team organized to deliver the health and family welfare services in existing socio-economic, political and cultural environment.

vi) To communicate effectively with patients and the community.

2) Other Details:

i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.

ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

iii) Every candidate shall be required, after passing the final Pharm. D. examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm. D. as the case may be.

Guidelines for Internship at any other Indian / Foreign Institution under Pharm. D. Regulations, 2008:

1. A candidate shall undergo internship or residency training for not more than 3 months under regulation 7 and 16 in some other hospital / super-specialty hospital/ Clinical setting in India or aboard (read with Regulation 2 (i) of Appendix-C of Pharm. D. Regulations, 2008 may be allowed)

2. The institution should have a Memorandum of Understanding or a Memorandum of Agreement with the other hospital / super-specialty hospital/ Clinical setting in India or aboard in which the candidates undergo internship or residency training for not more than 3 months.

3. The candidates with academic credentials from first to fifth year and a record of regular attendance will be considered eligible for exchange of internship. However the expenses towards travel, accommodation and internship fee (if any) are to be incurred by the candidate.

4. For the students who take internship abroad, the days of travel shall not be taken into consideration for attendance. It has to be extended by the students mandatorily.

The same guidelines are applicable for the students from other Indian or foreign Institutions opting to undergo internship in the host institution

Internship or residency training including postings in specialty units. Student should independently provide the clinical pharmacy services to the allotted wards as given below:

(i) Six months in General Medicine department (inclusive of Medical oncology, dispensing in Hospital pharmacy, Community Pharmacy, clinical research unit, drug information and pharmacovigilance centers)

(ii) Two months each in three other specialty departments

Department	**Total Duration**	
	No. of Days × hrs/day	**(hours/ year)**
General Medicine (Inclusive of 62 days of postings in General Medicine inpatient and outpatient units, 30 days of postings each in Medical Oncology Unit, Hospital Pharmacy division, Clinical Research Division and Community Pharmacy in Sri Ramachandra Rural Health and Training Center, Vayalanallur,	182 days **×** 5 hrs/day (8:00 am to 1:00 pm)	910

Tamil Nadu)		
Paediatrics	61 days × 5 hrs /day (8:00 am to 1:00 pm)	305
Obstetrics & Gynaecology	61days × 5 hrs /day (8:00 am to 1:00 pm)	305
General Surgery / Psychiatry / Dermatology / Orthopaedics	61 days × 5 hrs /day (8:00 am to 1:00 pm)	305
Drugs and Poison Information Center	61 days × 2hrs/day (2:00 to 4:00 pm)	122
Pharmacovigilance Center	61 days × 2hrs/day (2:00 to 4:00 pm)	122
Patient Counselling Center	60 days × 2hrs/day (2:00 to 4:00 pm)	120
Total Parenteral Nutrition Preparations	61 days × 2hrs/day (2:00 to 4:00 pm)	122
Antibiotic Auditing	61 days × 2hrs/day (2:00 to 4:00 pm)	122
Unit Dose Dispensing	61 days ×2 hrs/day (2:00 to 4:00 pm)	122
Total hours	**365 days × 7 hrs/day (8:00 to 4:00 pm)**	**2555**

3) Assessment of Internship:

i) Each intern shall maintain a record of activities in the log book in the prescribed format, which is to be verified and certified by the preceptor (teacher practitioner) under whom he works in each clinical department. Apart from scrutiny of the record of work, assessment and evaluation of training s hall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. At the end of the Internship each student should submit a log book of their internship activities in each department, duly signed by their concerned preceptors and duly attested by the Head of the Department or Institution to be qualified for certification of completion of the Internship.

Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.

ii) Satisfactory completion of internship shall be determined on the basis of the following:-

(1) Proficiency of knowledge required for each case management SCORE 0-5

(2) The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5

(3) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5

(4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE0-5

(5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

SRI RAMACHANDRA

INSTITUTE OF HIGHER EDUCATION AND RESEARCH

(Deemed to be University)

(Declared under Section 3 of the UGC Act, 1956)

Porur, Chennai - 600 116

REGULATIONS AND SYLLABUS
FOR
MASTER OF PHARMACY (M. Pharm) DEGREE PROGRAM

[Credit Based Semester System]

M. PHARM - PHARMACY PRACTICE
M. PHARM - PHARMACEUTICS
M. PHARM - PHARMACEUTICAL QUALITY ASSURANCE
M. PHARM – PHARMACOGNOSY
M. PHARM – PHARMACEUTICAL ANALYSIS
M. PHARM – PHARMACOLOGY
M. PHARM – PHARMACEUTICAL CHEMISTRY
M. PHARM – PHARMACEUTICAL REGULATORY AFFAIRS

(Effective from the Academic year 2019 – 2020)

TABLE 1: SUMMARY SCHEME FOR CREDIT BASED SEMESTER SYSTEM

Semester	Course Code	Pharmacy Practice	Pharmaceutics	Pharmaceutical Quality Assurance	Pharmacognosy	Pharmaceutical analysis	Pharmacology	Pharmaceutical Chemistry	Pharmaceutical Regulatory Affairs	Total Credits
I	Core Course (Theory)	MPP101T	MPH101T	MQA101T	MPG101T	MPA101T	MPL101T	MPC101T	MRA101T	**4**
		MPP102T	MPH102T	MQA102T	MPG102T	MPA102T	MPL102T	MPC102T	MRA102T	4
		MPP103T	MPH103T	MQA103T	MPG103T	MPA103T	MPL103T	MPC103T	MRA103T	4
		MPP104T	MPH104T	MQA104T	MPG104T	MPA104T	MPL104T	MPC104T	MRA104T	4
	Core Course (Practical)	MPP105P	MPH105P	MQA105P	MPG105P	MPA105P	MPL105P	MPC105P	MRA105P	6
	Seminar	MPP106S	MPH106S	MQA106S	MPG106S	MPA106S	MPL106S	MPC106S	MRA106S	4
	Total credits									**26**
II	Core Course (Theory)	MPP201T	MPH201T	MQA201T	MPG201T	MPA201T	MPL201T	MPC201T	MRA201T	**4**
		MPP202T	MPH202T	MQA202T	MPG202T	MPA202T	MPL202T	MPC202T	MRA202T	**4**
		MPP203T	MPH203T	MQA203T	MPG203T	MPA203T	MPL203T	MPC203T	MRA203T	**4**
		MPP204T	MPH204T	MQA204T	MPG204T	MPA204T	MPL204T	MPC204T	MRA204T	**4**
	Core Course (Practical)	MPP205P	MPH205P	MQA205P	MPG205P	MPA205P	MPL205P	MPC205P	MRA205P	6
	Seminar	MPP206S	MPH206S	MQA206S	MPG206S	MPA206S	MPL206S	MPC206S	MRA206S	4
	Total credits									**26**
III	Research Methodology and Biostatistics	MRM301T	MRM301T	MRM301T	MRM301T	MRM301T	MRM301T	MRM301T	MRM301T	4
	Journal Club - I	MJC302P	MJC302P	MJC302P	MJC302P	MJC302P	MJC302P	MJC302P	MJC302P	1
	Dissertation Proposal – Oral Presentation	MPP303P	MPP303P	MPP303P	MPP303P	MPP303P	MPP303P	MPP303P	MPP303P	2
	Dissertation-Orientation Report	MRP304P	MRP304P	MRP304P	MRP304P	MRP304P	MRP304P	MRP304P	MRP304P	15
	Total credits									**22**
IV	Journal club - II	MJC401P	MJC401P	MJC401P	MJC401P	MJC401P	MJC401P	MJC401P	MJC401P	1
	Dissertation and Viva voce	MRP402P	MRP402P	MRP402P	MRP402P	MRP402P	MRP402P	MRP402P	MRP402P	3
	Research Colloquium	MRP403P	MRP403P	MRP403P	MRP403P	MRP403P	MRP403P	MRP403P	MRP403P	17
	Total Credits									**21**
Co-curricular Activities (Attending conference, scientific presentations and other scholarly activities) (Common for all specializations)										5
GRAND TOTAL CREDIT POINTS (* Minimum; ** Maximum)										**95 * 100 ****

REGULATIONS FOR MASTER OF PHARMACY DEGREE PROGRAM

INTRODUCTION

The Master of Pharmacy degree course is a 2-year postgraduate program in pharmacy for students with a Bachelors degree in Pharmacy. This program covers relevant topics and a research project in the area of specialization. The aim of this postgraduate program is to provide a thorough training in a particularsubject area through formal lectures and / or seminar programs. The research project provides training in a particular area through original exploration and experiment culminating in the preparation of the project report. This programwill impart advanced theoretical and practical aspects of subjects previously studied at the undergraduate level.

In exercise of the powers conferred by rule 12.1 (iv) of Memorandum of Association & Rules and clause 21 of Bye-laws of Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai-600116, the Academic Council of the University hereby makes the following regulations:

1. SHORT TITLE AND COMMENCEMENT

These regulations may be called "THE REGULATIONS AND SYLLABUS FOR THE MASTER OF PHARMACY (M.Pharm) DEGREE PROGRAM (CBSS) OF SRI RAMACHANDRA INSTITUTE OF HIGHER EDUCATION AND RESEARCH (Deemed to be University),PORUR, CHENNAI - 600116", as per the regulations of Pharmacy Council of India (PCI), New Delhi.

These regulations shall be deemed to have come into force from the academic year 2019-20. These regulations are subject to such modifications as may be approved by the Academic Council from time to time.

2. ELIGIBILITY FOR ADMISSION

(a) A candidate who seeks admission to Master of Pharmacy degree course should have passed B. Pharm degree awarded by any recognized University and approved by Pharmacy Council of India and has scored not less than 55 % (incase of SC/ST/OBC 50 % aggregate marks) of the maximum marks (aggregate of 4 years of B. Pharm.)

(b) Every student, for admission to M. Pharm program should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled and he/she will not be permitted to undergo the M. Pharm course.

2.1. Age Limit for Admission

A candidate should have completed the age of 21 years as on 31st December of the year of admission.

2. 2. Medical Fitness Certificate

A candidate shall at the time of admission submit to the Head of the Institution, Certificate of Medical fitness from an authorized Medical Officer certifying that the candidate is physically fit to undergo the academic course.

2. 3. Eligibility Certificate

Candidates, who have qualified for the Bachelor of Pharmacy Degree from any University other than Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), shall obtain Eligibility certificate from the University at the time of admission and remit recognition fee as prescribed.

2. 4. Registration

A candidate admitted to the Course shall register his/her name with the University by submitting the prescribed application form for registration, duly filled in along with the prescribed fee, through the Head of the Institution within the stipulated time.

3. DURATION OF THE PROGRAM

The program of study for M. Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be based on those notified by Pharmacy Council of India, New Delhi, from time to time.

4. COMMENCEMENT OF PROGRAM

The first year of the course will normally start from 1st July of every year.

i. Odd Semester – 1, 3	July – December
ii. Even Semester – 2, 4	January – June

5. CUT- OFF DATES FOR ADMISSION TO THE EXAMINATION

The candidates admitted from 1st July to 31st August of the year shall be registered to take their first semester examination, after fulfillment of other regulations concerned, in the month of December of that year.

6. COMMENCEMENT OF EXAMINATIONS

There shall be two sessions of University examinations in an academic year, viz., June (End of even semesters) and December (End of odd semesters)

7. MEDIUM OF INSTRUCTION

The medium of instruction and examination for all subjects shall be in English.

8. WORKING DAYS IN A SEMESTER

Each semester shall consist of not less than 100 working days and each academic year shall have a total of 200 working days.

9. PROGRAM COMMITTEE

1. The M. Pharm. program shall have a Program Committee constituted by the Head of the institution in

consultation with all the Heads of the departments to monitor the conduct of the program and syllabus content.

2. The composition of the Programme Committee shall be as follows:

A teacher at the cadre of Professor shall be the Chairperson; One teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

10. CURRICULUM & CREDITS

The curriculum and the syllabus for the program shall be based on those notified by the Pharmacy Council of India, New Delhi, from time to time and approved by the Academic Council of this University, on the recommendations of Board of Studies.

Structure of Curriculum

For PG Program, each course will be provided a structured syllabus in the following style:

Category	Credits	Syllabus units
Core Theory	4	5
Core Lab	6	10- 15 experiments
Core Projects	19	-

The program will be conducted on a credit based semester pattern as described below:

10. 1. Program / Course Credit Structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra- curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

10. 2. Credits

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory)/ tutorial hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having twelve laboratory hours per week throughout semester carries a credit of 6.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, discussions/proposal presentations with the supervisor shall be considered as theory course and multiplied by 1.

10. 3. Minimum credit requirements

The minimum credit points required for the award of **M. Pharm. degree is 95.** However, based on the credit points earned by the students under the head of co-curricular activities (as explained in Table 3), a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Project work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 2. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

TABLE – 2: SEMESTER WISE CREDITS DISTRIBUTION

Semester	Credits

I	26
II	26
III	22
IV	21
Co-curricular Activities $^{\beta}$ (Attending conference, scientific presentations and other scholarly activities)	5 $^{\beta}$
Total Credit Points	Minimum =95 Maximum =100

$^{\beta}$ Credit Points for Co-curricular Activities

(Out of 7 credits for Co-curricular Activities, 2 credit points assigned as minimum requirement are added as one credit each in the third and the fourth semesters).

TABLE – 3: GUIDELINES FOR AWARDING CREDIT POINTS FOR CO-CURRICULAR ACTIVITIES

Name of the Activity	**Maximum Credit Points Eligible / Activity $^{\beta}$**
Participation in National Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student)	01
Participation in International Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/ National Agencies	01
Academic Award/ Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02
Note: International Conference: Held Outside India	

International Journal: The Editorial Board outside India

$^{\beta}$ The credit points assigned for extracurricular and or co-curricular activities shall be evaluated during 3 and 4 semester project evaluations and the same shall be submitted to the University along with the assessments of project/ colloquim/ journal club.

11. GRADING SYSTEM

11. 1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table 4

TABLE – 4: LETTER GRADES AND GRADE POINTS EQUIVALENT TO PERCENTAGE OF MARKS AND PERFORMANCES

Percentage of Marks Obtained	Grade Letter	Grade Point (Gi)	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of 'AB' and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

11. 2. The Semester Grade Point Average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester.

11. 3. Computation of SGPA and CGPA

i. The SGPA is the ratio of sum of the product of the number of credits with the grade points scored by a student in all the courses taken by a student and the sum of the number of credits of all the courses undergone by a student, *i.e*.,

SGPA (Si) =∑(CixGi) /∑Ci

Where, Ci is the number of credits of the ith course and Gi is the grade point scored by the student in the ith course (as shown in Table 4 & 5).

ii. The CGPA is also calculated in the same manner considering all the courses undergone by a student over all the semesters of a programme, *i.e*.,

CGPA = ∑(Ci x Si) / ∑ Ci

where Si is the SGPA of the ith semester and Ci is the total number of credits in that semester (as shown in Table 6).

iii. The SGPA and CGPA shall be rounded off to 2 decimal points and reported in the transcripts.

Illustration of Computation of SGPA and CGPA and Format for Transcripts

i. Computation of SGPA
ii. Computation of CGPA

TABLE-5: ILLUSTRATION OF GRADE AND GRADE POINT

Master in Pharmacy (Pharmacy Practice) Semester - I					
Category	**Course title**	**Credit Points (Ci)**	**Grade Letter**	**Grade Point (Gi)**	**Credit Point (Ci x Gi)**
MPP101T	Clinical Pharmacy Practice	4	A	9	4 x 9 = 36
MPP102T	Pharmacotherapeutics-I	4	O	10	4 x 10 = 40
MPP103T	Hospital & Community Pharmacy	4	B	8	4 x 8 = 32
MPP104T	Clinical Research	4	C	7	4 x 7 = 28
MPP105P	Pharmacy Practice Practical I	6	D	6	6 x 6 = 36
-	Seminar	4	A	9	7 x 9=63
	Total	**26**			**235**
Thus, SGPA = 235/26 = 9.04 (Si)					

The SGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.

TABLE- 6: ILLUSTRATION OF COMPUTATION OF SGPA AND CGPA AND FORMAT FOR TRANSCRIPTS

Semester 1	**Semester 2**	**Semester 3**	**Semester 4**
Credit: 26 SGPA: 9.34	Credit: 26 SGPA: 9.25	Credit: 22 SGPA: 9.01	Credit: 21 SGPA: 9.05
CGPA = $\frac{26 \times 9.74 + 26 \times 9.25 + 22 \times 9..21 + 21 \times 9.05}{95}$ **=** 9.17			

12. EXAMINATIONS / ASSESSMENTS

i. For all category of Core Theory courses offered, the assessment will comprise of Internal Assessments (IA) and the End Semester University examination (ES). For each course the total of 100 % per course is determined from the IA evaluation weighted at 25 % and the ES weighted at 75 %.

ii. For the category of Core Lab – Practical courses offered, the assessment will comprise of Internal Assessments (IA) and the End Semester University examination (ES) weighted at 33 % and 67 % for each course.

iii. For the category of Non-University examination courses (*) offered, the continuous internal assessment weighted at 100 % shall be conducted internally by the subject experts at the college level. The course Research Methodology & Biostatistics shall have 25 % as CIA and 75% for final qualifying exam evaluated by college level experts.

iv. A candidate failed in any course in the University examination will be provided an opportunity to improve his/her internal marks (theory or practical only) which will be called “Improvement I.A. Examinations”.

v. If a failed candidate does not appear for such "Improvement I.A. Examinations" for internal marks in the failed course(s), the internal marks (both theory, practical) already secured by him/her shall be carried over for his/her subsequent appearance(s) in the University examinations.

vi. IA Marks shall be submitted to the University for each Course separately by the Head of the department/ program co-ordinator 15 days prior to the commencement of the University examinations, through the Principal.

12. 1. Internal assessment

I. Evaluation for a course shall be done on a continuous basis. The uniform procedures to be adopted under the Credit based semester system (CBSS) are to conduct at least two internal assessments followed by Universityexamination for each course.

II. A regular record of attendance in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation sh all be maintained by the department / teaching staff of respective courses.

Internal assessment is the sum of Sessional exams (15 marks for theory and 30 marks for Practical) and continuous mode of assessment (10 marks for theory and 20 marks for Practical). Two sessional exams shall be conducted for each theory for 30 marks, a model exam for each theory for 75 marks and one sessional exam for practical course for 60 marks as per the schedule fixed by the college (s). The scheme of question paper for theory and practical sessional examinations is given below. The average marks of two sessional exams for theory converted to 15 marks and practical converted to 30 marks shall be computed for internal assessment as per the requirements.

PATTERN OF QUESTION PAPER - INTERNALSESSIONAL EXAMINATION

(For courses subjected to End Semester University and Non-University Examination)

Theory		**Duration: 1hour & 30min**
Essays	(1 x 15)	15 marks
Short notes (300 words)	(3 x 5)	15 marks
Total		**30 marks**
Practical		**Duration: 3 hours**
Synopsis		10 marks
Major Experiment		25 marks
Minor Experiment		15 marks
Viva		10 marks
Total		**60 marks**

PATTERN OF QUESTION PAPER – FINAL QUALIFYING EXAMINATION

(For courses subjected to Non-University examination *)

Theory		**Duration: 3 hours**
Essays	(3 x 15)	45 marks
Short notes (300 words)	(6 x 5)	30 marks
Total		**75 marks**

The internal assessment marks (theory, practical, Seminar, Journal club, Project proposal presentation, Orientation and Project report submission) should be submitted to the Controller of Examinations of the University with endorsement of the Head of the Department, 15 days prior to the commencement of the end semester theory examination.

12. 2. Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given in Tables 7&8.

TABLE – 7: SCHEME FOR AWARDING INTERNAL ASSESSMENT CONTINUOUS MODE

Theory	
Criteria	**Maximum**
Attendance (Refer Table 8)	8
Student -Teacher interaction	2
Total	**10**
Practical	
Attendance (Refer Table 8)	10
Based on Practical Records/ Regular Viva Voce. etc	10
Total	**20**

TABLE – 8: GUIDELINES FOR THE ALLOTMENT OF MARKS FOR ATTENDANCE

Theory		**Practical**	
Percentage of Attendance	**Marks**	**Percentage of Attendance**	**Marks**
99 -100	8	100	10
96 -98	7	99	9
93 -95	6	98	8
90 -92	5	95-97	7
87 -89	4	92-94	6
84 -86	3	89-91	5
81 -83	2	86-88	4
80	1	83-85	3
Less than 80	0	80-82	2
		Less than 80	0

12. 3. Eligibility for Admission to Examinations

I. Only those candidates having ≥ 80 % attendance and obtaining 50 % in the internal assessments for each of the courses [theory and/ or practical, non-University examination courses; research projects; seminars etc.] are eligible to appear for the University examinations.

12. 3.1. Attendance Requirements

a) No candidate shall be permitted to appear for the University examinations, unless he/she attends the program for the prescribed period and produces the necessary certificate of attendance and progress and a satisfactory conduct from the Head of the Institution.

b) Every candidate is required to put in a minimum of 80 % of attendance in theory and practical course in the semester concerned to become eligible to appear for admission to the University examination.

c) A candidate lacking the prescribed attendance in any course shall not be allowed to appear for University examination in that course only.

12. 3. 2. Internal Examination related requirements (IA for all theory and Practical courses)

a) For theory and practical component, a candidate should obtain a minimum of 50% marks in IA theory and practical each to be eligible to appear for University examination of each course in a semester.

b) **Improvement of Internal Assessment**

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

13. END SEMESTER UNIVERSITY EXAMINATIONS

The End Semester University Examinations for each theory and practical course through semesters I to IV (as shown in tables 11 to 18) shall be conducted by the University except for the subject with asterix symbol (*) in Table 19 for which examinations shall be conducted internally by two subject experts at the University level and the marks/grades shall be submitted to the university.

13. 1. Assessments in Examinations:

i. The process of assessment in examinations for all the theory and practical courses offered in Semesters I & II, Dissertation examinations at the end of Semester IV shall be undertaken by internal and external who will be appointed by the Controller of Examinations based on the panel of examiners provided by the respective department heads / BoS.

PATTERN OF QUESTION PAPER - END SEMESTER EXAMINATION

Theory		**Duration: 3 hours**
Essays	(3 x 15)	45 marks
Short notes (300 words)	(6 x 5)	30 marks
Total		**75 marks**
Practical		**Duration: 6 hours**
Synopsis		15 marks
Major Experiment		30 marks
Minor Experiment -I		20 marks
Minor Experiment -II		20 marks
Viva		15 marks
Total		**100 marks**

14. 0. ORIENTATION & DISSERTATION

14. 1. Orientation

The first part of the Dissertation is the Orientation.Each candidate will be assigned a recognized guide at the beginning of third semester in the college of Pharmacy.

All candidates registered for the M. Pharm Program shall submit a orientation report at the end of third semester.

The students shall carry out their work either in college/Industry/hospital and shall submit soft copy of the report, to the HOD through their guides and the same shall be evaluated internally in the college. The report should not exceed 25 pages (Times New Roman, font size 12, 1.5 line spacing) evaluated for a total of 400 marks with the details as follows.

a) Students pursuing their orientation/dissertation in the industry/hospital shall be monitored and evaluatedby the both institutional and industrial/clinical guide for 50 marks for CIA as Proposal presentation and 350 marks for Non-University end semester examination, evaluated by two internal examiners (as shown in Table 9) and hence for a total of 400 marks.

The candidate is declared to be Pass if he/she secures 50 % marksfor each of the components [viz., Dissertation Proposal – Oral Presentation and for Dissertation-Orientation Report].The orientation end semester exam shall be conducted in the month of November (preferably last week) by two internal examiners and the marks secured shall be sent to the controller of examination of this University before the commencement of University examinations.

TABLE – 9: GUIDELINES FOR THE ALLOTMENT OF MARKS FOR ORIENTATION

Proposal Presentation (CIA)	50 marks
Introduction	50 marks
Review of literature	100 marks
Objective and scope	50 marks
Plan of work (Inclusive of Timeline)	100 marks
Defence	50 marks
Total	**400 marks**

14. 2. Dissertation

(a) All candidates registered for the M.Pharm Program shall submit a dissertation at the end of fourth semester individually.

(b) Each candidate will be assigned a recognized guide at the beginning of third semester.

(c) The topic assigned to the candidate will be intimated to the HoD for registration of topic at the end of third semester. The same shall be sent to the Controller of Examination of this University.

(d) Candidate may be permitted to obtain approval by the appropriate ethics if necessary (medical and animal) committees by the end of the third semester.

(e) The dissertation work will be individual dissertation and will consist of experimental work, data collection and interpretation and in-silico analysis (wherever applicable).

(f) The dissertation work shall be submitted for evaluation on the date announced in a hard-bound volume not exceeding 75 pages (Times New Roman, font size 12, 1.5 line spacing and on both side of A4 size paper) excluding references.

(g) Four copies of the dissertation work shall be submitted one month prior to the commencement of the University examination and forwarded to the Controller of Examination of the University.

14.2. 1. Continuous and Summative assessments for Dissertations:

a) The dissertation / core project will be taken up by each student during the fourth semester of their course work.

b) The head of the department/ interdepartmental examiner may evaluate the performance of the candidate for the formative assessment marks (75). Oral presentation along with a laboratory notebook/ logbook practical observation notebook maintained by the student and endorsed by the guide will be evaluated during the continuous assessments. The objective is to encourage students to maintain and learn how to record independently planned exercises – an international requirement. The **passing minimum of 50 % is essential for appearing for End Semester University examinations.**

c) The marks allotted for the Research Colloquiumis 400 in the university examination. It shall be evaluated by two examiners (400 each) under the following scheme –

TABLE – 10: GUIDELINES FOR THE ALLOTMENT OF MARKS FOR UNIVERSITY EXAMINATION

Introduction, Review of literature and Methodology	100 marks
Objective and scope	50 marks
Results and discussion	150 marks
Conclusion and Outcomes (including oral presentation)	50 marks
Viva-voce	50 marks
Total	**400 marks**

This evaluation would reflect the quality of work put into the dissertation by the student.

d) One external and one internal appointed by the University shall evaluate the project report before the defence and viva-voce examinations for specializations other than Pharmacy Practice.

e) For Pharmacy Practice Specialisation, One external, one internal and an interdepartmental (clinical) examiner appointed by the University shall evaluate the project report before the defence and viva-voce examinations.

15. CRITERIA FOR PASSING

15. 1. Marks qualifying for a Pass for M.Pharm Program

A candidate shall be declared to have passed the examination if he/she obtains the following minimum qualifying grade / marks:-

(a) Grade D (50 % of marks) in the University End Semester Examination Theory, Practical, and Dissertation (ESE)

(b) Grade D (50 %) aggregate in each course which includes both Continuous Internal Assessment and End Semester Examinations.

15. 2. Reappearance for arrear subjects:

- In case a student fails to secure the minimum 50% in any Theory or Practical course (s), then he/she shall reappear for the end semester examination of that course only.

- However, his/her marks of the Internal Assessment shall be carried over and he/she will be entitled for grade obtained by him/her on passing, subject to provisions under 12.0 (iv& v)

15. 3. Carry-over of courses

A student will be eligible to carry forward all the failed courses (including Grade AB) of I and II semesters till the III semester examinations but he/she will not be eligible to appear for the University examinations of IV semester until all the courses of I, II and III semesters are successfully completed. However, the student may be permitted to attend and complete the course requirements **ONLY,** for courses in the IV semester.

On successful completion of all courses until third semester such candidates are eligible to appear for the end semester examinations of the IV semester.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters as per the norms of the University.

16. END SEMESTER SUPPLEMENTARY EXAMINATIONS

End semester supplementary examinations shall be conducted as per the schedule given in Table 11. The exact dates of examinations shall be notified from time to time.

TABLE – 11: TENTATIVE SCHEDULE OF END SEMESTER SUPPLEMENTARY EXAMINATIONS

Semester	Regular exams	Supplementary exams
I and III	December	June
II and IV	June	December

17. CLASSIFICATION OF SUCCESSFUL CANDIDATES

The class shall be awarded based on CGPA as follows:

≥ 7.50	First Class with Distinction	First attempt only
6.00 to 7.49	First Class	Class will be awarded only when the course is completed within the stipulated period. All others would be declared as 'P**ass'**
5.00 to 5.99	Second Class	

All assessments of M. Pharm program on an absolute mark basis will be considered and passed by the respective results passing Boards in accordance with the rules of the University. Thereafter the Controller of Examinations shall convert the marks for each course to the corresponding letter grade as mentioned in Table 4, compute the grade point average and cumulative grade point average, and prepare the grade and mark sheets. On satisfactory completion of the courses, a candidate earns the prescribed credits.

18. AWARD OF RANKS

Ranks and medals shall be awarded based on final CGPA for candidates who pass in the first attempt and the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of ranks. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks.

19. AWARD OF DEGREE

The University will award the degree after a candidate successfully completes the required University examinations (all semesters).

20. DURATION FOR COMPLETION OF THE PROGRAM OF STUDY / DISCHARGE FROM PROGRAM

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students should pass within the said period, otherwise they should seek fresh Registration.

21. RE-EVALUATION / RETOTALING OF ANSWER PAPERS

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

22. RE-ADMISSION AFTER BREAK OF STUDY

A candidate having a break of study shall be re-admitted after satisfactory fulfillment of the regulations of the University at the commencement of an academic year only and shall undergo the full duration of the Program. No exemption for the period of study already undergone or for the examination already passed shall be granted. The candidate will be required to appear for all the examinations as prescribed in the regulations and syllabus in vogue at the time of readmission.

A candidate having a break of study of four years and above from the date of admission and more than two spells of break will not be considered for re-admission.The four years' period of break of study shall be calculated from the date of first admission of the candidate to the course inclusive of all the subsequent spells of break of studies.

23. SCHEME OF CURRICULUM AND EVALUATION

The specializations in M.Pharm program and their codes are given in Table 12.

TABLE- 12: LIST OF M. PHARM SPECIALIZATIONS AND THEIR CODE

S. No	**Specialization**	**Code**
1.	Pharmacy Practice	MPP
2.	Pharmaceutics	MPH
3.	Pharmaceutical Quality Assurance	MQA
4.	Pharmacognosy	MPG
5.	Pharmaceutical Analysis	MPA
6.	Pharmacology	MPL
7.	Pharmaceutical Chemistry	MPC
8.	Pharmaceutical Regulatory Affairs	MRA

The course of study for M. Pharm specializations shall include semester wise theory and practical. The scheme of curriculum and evaluation of the programfor semesters I and II for all specializations are given in tables 13 to 20. The schemes for internal assessment for semesters III and IV are given in Tables 21 and 22 respectively.The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Tables 13 to 22.

23. 1. M.PHARM – PHARMACY PRACTICE (YEAR - 1)
TABLE 13: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Credits (hours) / Week			Credits (C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) – Theory / Practical (a)	End Semester Assessment		Grand Total
				Lecture (L)	Tutorial (T) / Clinical	Practical (P) / Research		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 150
Year 1 – Semester- I, 2019																
1	MPP101T	CT	Clinical Pharmacy Practice	4	0	0	4	60	0	0	60	80	25	75	0	100
2	MPP102T	CT	Pharmacotherapeutics - I	4	0	0	4	60	0	0	60	80	25	75	0	100
3	MPP103T	CT	Hospital &Community Pharmacy	4	0	0	4	60	0	0	60	80	25	75	0	100
4	MPP104T	CT	Clinical Research	4	0	0	4	60	0	0	60	80	25	75	0	100
5	MPP105P	CL	Pharmacy Practice Practical I	0	0	12	6	0	0	180	180	80	50	0	100	150
6	MPP106S	CT	Seminar – I [#]	0	7	0	4	0	105	0	105	80	100[#]	0	0	100
Year 1 – Semester- I			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**--**	**250**	**300**	**100**	**650**
Year 1 – Semester- II, 2019																
7	MPP201T	CT	Principles of Quality Use of Medicines	4	0	0	4	60	0	0	60	80	25	75	0	100
8	MPP202T	CT	Pharmacotherapeutics - II	4	0	0	4	60	0	0	60	80	25	75	0	100
9	MPP203T	CT	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	0	0	4	60	0	0	60	80	25	75	0	100
10	MPP204T	CT	Pharmacoepidemiology&Pharmacoeconomics	4	0	0	4	60	0	0	60	80	25	75	0	100
11	MPP205P	CL	Pharmacy Practice Practical II	0	0	12	6	0	0	180	180	80	50	0	100	150
12	MPP206S	CT	Seminar – II [#]	0	7	0	4	0	105	0	105	80	100[#]	0	0	100
Year 1 – Semester- II			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**		**250**	**300**	**100**	**650**

[#] Continuous Internal Assessment (Average of the seminar marks of four subjects in the semester)

23. 2. M.PHARM – PHARMACEUTICS (YEAR - 1)
TABLE 14: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Credits (hours) / Week			Credits (C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) – Theory / Practical (a)	End Semester Assessment		Grand Total
				Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 150
Year 1 – Semester- I, 2019																
1	MPH101T	CT	Modern Pharmaceutical Analytical techniques	4	0	0	4	60	0	0	60	80	25	75	0	100
2	MPH102T	CT	Drug Delivery Systems	4	0	0	4	60	0	0	60	80	25	75	0	100
3	MPH103T	CT	Modern Pharmaceutics	4	0	0	4	60	0	0	60	80	25	75	0	100
4	MPH104T	CT	Regulatory Affairs	4	0	0	4	60	0	0	60	80	25	75	0	100
5	MPH105P	CL	Pharmaceutics Practical I	0	0	12	6	0	0	180	180	80	50	0	100	150
6	MPH106S	CT	Seminar –I [#]	0	7	0	4	0	105	0	105	80	100[#]	0	0	100
Year 1 – Semester- I			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**
Year 1 – Semester- II, 2019																
7	MPH201T	CT	Molecular Pharmaceutics (Nano Technology and Targeted Drug Delivery Systems)	4	0	0	4	60	0	0	60	80	25	75	0	100
8	MPH202T	CT	Advanced Biopharmaceutics & Pharmacokinetics	4	0	0	4	60	0	0	60	80	25	75	0	100
9	MPH203T	CT	Computer Aided Drug Development	4	0	0	4	60	0	0	60	80	25	75	0	100
10	MPH204T	CT	Cosmetic s and Cosmeceuticals	4	0	0	4	60	0	0	60	80	25	75	0	100
11	MPH205P	CT	Pharmaceutics Practical II	0	0	12	6	60	0	0	60	80	50	0	100	150
12	MPH206S	CT	Seminar – II [#]	0	7	0	4	0	105	0	105	80	100[#]	0	0	100
Year 1 – Semester- II			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**

[#]Continuous Internal Assessment (Average of the seminar marks of four subjects in the semester)

23. 3. M.PHARM – PHARMACEUTICAL QUALITY ASSURANCE (YEAR - 1)
TABLE 15: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Credits (hours) / Week			Credits (C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) – Theory / Practical (a)	End Semester Assessment		Grand Total
				Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 150
Year 1 – Semester- I, 2019																
1	MQA101T	CT	Modern Pharmaceutical Analytical Techniques	4	0	0	4	60	0	0	60	80	25	75	0	100
2	MQA102T	CT	Quality Management Systems	4	0	0	4	60	0	0	60	80	25	75	0	100
3	MQA103T	CT	Quality Control and Quality Assurance	4	0	0	4	60	0	0	60	80	25	75	0	100
4	MQA104T	CT	Product Development and Technology Transfer	4	0	0	4	60	0	0	60	80	25	75	0	100
5	MQA105P	CL	Pharmaceutical Quality Assurance Practical I	0	0	12	6	0	0	180	180	80	50	0	100	150
6	MQA106S	CT	Seminar – I #	0	7	0	4	0	105	0	105	80	100#	0	0	100
Year 1 – Semester- I			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**
Year 1 – Semester- II, 2019																
7	MQA201T	CT	Hazards and Safety Management	4	0	0	4	60	0	0	60	80	25	75	0	100
8	MQA202T	CT	Pharmaceutical Validation	4	0	0	4	60	0	0	60	80	25	75	0	100
9	MQA203T	CT	Audits and Regulatory Compliance	4	0	0	4	60	0	0	60	80	25	75	0	100
10	MQA204T	CT	Pharmaceutical Manufacturing Technology	4	0	0	4	60	0	0	60	80	25	75	0	100
11	MQA205P	CL	Pharmaceutical Quality Assurance Practical II	0	0	12	6	0	0	180	180	80	50	0	100	150
12	MQA206S	CT	Seminar – II #	0	7	0	4	0	105	0	105	80	100#	0	0	100
Year 1 – Semester- II			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**

#Continuous Internal Assessment (Average of the seminar marks of four subjects in the semester)

23. 4. M.PHARM – PHARMACOGNOSY (YEAR - 1)
TABLE 16: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Credits (hours) / Week			Credits (C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) – Theory / Practical (a)	End Semester Assessment		Grand Total
				Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 150
Year 1 – Semester- I, 2019																
1	MPG101T	CT	Modern Pharmaceutical Analytical Techniques	4	0	0	4	60	0	0	60	80	25	75	0	100
2	MPG102T	CT	Advanced Pharmacognosy-I	4	0	0	4	60	0	0	60	80	25	75	0	100
3	MPG103T	CT	Phytochemistry	4	0	0	4	60	0	0	60	80	25	75	0	100
4	MPG104T	CT	Industrial Pharmacognostical Technology	4	0	0	4	60	0	0	60	80	25	75	0	100
5	MPG105P	CL	Pharmacognosy Practical I	0	0	12	6	0	0	180	180	80	50	0	100	150
6	MPG106S	CT	Seminar – I #	0	7	0	4	0	105	0	105	80	100#	0	0	100
Year 1 – Semester- I			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**
Year 1 – Semester- II, 2019																
7	MPG201T	CT	Medicinal Plant biotechnology	4	0	0	4	60	0	0	60	80	25	75	0	100
8	MPG202T	CT	Advanced Pharmacognosy-II	4	0	0	4	60	0	0	60	80	25	75	0	100
9	MPG203T	CT	Indian system of medicine	4	0	0	4	60	0	0	60	80	25	75	0	100
10	MPG204T	CT	Herbal cosmetics	4	0	0	4	60	0	0	60	80	25	75	0	100
11	MPG205P	CL	Pharmacognosy Practical II	0	0	12	6	0	0	180	180	80	50	0	100	150
12	MPG206S	CT	Seminar – II #	0	7	0	4	0	105	0	105	80	100#	0	0	100
Year 1 – Semester- II			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**

#Continuous Internal Assessment (Average of the seminar marks of four subjects in the semester)

23. 5. M.PHARM – PHARMACEUTICAL ANALYSIS (YEAR - 1)
TABLE 17: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Credits (hours) / Week			Credits (C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) – Theory / Practical (a)	End Semester Assessment		Grand Total
				Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 150
Year 1 – Semester- I, 2019																
1	MPA101T	CT	Modern Pharmaceutical Analytical Techniques	4	0	0	4	60	0	0	60	80	25	75	0	100
2	MPA102T	CT	Advanced Pharmaceutical Analysis	4	0	0	4	60	0	0	60	80	25	75	0	100
3	MPA103T	CT	Pharmaceutical Validation	4	0	0	4	60	0	0	60	80	25	75	0	100
4	MPA104T	CT	Quality Control and Quality Assurance	4	0	0	4	60	0	0	60	80	25	75	0	100
5	MPA105P	CL	Pharmaceutical Analysis Practical I	0	0	12	6	0	0	180	180	80	50	0	100	150
6	MPA106S	CT	Seminar – I #	0	7	0	4	0	105	0	105	80	100#	0	0	100
Year 1 – Semester- I			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**
Year 1 – Semester- II, 2019																
7	MPA201T	CT	Advanced Instrumental Analysis	4	0	0	4	60	0	0	60	80	25	75	0	100
8	MPA202T	CT	Modern Bio- Analytical Techniques	4	0	0	4	60	0	0	60	80	25	75	0	100
9	MPA203T	CT	Food Analysis	4	0	0	4	60	0	0	60	80	25	75	0	100
10	MPA204T	CT	Herbal and Cosmetic analysis	4	0	0	4	60	0	0	60	80	25	75	0	100
11	MPA205P	CL	Pharmaceutical Analysis Practical II	0	0	12	6	0	0	180	180	80	50	0	100	150
12	MPA206S	CT	Seminar – II #	0	7	0	4	0	105	0	105	80	100#	0	0	100
Year 1 – Semester- II			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**

[#]Continuous Internal Assessment (Average of the seminar marks of four subjects in the semester)

23. 6. M.PHARM – PHARMACOLOGY(YEAR - 1)

TABLE 18: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Credits (hours) / Week			Credits (C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) – Theory / Practical (a)	End Semester Assessment		Grand Total
				Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 150
Year 1 – Semester- I, 2019																
1	MPL101T	CT	Modern Pharmaceutical Analytical Techniques	4	0	0	4	60	0	0	60	80	25	75	0	100
2	MPL102T	CT	Advanced Pharmacology-I	4	0	0	4	60	0	0	60	80	25	75	0	100
3	MPL103T	CT	Pharmacological and Toxicological Screening Methods-I	4	0	0	4	60	0	0	60	80	25	75	0	100
4	MPL104T	CT	Cellular and Molecular Pharmacology	4	0	0	4	60	0	0	60	80	25	75	0	100
5	MPL105P	CL	Pharmacology Practical I	0	0	12	6	0	0	180	180	80	50	0	100	150
6	MPL106S	CT	Seminar – I [#]	0	7	0	4	0	105	0	105	80	100[#]	0	0	100
Year 1 – Semester- I			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**
Year 1 – Semester- II, 2019																
7	MPL201T	CT	Advanced Pharmacology - II	4	0	0	4	60	0	0	60	80	25	75	0	100
8	MPL202T	CT	Pharmacological and Toxicological Screening Methods-II	4	0	0	4	60	0	0	60	80	25	75	0	100
9	MPL203T	CT	Principles of Drug Discovery	4	0	0	4	60	0	0	60	80	25	75	0	100
10	MPL204T	CT	Clinical Research and Pharmacovigilance	4	0	0	4	60	0	0	60	80	25	75	0	100
11	MPL205P	CL	Pharmacology Practical II	0	0	12	6	0	0	180	180	80	50	0	100	150
12	MPL206S	CT	Seminar – II [#]	0	7	0	4	0	105	0	105	80	100[#]	0	0	100
Year 1 – Semester- II			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**

[#]Continuous Internal Assessment (Average of the seminar marks of four subjects in the semester)

23. 7. M.PHARM – PHARMACEUTICAL CHEMISTRY(YEAR - 1)

TABLE 19: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Credits (hours) / Week			Credits (C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA)	End Semester Assessment		Grand Total
				Lecture (L)	Tutorial (T) / Clinical Training	Practical (P) / Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 150
Year 1 – Semester- I, 2019																
1	MPC101T	CT	Modern Pharmaceutical Analytical Techniques	4	0	0	4	60	0	0	60	80	25	75	0	100
2	MPC102T	CT	Advanced Organic Chemistry –I	4	0	0	4	60	0	0	60	80	25	75	0	100
3	MPC103T	CT	Advanced Medicinal chemistry	4	0	0	4	60	0	0	60	80	25	75	0	100
4	MPC104T	CT	Chemistry of Natural Products	4	0	0	4	60	0	0	60	80	25	75	0	100
5	MPC105P	CL	Pharmaceutical Chemistry Practical I	0	0	12	6	0	0	180	180	80	50	0	100	150
6	MPC106S	CT	Seminar – I [#]	0	7	0	4	0	105	0	105	80	100[#]	0	0	100
Year 1 – Semester- I			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**
Year 1 – Semester- II, 2019																
7	MPC201T	CT	Advanced Spectral Analysis	4	0	0	4	60	0	0	60	80	25	75	0	100
8	MPC202T	CT	Advanced Organic Chemistry –II	4	0	0	4	60	0	0	60	80	25	75	0	100
9	MPC203T	CT	Computer Aided Drug Design	4	0	0	4	60	0	0	60	80	25	75	0	100
10	MPC204T	CT	Pharmaceutical Process Chemistry	4	0	0	4	60	0	0	60	80	25	75	0	100
11	MPC205P	CL	Pharmaceutical Chemistry Practical II	0	0	12	6	0	0	180	180	80	50	0	100	150
12	MPC206S	CT	Seminar – II [#]	0	7	0	4	0	105	0	105	80	100[#]	0	0	100
Year 1 – Semester- I			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**

[#] Continuous Internal Assessment (Average of the seminar marks of four subjects in the semester)

23. 8. M.PHARM – PHARMACEUTICAL REGULATORY AFFAIRS (YEAR - 1)
TABLE 20: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Credits (hours) / Week			Credits (C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA)	End Semester Assessment		Grand Total
				Lecture (L)	Tutorial (T) / Clinical Training (CT)	Practical (P) / Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b = 100 Practical: a + c = 150
Year 1 – Semester- I, 2019																
1	MRA101T	CT	Good Regulatory Practices	4	0	0	4	60	0	0	60	80	25	75	0	100
2	MRA102T	CT	Documentation and Regulatory Writing	4	0	0	4	60	0	0	60	80	25	75	0	100
3	MRA103T	CT	Clinical Research Regulations	4	0	0	4	60	0	0	60	80	25	75	0	100
4	MRA104T	CT	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India and Intellectual Property Rights	4	0	0	4	60	0	0	60	80	25	75	0	100
5	MRA105P	CL	Regulatory Affairs Practical I	0	0	12	6	0	0	180	180	80	50	0	100	150
6	MRA106S	CT	Seminar – I [#]	0	7	0	4	0	105	0	105	80	100[#]	0	0	100
Year 1 – Semester- I			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**
Year 1 – Semester- II, 2019																
7	MRA201T	CT	Regulatory Aspects of Drugs & Cosmetics	4	0	0	4	60	0	0	60	80	25	75	0	100
8	MRA202T	CT	Regulatory Aspects of Herbals & Biologicals	4	0	0	4	60	0	0	60	80	25	75	0	100
9	MRA203T	CT	Regulatory Aspects of Medical Devices	4	0	0	4	60	0	0	60	80	25	75	0	100
10	MRA204T	CT	Regulatory Aspects of Food & Nutraceuticals	4	0	0	4	60	0	0	60	80	25	75	0	100
11	MRA205P	CL	Regulatory Affairs Practical II	0	0	12	6	0	0	180	180	80	50	0	100	150
12	MRA206S	CT	Seminar – II [#]	0	7	0	4	0	105	0	105	80	100[#]	0	0	100
Year 1 – Semester- II			**Total**	**16**	**7**	**12**	**26**	**240**	**105**	**180**	**525**	**-**	**250**	**300**	**100**	**650**

[#] Continuous Internal Assessment (Average of the seminar marks of four subjects in the semester)

23. 9. YEAR 2 - SEMESTER III (COMMON FOR ALL SPECIALIZATIONS)
TABLE – 21: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Credits (hours) / Week			Credits (C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) - Theory / Practical (a)	End Semester Assessment (ESE)		Grand Total
				Lecture (L)	Tutorial(T)/ Clinical Training(CT)	Practical (P) /Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a +b Practical:a + c
13	MRM301T	CT	Research Methodology and Biostatistics*	4	0	0	4	60	0	0	60	80	25	75*	0	100
14	MJC302P	CT	Journal Club– I[#]	0	1	0	1	0	15	0	15	80	25[#]	0	0	25
15	MRP303P	RP	Dissertation Proposal – Oral Presentation [#]	0	2	0	2	0	30	0	30	80	50[#]	0	0	50
16	MRP304P	RP	Dissertation-Orientation Report*	0	0	30	15	0	0	450	450	80	0	0	350*	350
Year 2 – Semester- III			**Total**	**4**	**3**	**30**	**22**	**60**	**45**	**450**	**555**	**-**	**100**	**75**	**350**	**525**

* Non- University End semester Examination - to be conducted by two internal e-xaminers
[#] Continuous Internal Assessment
(One credit from the minimum 2 credits allotted for co-curricular activities is added with the 14 credits for Dissertation-Orientation Report to sum up to 15 credits)

23. 10. YEAR 2 - SEMESTER IV (COMMON FOR ALL SPECIALIZATIONS)
TABLE – 22: SCHEME OF CURRICULUM AND EVALUATION OF THE PROGRAM, 2019

Course Number	Course Code	Category	Course Title	Credits (hours) / Week			Credits (C)	Hours/ semester (Credits x 15 weeks)				Attendance (%)	Continuous Internal assessment (CIA) - Theory / Practical (a)	End Semester Assessment (ESE)		Grand Total
				Lecture (L)	Tutorial(T)/ Clinical Training(CT)	Practical (P) /Research Project		Lecture	Tutorial	Practical	Total hours			Theory (b)	Practical/ Viva (c)	Theory: a+b Practical: a + c
17	MJC401P	CT	Journal club– II #	0	1	0	1	0	15	0	15	80	25#	0	0	25
18	MRP402P	RP	Dissertation and Viva voce*	0	3	0	3	0	45	0	45	80	75*	0	0	75
19	MRP403P	RP	Research Colloquium $	0	0	34	17	0	0	510	510	80	0	0	400$	400
Year 2 – Semester- IV			**Total**	**0**	**4**	**34**	**21**	**0**	**60**	**510**	**570**	**-**	**100**	**0**	**400**	**500**
GRAND TOTAL				**36**	**21**	**88**	**95**	**540**	**315**	**1320**	**2175**	**-**	**700**	**675**	**950**	**2325**

Continuous Internal Assessment; * End semester Examination (to be conducted by two internal examiners);$ Duration of examination – 1 hour
(One credit from the minimum 2 credits allotted for co-curricular activities is added with the 16 credits for Research Colloquim to sum up to 17 credits)

a: CIA Theory & Practical (eligibility for ESE Min.50 % each, CIA marks to be submitted to the University 15 days before the ESE)

b: EST (Pass Min 50%, CIA & ESE Aggregate 50%)

c: ESP (Pass Min 50%, CIA & ESE Aggregate 50%)

24. COURSE CONTENT
M.PHARM PHARMACY PRACTICE (MPP)

PROGRAM OUTCOMES (POs)

Upon completion of this program, the students shall be able to:

PO1: Demonstrate and apply knowledge and skills to integrate the principles of pathophysiology, pharmacotherapeutics, hospital and clinical pharmacy to deliver patient care and improve population health.

PO2: Apply the basics of pharmacoepidemiology, pharmacoeconomics and therapeutic drug monitoring in the promotion of patient specific rational drug use in a clinical and ambulatory setting.

PO3: Demonstrate application of analytical and critical thinking skills towards problem solving and decision making in a professional practice setting.

PO4: Actively participate and engage in team building and leadership activities by demonstrating mutual respect, understanding, accountability and responsibility in combating the professional needs and demands.

PO5: Apply the pharmacy practice knowledge and skills as a competent pharmacist in the delivery of pharmaceutical care in a healthcare setting based on recent scientific/clinical evidences and novel technologies.

PO6: Display knowledge, skills and quest for successful professional attainment in diverse fields of scientific and clinical research and exhibit writing skills in scientific presentations, report preparations and documentations.

PO7: Demonstrate mastery in the areas of Pharmacovigilance, medical writing, Regulatory and data management.

PO8: Identify and implement strategies to overcome social determinants of ailment and promote health and wellbeing of the community through safe and rational use of medicines.

PO9: Uphold highest standards in maintaining professionalism, legal and ethical behavior towards protecting patient privacy and autonomy, respect and integrity of the teammates and the society.

PO10: Communicate with patients, health care professionals, students, colleagues and the public adopting suitable levels of assertiveness, confidence, empathy, and respect.

PO11: Effectively utilize information and technology, modern tools and softwares in appropriate areas to optimize outcomes in patient care, academia and research.

PSO12: Demonstrate commitment towards self-directed life-long learning and personal improvement through continuing professional development.

SEMESTER - I
CLINICAL PHARMACY PRACTICE (MPP 101T)

Scope:

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

Objectives:

Upon completion of this course it is expected that students shall understand the:

- Elements of pharmaceutical care and provide comprehensive patient care services.
- Interpretation of the laboratory results to aid the clinical diagnosis of various disorders.
- Steps involved in provision of integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management.

Course Outcomes:

Upon completion of this course, the students shall be able to:

CO1: Define and explain the scope and evolution of Clinical Pharmacy practice in the National and International scenario.

CO2: Elucidate the concept and the key elements of Clinical Pharmacy services and Pharmaceutical care.

CO3: Depict a systematic understanding of the steps involved in ward round participation and demonstrate skills required to actively take part in ward round participation along with the health care team in a clinical setting.

CO4: Execute drug therapy monitoring through patient medication history interview and review of the patients' medication orders and provide appropriate interventions to the health care team in the clinical setting.

CO5: Employ the knowledge in identifying the laboratory test results and relate them to the clinical condition of the patients.

CO6: Analyse and interpret the laboratory test results in the patients' case records with respect to their prognosis and therapeutic outcomes.

CO7: Define and state the significance of Pharmacovigilance, Hemovigilance, Materiovigilance and AEFI

CO8: Engage in the identification and causality assessment of the suspected adverse drug reactions in a clinical setting.

CO9: Demonstrate knowledge and skills in the provision of Patient medication counseling in a patient care setting.

CO10: Illustrate the principles, types, process and the applications of Drug utilization evaluation and identify the target drugs or therapeutic areas of practice for possible conduct of the Drug utilization evaluation.

CO11: Explain the significance and methods involved in documentation of clinical pharmacy services and exercise professional autonomy in the documentation of the clinical pharmacy services.

CO12: Provide integrated, critically analyzed medicine and poison information to facilitate healthcare professionals in the efficient patient management.

Theory **60 hrs**

1. Introduction to Clinical Pharmacy: **12 hrs**

Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care.

Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions).

2. Clinical Pharmacy Services: **12 hrs**

Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilization evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services.

3. Patient Data Analysis: **12 hrs**

Patient Data & Practice Skills: Patient's case history - its structure and significances in Drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services.

4. Lab Data Interpretation: **12 hrs**

Hematological tests, Renal function tests, Liver function tests

Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests

5. Medicines & Poison Information Services **12 hrs**

Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a Drug information centre.

Poison Information Service: Definition, need, organization and functions of poison information centre.

References:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata.
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
4. AHFS Drug information.
5. Drug information –A guide for pharmacists by William G.
6. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS- I (MPP 102T)

Scope:

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing Drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for Drug therapy.
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence.
- Discuss the clinical controversies in Drug therapy and evidence based medicine.
- Prepare individualized therapeutic plans based on diagnosis.
- Identify the patient specific parameters relevant in initiating Drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s).

Course Outcomes:

Upon completion of this course, the students shall be able to:

CO1: Describe the etiology, pathophysiology and clinical manifestations of the selected cardiovascular, respiratory, gastro intestinal, dermatological, ophthalmological, bone and joint disease states and the rationale for the use of selected pharmacotherapy interventions.

CO2: Demonstrate an understanding of the selection and use of drugs in the management and treatment of the selected disease states

CO3: Explain the pharmacology (mechanism of action, effects, pharmacokinetics, side effects, etc.) of the drugs discussed for each disease.

CO4: Apply pharmacokinetics and pharmacodynamics to patient's clinical context and their social context especially financial status in the selection of drugs

CO5: Discuss drugs of choice and alternatives for a given patient and disease in alignment with latest evidences

CO6: Evaluate prescribed drug regimens for safety, clinical efficacy and outcomes and identify potential side effects, adverse reactions, and discuss their management.

CO7: Identify and incorporate special considerations when prescribing for specific populations: pregnancy, breastfeeding, older adults, children and infants, and genetic factors

CO8: Communicate the appropriate patient education information regarding drug therapy for a given disease.

Theory **60 hrs**

Etiopathogenesis and pharmacotherapy of diseases associated with following systems.

1. Cardiovascular system: **12 hrs**

Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias.

2. Respiratory system: **12hrs**

Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
Endocrine system: Diabetes, Thyroid diseases.

3. Gastrointestinal system: **12 hrs**

Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis.

4. Gastrointestinal system: **12hrs**

Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease

Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders.

5. Bone and joint disorders: **12hrs**

Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis.

Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, Drug induced skin disorders.

Ophthalmology: Conjunctivitis, Glaucoma.

References:

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange.
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication.
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication.
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins.
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication.
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins.
8. Harrison's. Principles of Internal Medicine - McGraw Hill.
9. The Merck Manual of diagnosis and therapy.
10. Comprehensive pharmacy Review by Leon Shargel, Alan H. Mutnick, Paul F.Souney & Larry N. Swanson.
11. Relevant review articles from recent medical and pharmaceutical literature.

HOSPITAL & COMMUNITY PHARMACY (MPP 103T)

Scope:

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Understand the organizational structure of hospital pharmacy.
- Understand Drug policy and Drug committees.
- Explain the drug procurement & Drug distribution practices.
- Understand the admixtures of radiopharmaceuticals.
- Understand the community pharmacy management.
- Explain the value added services in community pharmacies.

Course outcomes:

Upon completion of this course, the students shall be able to:

CO1: Explain the organizational structure and functions of a hospital pharmacy and community Pharmacy

CO2: Execute the responsibilities of a hospital Pharmacist in the management of a hospital pharmacy and in Drug policy and Drug committees.

CO3: Apply knowledge and skills on various drug distribution and dispensing methods, handling of radiopharmaceuticals and controlled substances in a hospital and apply it in the hospital pharmacy practice career setting.

CO4: Demonstrate professional practice management skills and demonstrate code of ethics in the hospital and community pharmacies.

CO5: Prepare and implement a budget, carry out purchase and inventory control of drugs in a hospital or community pharmacy

CO6: Organize and stock the drugs including the investigational drugs and manage a pharmacy store in a practice setup.

CO7: Demonstrate knowledge and ability on the manufacturing practices of various formulations and admixture of radiopharmaceuticals in a hospital set up.

CO8: Identify symptoms of minor ailments and provide appropriate medications including over the counter medicines and participate in prevention programs of communicable diseases.

CO9: Demonstrate professional ethics in educating patients through counseling

CO10: Provide health screening services to public and promoting safe and appropriate medication use throughout society.

CO11: Develop aptitude for continuous education, training and professional development of self and of the fellow health care team.

Theory **60 Hrs**

1. Introduction to Hospitals: **12 hrs**

Definition, classification, organizational structure

Hospital Pharmacy**:** Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management

Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH.

2. Hospital Formulary: **12 hrs**

Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management.

3. Education and training: **12 hrs**

Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter.

Community Pharmacy Practice:

Definition, Roles & responsibilities of community pharmacists and their relationship with other health care providers.

Community Pharmacy management:

Legal requirements to start community pharmacy, site selection, lay out & design, Drug display, super Drug store model, accounts and audits, Good dispensing practices, Different softwares& databases used in community pharmacies. Entrepreneurship in community pharmacy.

4. Prescription: 12 hrs

Legal requirements & interpretation, prescription related problems

Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and Drug allergy.

OTC medication:

Rational use of over the counter medications Medication counseling and use of patient information leaflets Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence.

Patient referrals to the doctors.

ADR monitoring in community pharmacies.

5. Health Promotion: 12hrs

Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care.

National Health Programs- Role of Community Pharmacist in Malaria and TB control programs.

Home Medicines review program – Definition, objectives, Guidelines, method and outcomes

Research in community pharmacy Practice.

References:

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. A text book of hospital Pharmacy by S.H. Merchant&DR. J.S. Quadry.
3. Textbook of hospital pharmacy - Allwood MC and Blackwell, Scientific Publications.
4. Avery's Drug Treatment, Adis International Limited.
5. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad.
6. Textbook of Preventive and Social Medicine – J.E. Park & K. Park.
7. Remington Pharmaceutical Sciences.
8. Relevant review articles from recent medical and pharmaceutical literature.

CLINICAL RESEARCH (MPP 104T)

Scope:

This course aims to provide the students an opportunity to learn Drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to impart knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Know the new Drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities.
- Know safety monitoring and reporting in clinical trials.
- Manage the trial coordination process.

Course Outcomes:

Upon completion of this course, the students shall be able to:

CO1: Explain the principles involved in the new drug development process

CO2: Explain various phases involved in the clinical trials and the roles and responsibilities of a clinical trial personnel.

CO3: Demonstrate knowledge on the good clinical practice guidelines and the regulatory requirements for the conduct of clinical trial.

CO4: Describe the ethical guidelines, the roles and responsibilities of a IRB/IEC.

CO5: Demonstrate knowledge and skills required for designing of clinical study documents.

CO6: Explain the significance of safety monitoring, reporting and the procedures and requirements for data management in clinical trials.

CO7: Describe the process of quality control and quality assurance in a clinical trial setting.

CO8: Develop knowledge on activities related to clinical trial start up, monitoring and close out.

CO9: Demonstrate skills for design, conduct, analysis and reporting of a clinical trial in a trial setting.

Theory **60 hrs**

1. Drug development process: **12 hrs**

Introduction, various approaches to Drug discovery, Investigational new Drug application submission. Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.

2. Types and Designs used in Clinical Research: **12 hrs**

Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic).

Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.

3. Clinical trial Documents: 12 hrs

Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards

Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission.

4. Investigational Product: 12 hrs

Procurement and Storage of investigational product.

Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up Clinical Trial Monitoring and Close out: Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up.

Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.

5. Quality Assurance and Quality Control in Clinical Trials: 12 hrs

Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management.

Data Management, Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival.

Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.

References:

1. Principles and practice of pharmaceutical medicine, Second edition. Authors: Lionel. D. Edward, Andrew.J. Flethernthony W Fos, Peter D Sloaier Publisher:Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Guide to Clinical Trials by Bert Spilker.
11. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I (MPP 105P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

1. Treatment Chart Review (one).
2. Medication History Interview (one).
3. Patient Medication Counseling (two).
4. Drug Information Query (two).
5. Poison Information Query (one).
6. Lab Data Interpretation (two).
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight).
8. ABC Analysis of a given list of medications (one).
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one).
10. Formulation and dispensing of a given IV admixtures (one).
11. Preparation of a patient information leaflet (two).
12. Preparation of Study Protocol (one).
13. Preparation of Informed Consent Form (one).

SEMESTER - II

PRINCIPLES OF QUALITY USE OF MEDICINES (MPP 201T)

Scope:

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines.
- Know the benefits and risks associated with use of medicines.
- Understand regulatory aspects of quality use of medicines.
- Identify and resolve medication related problems.
- Promote quality use of medicines.
- Practice evidence-based medicines.

Course Outcomes:

Upon completion of this course, the students shall be able to:

CO1: Explain the principles of quality use of medicines (QUM) and the roles and responsibilities of key partners involved in promotion of QUM.

CO2: Demonstrate the benefits and risks associated with use of medicines.

CO3: Explain the concept of evidence based medicine and its implication in promoting quality use of medicines in a clinical Practice setting.

CO4: Describe the building blocks and regulatory aspects of quality use of medicines including over the counter medicines and Complementary & alternative medicines.

CO5: Classify and detect medication errors and provide necessary interventions to prevent or resolve the errors.

CO6: Define and discuss the concepts and significance of essential drug list and rational use of drugs.

CO7: Apply the knowledge and skills in the promotion of QUM in various patient care settings and in special population.

CO8: Define Pharmacovigilance and identify adverse drug reactions, monitor, assess and document adverse drug reactions.

Theory **60 hrs**

1. Introduction to Quality use of medicines (QUM): 12 hrs

Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.

2. Concepts in QUM: 12 hrs

Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings

Essential Drugs: Definition, need, concept of essential Drug, National essential Drug policy and list.

Rational Drug use: Definition, concept and need for rational Drug use, Rational Drug prescribing, Role of pharmacist in rational Drug use.

3. QUM in various settings: 12 hrs

Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care. QUM in special population: Pediatric prescribing, Geriatric prescribing, prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients.

4. Regulatory aspects of QUM in India: 12 hrs

Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.

5. Medication errors: 12 hrs

Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors

Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse Drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.

References:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata.
2. Andrews EB, Moore N. Mann's Pharmacovigilance.
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach.
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it.
5. Cohen Michael R. Medication Errors.

Online:

http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Red uced.pdf.
http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf.
Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS- II (MPP 202T)

Scope:

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing Drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for Drug therapy.
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence.
- Discuss the clinical controversies in Drug therapy and evidence based medicine.
- Prepare individualized therapeutic plans based on diagnosis.
- Identify the patient specific parameters relevant in initiating Drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s).

Course Outcomes:

Upon completion of this course, the students shall be able to:

CO1: Describe the etiology, pathophysiology and clinical manifestations of the selected nervous system, renal, psychiatric, gynecological, infectious disease states and certain cancers and the rationale for the use of selected pharmacotherapeutic interventions.

CO2: Demonstrate an understanding of the selection and use of drugs in the management and treatment of the selected disease states.

CO3: Identify the patient specific parameters relevant in initiating Drug therapy, and Monitoring therapy (including alternatives, time- course of clinical and laboratory Indices of therapeutic response and adverse effect/s).

CO4: Explain the pharmacology (mechanism of action, effects, pharmacokinetics, side effects, etc.) of the drugs discussed for each disease.

CO5: Apply pharmacokinetics and pharmacodynamics to patient's clinical context and their social context especially financial status in the selection of drugs

CO6: Discuss drugs of choice and alternatives for a given patient and disease, the clinical controversies in Drug therapy, in alignment with evidence based medicine.

CO7: Evaluate prescribed drug regimens for safety, clinical efficacy and outcomes and identify potential side effects, adverse reactions, and discuss their management.

CO8: Identify and incorporate special considerations when prescribing for specific populations: pregnancy, breastfeeding, older adults, children and infants, and genetic factors.

CO9: Communicate the appropriate patient education information regarding drug therapy for a given disease.

Theory **60 hrs**

1. Nervous system: **12 hrs**

Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management.

2. Psychiatric disorders: **12 hrs**

Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease.

3. Infectious diseases: **12 hrs**

General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.

4. Infectious diseases: **12 hrs**

Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections.

Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.

5. Oncology: **12 hrs**

General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care.

References:

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange.
3. Robins SL. Pathologic basis of disease -W.B. Saunders publications.
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publications.
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins.
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication.
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins.
8. Harrison's. Principles of Internal Medicine - McGraw Hill.
9. The Merck Manual of diagnosis and therapy.
10. Comprehensive Pharmacy Review by Leon Shargel, Alan H. Mutnick, Paul F.Souney & Larry N. Swanson.
11. Relevant review articles from recent medical and pharmaceutical literature.

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

(MPP 203T)

Scope:

This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma Drug concentration profile in altered pharmacokinetics, Drug interactions and in therapeutic Drug monitoring processes to optimize the Drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Design the Drug dosage regimen for individual patients.
- Interpret and correlate the plasma Drug concentrations with patients' therapeutic outcomes.
- Recommend dosage adjustment for patients with renal/ hepatic impairment.
- Recommend dosage adjustment for pediatrics and geriatrics.
- Manage pharmacokinetic Drug interactions.
- Apply pharmacokinetic parameters in clinical settings.
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of Drugs.
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics.

Course Outcomes:

Upon completion of this course, the students shall be able to:

CO1: Design the Drug dosage regimen for individual patients.

CO2: Interpret and correlate the plasma Drug concentrations with patients' therapeutic outcomes.

CO3: Recommend dosage adjustment for patients with renal/ hepatic impairment, pediatrics and geriatrics.

CO4: Identify and manage pharmacokinetic Drug interactions.

CO5: Apply pharmacokinetic parameters in drug dosing and monitoring for drug interactions in clinical settings.

CO6: Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of Drugs.

CO7: Conduct pharmacokinetic modeling for the given data using the principles of pharmacometrics.

Theory **60 hrs**

1. Introduction to Clinical pharmacokinetics: **12 hrs**

Compartmental and Non-compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses.

Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

2. Pharmacokinetics of Drug Interaction: **12 hrs**

Pharmacokinetic Drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion.

Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.

3. Non-Linear Mixed Effects Modelling: **12 hrs**

The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.

4. Altered Pharmacokinetics: 12 hrs

Drug dosing in the elderly, Drug dosing in the pediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drugdosing in the renal failure and extracorporeal removal of Drugs, Drug dosing in the in hepatic failure.

5. Therapeutic Drug monitoring: 12 hrs

Introduction, Individualization of Drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting Drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in Drug therapy, TDM of Drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem.

References:

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. lippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M. Pruemer.Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Lippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health System Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. Lippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E.Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health-System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP 204T)

Scope:

This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

Course Outcomes:

Upon completion of this course, the students shall be able to:

CO1: Define and explain the concept of pharmacoepidemiology, different pharmaco epidemiological study methods and their applications.

CO2: Demonstrate skills in the design, conduct and interpretation of Pharmacoepidemiological studies.

CO3: Explain the concepts of risk and measures of outcome and their applications in Pharmacoepidemiology.

CO4: Identify and determine relevant cost and consequences associated with pharmacy products and services.

CO5: Explain the Pharmacoeconomic decision analysis methods, its significance and applications.

CO6: Describe various Pharmacoeconomic methods and perform Pharmacoeconomicanalysis in study settings.

Theory **60 hrs**

1. Introduction to Pharmacoepidemiology: **12 hrs**

Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of Drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence,Incidence rate, Monetary units, number of prescriptions, unit of Drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio.

2. Pharmacoepidemiological Methods: **12 hrs**

Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology.

3. Introduction to Pharmacoeconomics: 12 hrs

Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies inIndian healthcare system.

Cost categorization and resources for cost estimation: Directcosts. Indirect costs. Intangible costs.

Outcomes and Measurements of Pharmacoeconomics: Typesof outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost EffectiveRatio, PersonTime, Willingness to Pay, Time Trade Off and Discounting.

4. Pharmacoeconomic evaluations: 12 hrs

Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), CostUtility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

5. Definition, Steps involved, Applications, Advantages and disadvantages of the following: 12 hrs

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures.

Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics.

References:

1. Pharmacoepidemiology, 5th Edition, Brian L. Strom, Stephen E. Kimmel, Sean Hennessy
2. Textbook of Pharmacoepidemiology Edited by Brian L. Strom and Stephen E. Kimmel
3. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
4. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
5. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
6. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
7. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
8. Graker, Dennis. Pharmacoeconomics and outcomes.
9. Walley, Pharmacoeconomics.
10. Pharmacoeconomicsby Nowakowska – University of Medical Sciences, Poznan.
11. Pharmacoeconomics by Renee J. G. Arnold
12. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - II (MPP 205P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics &Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (24).

1. Causality assessment of adverse Drug reactions (three).
2. Detection and management of medication errors (three).
3. Rational use of medicines in special population (three).
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight).
5. Calculation of Bioavailability and Bioequivalence from the given data (two).
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three).
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two).

M.PHARM PHARMACEUTICS (MPH)

PROGRAM OUTCOMES:

Upon completion of the course, student shall be able to:

PO1: Apply the knowledge of basic of pharmaceutics in order to maintain the quality and safety of pharmaceutical products.

PO2: Identify, formulate, and solve pharmaceutical problems.

PO3: Handle various dossier preparation and submission.

PO4: Apply knowledge of pharmacokinetics principle to design and conduct experiments, as well as to analyze and interpret data.

PO5: Demonstrate ethical and professional behavior in compliance with laws, regulations and professional standards in various pharmaceutical environment.

PO6: Formulate different dosage forms in order to deliver the best pharmaceutical care to the patients.

PO7: Evaluate different dosage forms based on official standards.

PO8: Develop and characterize novel drug delivery system for different routes of administration.

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)
SEMESTER - I

Scope:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of Drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives:

After completion of course, the student will be able to know:

- The analysis of Chemicals and Excipients.
- The analysis of various Drugs in single and combination dosage forms.
- Theoretical and practical skills of the instruments.

Course Outcomes

Upon completion of the course, the student shall be able to

CO1: Select the method for the analysis of drugs and chemicals

CO2: Understand the principle and theory involved in the various instrumental techniques

CO3: Know the various chromatographic techniques involved in the analysis of excipients and drugs

CO4: Acquire the knowledge and practical skills required to analyse drugs

CO5: Interpret the data obtained in various spectroscopic methods

CO6: Explain the applications of instrumental techniques in various fields

CO7: Apply instrumental and non-instrumental techniques in the analysis of different formulations

CO8: Perform qualitative and quantitative analysis of pharmaceuticals using various analytical techniques

Theory **60 hrs**

1. a. **UV-Visible spectroscopy**: **10 hrs**

Introduction, Theory, Laws, and Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect, Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

b. **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of Drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy **10 hrs**

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR, Applications of NMR spectroscopy.

3. Mass Spectroscopy **10 hrs**

Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of

Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

4. Chromatography **10 hrs**

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of Drug from excipients, data interpretation and applications of the following:

a. Paper Chromatography
b. Thin Layer Chromatography
c. High Performance Thin Layer Chromatography
d. Ion Exchange Chromatography
e. Column Chromatography
f. Gas Chromatography
g. High Performance Liquid Chromatography
h. Ultra High Performance Liquid Chromatography
i. Affinity Chromatography
j. Gel Chromatography

5. a**. Electrophoresis:** **20 hrs**

Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

i. Paper electrophoresis, ii. Gel electrophoresis, iii. Capillary electrophoresis, iv. Zone electrophoresis, v. Moving boundary electrophoresis, vi. Iso-electric focusing.

b. **X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

c. **Radio Immunological Assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.

d. **Potentiometry:**

i. Principle, working, Ion selective Electrodes and Application of potentiometry.

ii. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation, advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

Thermal gravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

References:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F.James Holler,Timothy A.Nieman,5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edition, P.S/Kalsi, Wiley Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 1982.

DRUG DELIVERY SYSTEMS (MPH 102T)

Scope:

This course is designed to impart knowledge on the area of advances in novel Drug delivery systems.

Objectives:

Upon completion of the course, student shall be able to understand:

- The various approaches for development of novel Drug delivery systems.
- The criteria for selection of Drugs and polymers for the development of delivering system.
- The formulation and evaluation of Novel Drug delivery systems.

Course outcomes:

Upon completion of the course, student shall be able to:

CO1: List out pros and cons of drug delivery systems and explain the need for new drug delivery systems

CO2: Classify dosage forms by formulation, route of administration and mechanism of drug release

CO3: Explain current drug delivery systems in research

CO4: Explain the design and application of drug delivery systems

CO5: Explain the various approaches for development of novel drug delivery systems.

CO6: Describe the criteria for selection of drugs and polymers for the development of delivering system.

CO7: Discuss modified release dosage forms

CO8: Categorize and evaluate drug delivery systems

CO9: Compare between conventional and controlled delivery

CO10: Apply the principles and rationale of drug delivery.

CO11: Apply the principles kinetics of drug release using softwares

CO12: Design different approaches to sustained, controlled and targeted drug delivery.

CO13: Design the intranasal and ocular drug delivery systems.

CO14: Develop the transdermal delivery systems

CO15: Formulate various release systems (oral and parenterals) of drug

CO16: Read current journal articles on drug delivery topics and formulate a proposal for a new research topic.

Theory **60 hrs**

1. Sustained Release (SR) and Controlled Release (CR) formulations: **10 hrs**

Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application.

Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, categories of Patients for Personalized Medicines: Customized Drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

2. Rate Controlled Drug Delivery Systems: **10 hrs**

Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic Activated Drug Delivery Systems, Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

3. Gastro-Retentive Drug Delivery Systems: **10 hrs**

Principle, concepts, advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of Drug permeation, Methods of formulation and its evaluations.

4. Occular and Transdermal Drug Delivery Systems: 1**6 hrs**

a. Barriers of Drug permeation, Methods to overcome barriers.

b. Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

5. **Vaccines,Protein and Peptide Deliverysystems:** **14 hrs**

a. Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

b. Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

References:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York, Chichester/Weinheim.
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA).
2. Indian Drugs (IDMA).
3. Journal of controlled release (Elsevier Sciences) desirable.
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable.

MODERN PHARMACEUTICS (MPH 103T)

Scope:

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives:

Upon completion of the course, student shall be able to understand:

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic Drug Product development.
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

Course outcomes:

Upon completion of the course, student shall be able to:

CO1: Discuss different elements of preformulation studies.

CO2: Explain about powder technology.

CO3: Describe various preformulation concepts influencing stability of drugs

CO4: Elaborate the importance of validation and its types.

CO5: Define vendor certification.

CO6: Describe the validation approaches of pharmaceutical processes.

CO7: Describe the assumptions of Factorial ANOVA

CO8: Describe the current good manufacturing practices.

CO9: Describe the concept of pilot plant and explain the procedures and practices in optimization techniques in pharmaceutical formulations.

CO10: List out the reasons to use statistical parameters

CO11: Apply the knowledge of optimization techniques in designing pharmaceutical formulation.

CO12: Apply knowledge of excipients in developing pharmaceutical formulations.

CO13: Demonstrate the use of physicochemical properties in the formulation development and evaluation of dosage forms.

CO14: Draw diagrams and sketches of different types of validations protocol followed in pharmaceutical industry.

CO15: Apply validation principles and approaches in pharmaceutical industry.

CO16: Carry out validation of manufacturing processes.

CO17: Apply the knowledge of validation to instruments and equipments.

CO18: Apply the statistical tools in designing experiments.

CO19: Compare variables under study.

CO20: Employ the principles of linear regression and correlation, including least square method, predicting a particular value of y for a given value of x and significance of the correlation coefficient.

CO21: Demonstrate knowledge to impart management and leadership skills in pharma field.

CO22: Utilize and fulfill the requirements of GMP Systems in pharma industry.

Theory **60 hrs**

1. **a. Preformation Concepts** **10 hrs**

Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stabilitytesting Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

b. Optimization techniques in Pharmaceutical Formulation: **10 hrs**

Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation

2. Validation: **10 hrs**

Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.

3. **cGMP & Industrial Management:** **10 hrs**

Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

4. Compression and compaction: 10 hrs

Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.

5. Study of consolidation parameters: 10 hrs

Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

References:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann.
2. Pharmaceutical Dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred Martin.
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, 2nd edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P. P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encylopedia of Pharmaceutical technology, Vol I – III.

REGULATORY AFFAIRS (MPH 104T)

Scope:

Course designed to impart advanced knowledge and skills required to learn the concept of generic Drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

- To know the approval process
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements

Objectives:

Upon completion of the course, it is expected that the students will be able to understand:

- The concepts of innovator and generic Drugs, Drug development process.
- The Regulatory guidance's and guidelines for filing and approval process.
- Preparation of Dossiers and their submission to regulatory agencies in different countries.
- Post approval regulatory requirements for actives and Drug products.
- Submission of global documents in CTD/ eCTD formats.
- Clinical trials requirements for approvals for conducting clinical trials.
- Pharmacovigilance and process of monitoring in clinical trials.

Course outcomes:
Upon completion of the course, the students will be able to:

CO1: Define the drug legislation and regulation with a focus on US, UK and EU

CO2: Distinguish between brand, generic and substitute drugs

CO3: Describe the concepts of drug development process.

CO4: Describe different bio similar drugs

CO5: Describe the key differences of International regulatory environments

CO6: Explain WHO and ICH guidelines

CO7: Describe techniques of documentation

CO8: Exemplify patent extensions

CO9: Exhibit knowledge of domestic and international law, regulations, and guidelines, documents.

CO10: Explain the types, requirements, content and formats of INDA, NDA, ANDA AND DMF.

CO11: Describe submission of global documents in CTD/ eCTD formats.

CO12: Describe ASEAN Common Technical Dossier

CO13: Describe the responsibilities and ethics related to clinical conduct of study.

CO14: Discuss the importance of monitoring of clinical trials

CO15: Explain the technical aspects pertaining to the Marketing Authorization Application

and review regulatory documents.

CO16: Identify the key functions of Regulatory Affairs during the different phases of a drug life cycle

CO17: Identify and interpret regulations and guidance documents for domestic and international agencies relevant to medical products

CO18: Apply regulatory and ethical principles when conducting research, or when using the research results.

Theory **60 hrs**

1. Documentation in Pharmaceutical industry: **12 hrs**

Master formula record, DMF (Drug Master File), distribution records. Generic Drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION),Drug product performance, *in-vitro*, ANDA regulatory approval process, NDA approval process, BE and Drug product assessment, *in –vivo,* scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

2. Regulatory requirement for product approval: 12 hrs

API, biologics, novel, therapies obtaining NDA, ANDA for generic Drugs ways and means of US registration for foreign Drugs

3. CMC, post approval regulatory affairs: 12 hrs

Regulation for combination products and medical devices, CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

4. Non-clinical Drug development: 12 hrs

Global submission of IND, NDA, ANDA, Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

5. Clinical trials: 12 hrs

Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

References:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol. 185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations by Richard A. Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for Drug regulatory submissions by Sandy Weinberg, John Wiley & Sons. Inc.
5. FDA regulatory affairs: a guide for prescription Drugs, medical devices, and biologics/edited by Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams.
7. www.ich.org/
8. www.fda.gov/
9. www.europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICAL I (MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry.
3. Experiments based on HPLC.
4. Experiments based on Gas Chromatography.
5. Estimation of riboflavin/quinine sulphate by fluorimetry.
6. Estimation of sodium/potassium by flame photometry.
7. To perform *In-vitro* dissolution profile of CR/ SR marketed formulation.
8. Formulation and evaluation of sustained release matrix tablets.

9. Formulation and evaluation osmotically controlled DDS.
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS.
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of transdermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

SEMESTER - II
MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DRUG DELIVERY SYSTEMS) (MPH 201T)

Scope:
This course is designed to impart knowledge on the area of advances in novel Drug delivery systems.

Objectives:
Upon completion of the course student shall be able to understand:
- The various approaches for development of novel Drug delivery systems.
- The criteria for selection of Drugs and polymers for the development of NTDS
- The formulation and evaluation of novel Drug delivery systems.

Course outcomes:
Upon completion of the course, the student shall be able to:

CO1: Discuss the concept, advantages, limitations and formulation aspects of novel drug delivery systems.

CO2: Discuss the fundamental physical scaling laws applied to understanding the properties of materials at the nanometre scale.

CO3: Explain the fundamental principles of nanotechnology and their application to pharma field.

CO4: List out safety and handling methods required during characterization.

CO5: Explain the design and application of targeted drug delivery systems

CO6: Explain the problems involved with developing new drug delivery systems

CO7: Discuss the concept of Pulmonary drug delivery with suitable examples.

CO8: Explain the aerosol composition and function and its evaluation

CO9: Describe existing and new concepts, methodologies of nano technology and apply them in an academic or industrial research environment.

CO10: Describe DNA-based therapeutics

CO11: Explain the structure-function relationships for nucleic acids

CO12: Outline the principles of in-vivo gene therapy

CO13: Describe novel formulation approaches for peptide and protein injectables

CO14: Apply concepts to the nano-scale for formulation development

CO15: Identify challenges and strategies associated with pulmonary delivery of drugs

CO16: Critically evaluate lipid nanoparticles and polymer-based systems for delivery of drugs

Theory **60 hrs**

1. Targeted Drug Delivery Systems: **12 hrs**

Concepts, Events and biological process involved in Drug targeting. Tumor targeting and Brain specific delivery.

2. Targeting Methods: **12 hrs**

Introduction, preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

3. Micro Capsules / Micro Spheres: **12 hrs**

Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

4. Pulmonary Drug Delivery Systems: **12 hrs**

Aerosols, propellents, Containers, Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

5. Nucleic acid based therapeutic delivery systems: **12 hrs**

Gene therapy, introduction (*ex vivo&invivo* gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems.

Biodistribution and Pharmacokinetics: Knowledge of therapeutic antisense molecules and aptamers as Drugs of future.

References:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

Scope:

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

Objectives:

Upon completion of this course it is expected that students will be able understand:

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describes the process of Drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving Drug product equivalency.
- The design and evaluation of dosage regimens of the Drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetics.

Course outcomes:

Upon completion of this course, the students will be able to:

CO1: Explain the concepts in biopharmaceutics and pharmacokinetics.

CO2: Describe the physicochemical, dosage forms and patient related factors affecting absorption, distribution, metabolism and excretion of drugs.

CO3: Describe barrier to transport of drugs.

CO4: Explain the significance of A.D.M.E. in drug design.

CO5: Describe the regulatory aspects of BA-BE Studies drug delivery system.

CO6: List out the criteria for biowaivers.

CO7: Describe the basic principles of in vivo drug kinetics (linear and nonlinear)

CO8: List the assumptions made about drug distribution patterns in both one- and two-compartment models.

CO9: Describe compartment modeling with its assumptions.

CO10: Apply the use of raw data to describe the process of ADME of drug.

CO11: Evaluate the rate and extent of absorption of drug from a test formulation vs. reference formulation

CO12: Construct blood/plasma conc. profile curve of parent drug and major active metabolites

CO13: Calculate PK Parameters

CO14: Identify factors that cause interpatient variability in drug disposition and drug response.

CO15: Evaluate the quantity/concentration of drug in body at any point of time.

CO16: Estimate pharmacokinetic parameters using plasma and urine drug level data.

CO17: Carry out the protein binding studies of drugs.

CO18: Determine and solve the reaction order from experimental data.

Theory **60 hrs**

1. Drug Absorption from the Gastrointestinal Tract: **12 hrs**

Gastrointestinal tract, Mechanism of Drug absorption, Factors affecting Drug absorption, pH–partition theory of Drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and Drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of *in vivo* data with *in vitro* dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

2.Biopharmaceutic considerations in Drug product design and *In Vitro* Drug Product Performance: **12 hrs**

Introduction, biopharmaceutic factors affecting Drug bioavailability, rate-limiting steps in Drug absorption, physicochemical nature of the Drug formulation factors affecting Drug product performance, *in vitro*: dissolution and Drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of Drug products. *In vitro–in vivo* correlation, dissolution profile comparisons, Drug product stability, considerations in the design of a Drug product.

3. Pharmacokinetics: **12 hrs**

Basic considerations, pharmacokinetic models, compartment modeling: one compartment model-IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein- binding interactions, the effect of tissue-binding interactions, cytochrome p450-based Drug interactions, Drug interactions linked to transporters.

4. Drug Product Performance, *In Vivo*: **12 hrs**

Bioavailability and Bioequivalence: Drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: *In vitro, In situ and In vivo* methods, generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

5. Application of Pharmacokinetics: **12 hrs**

Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, Drug interactions. Pharmacokinetics and

pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

References:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991.
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B. Jaiswal, Vallab Prakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. L and Yu ABC, 2nd edition, Connecticut Appleton Century Crofts, 1985.
4. Textbook of Biopharmaceutics and Pharmacokinetics, DR. Shobha Rani R. Hiremath,Prism Book.
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc, New York, 1982.
6. Current Concepts in Pharmaceutical Sciences:Biopharmaceutics, Swarbrick. J,Leaand Febiger, Philadelphia, 1970.
7. Clinical Pharmacokinetics, Concepts and Applications, 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995.
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989.
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John.G.Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekaran, Philip J Breen, Pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Scope:

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire Drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the Drug development process are provided to help the students to clarify the concepts.

Objectives:

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

Course outcomes:
Upon completion of this course, the students will be able to:

CO1: Describe the history of computers in pharmaceutical research and development

CO2: List out the advantages and disadvantages of computer aided drug development

CO3: Explain the key principles of QbD

CO4: Describe the basic screening designs and expanded designs

CO5: Discuss the risk-based regulatory framework

CO6: Describe the optimization techniques in pharmaceutical formulation

CO7: Describe the QbD guidance review (ICH Q8/Q9/Q10/Q11)

CO8: Describe the QbD development process and flow/logic

CO9: Distinguish between Full vs fractional factorials design

CO10: Identify critical quality attributes (CQAs) and critical process parameters (CPPs)

CO11: Identify and suggest suitable process analytical tools for a given manufacturing environment

CO12: Interpret and practice the fundamental concepts of computational modeling of drug disposition

CO13: Implement a basic design of experiments (DoE) approach

CO14: Apply quality principles and employ quality parameters.

CO15: Develop and optimize process control strategies, including real-time release testing.

Theory **60 hrs**

1. a. Computers in Pharmaceutical Research and Development: **12 hrs**

A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

b. Quality-by-Design in Pharmaceutical Development:
Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

2. Computational Modeling of Drug Disposition: **12 hrs**

Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

3. Computer-aided formulation development: 12 hrs

Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion Drug Carriers, Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis.

4. a. Computer-aided biopharmaceutical characterization: 12 hrs

Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, *In vitro* dissolution and *in vitro- in vivo* correlation, Biowaiver considerations.

b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems.

5. Artificial Intelligence (AI), Robotics and Computational fluid dynamics: 12 hrs

General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

References:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS (MPH 204T)

Scope:

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives:

Upon completion of the course, the students shall be able to understand:

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market.
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals.
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course outcomes:

Upon completion of the course, the students shall be able to:

CO1: Discuss the key and role of ingredients used in cosmetics and cosmeceuticals.

CO2: Describe current cosmetics technologies in the market.

CO3: Categorize ingredients used in cosmetics.

CO4: Exhibit knowledge to optimize the technology of cosmetic product production

CO5: Explain the basic science to develop cosmetics and cosmeceuticals.

CO6: Describe chemical structure and properties of cosmetic materials, their compatibility and the possibility of interaction.

CO7: Exhibit knowledge to develop cosmetics and cosmeceuticals with desired safety, stability, and efficacy.

CO8: Explain US FDA cosmetic and drug regulations

CO9: Discuss about the raw materials used in cosmetics

CO10: Prepare various cosmeceuticals

CO11: Demonstrate knowledge of relevant governmental regulations (primarily US) which will help confirm product compliance.

CO12: Develop cosmetic and personal care products

CO13: Formulate cosmetics to meet desired product attributes using an understanding of the physical and chemical basis of these formulations.

Theory **60 hrs**

1. Cosmetics – Regulatory: **12 hrs**

Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

2. Cosmetics - Biological aspects: **12 hrs**

Structure of skin relating to problems like Dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

3. Formulation Building blocks: **12 hrs**

Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars.

Perfumes;Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4. Design of cosmeceutical products: 12 hrs

Sun protection, sunscreens classification and regulatory aspects. Addressing Dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odour, and dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

5. Herbal Cosmetics: 12 hrs

Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

References:

1. Harry's Cosmeticology, 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach, 3rd edition.
5. Cosmetic and Toiletries recent suppliers catalogue.
6. Cosmetic, Toiletry, and Fragrance Association (CTFA) directories.

PHARMACEUTICS PRACTICAL II (MPH 205P)

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation.
2. Preparation and evaluation of Alginate beads.
3. Formulation and evaluation of gelatin /albumin microspheres.
4. Formulation and evaluation of liposomes/niosomes.
5. Formulation and evaluation of spherules.
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands.
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug.
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline R software.
11. *In vitro* cell studies for permeability and metabolism.
12. DoE Using Design Expert ® Software.
13. Formulation data analysis Using Design Expert ® Software.
14. Quality-by-Design in Pharmaceutical Development.
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics.
16. Computational Modeling of Drug Disposition.
17. To develop Clinical Data Collection manual.
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams.
20. Development and evaluation of Shampoo and Toothpaste base.
21. To incorporate herbal and chemical actives to develop products.
22. To address dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.

M.PHARM PHARMACEUTICAL QUALITY ASSURANCE (MQA)

PROGRAM OUTCOMES:

Upon completion of the course, student shall be able to:

PO1: Develop, apply, revise, and maintain quality standards for processing materials into partially finished or finished products.

PO2: Perform project documentation audits and conduct supervisory review and approval and issue audit reports.

PO3: Review SOPs (standard operating procedures), forms and formats applicable/originated at USP-India.

PO4: Implement and follow Quality Management systems and document control.

PO5: Conduct internal audits independently / with a team of auditors, prepare reports and assess adequacy of CAPA.

PO6: Conduct cGMP site audits at of dietary supplements, active pharmaceutical ingredient (API), excipient, and dietary ingredient manufacturing sites, according to the appropriate cGMP guidelines and USP program requirements.

PO7: Coordinate and monitor the tasks in the laboratories and consults in the design and development of clinical trials.

PO8: Take up opportunities in fields like environment, biomedicine, computer and software testing, etc.

SEMESTER - I
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA 101T)

Scope:
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of Drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives:
After completion of course, the student will be able to know about:

- The analysis of chemicals and excipients.
- The analysis of various Drugs in single and combination dosage forms.
- Theoretical and practical skills of the instruments.

Course Outcomes
Upon completion of the course, the student shall be able to

CO1: Select the method for the analysis of drugs and chemicals

CO2: Understand the principle and theory involved in the various instrumental techniques

CO3: Know the various chromatographic techniques involved in the analysis of excipients and drugs

CO4: Acquire the knowledge and practical skills required to analyse drugs

CO5: Interpret the data obtained in various spectroscopic methods

CO6: Explain the applications of instrumental techniques in various fields

CO7: Apply instrumental and non-instrumental techniques in the analysis of different formulations

CO8: Perform qualitative and quantitative analysis of pharmaceuticals using various analytical techniques

Theory **60 hrs**

1. a. **UV-Visible spectroscopy**: **10 hrs**

Introduction, Theory, Laws, and Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect, Applications of UV-Visible spectroscopy, Difference / Derivative spectroscopy.

b. **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of Drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy **10 hrs**

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR, Applications of NMR spectroscopy.

3. Mass Spectroscopy **10 hrs**

Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

4. Chromatography **10 hrs**

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of Drug from excipients, data interpretation and applications of the following:

a. Paper Chromatography

b. Thin Layer chromatography

c. High Performance Thin Layer Chromatography

d. Ion exchange chromatography
e. Column chromatography
f. Gas chromatography
g. High Performance Liquid chromatography
h. Ultra High Performance Liquid chromatography
i. Affinity chromatography
j. Gel Chromatography

5. a**. Electrophoresis: 20 hrs**

Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

i. Paper electrophoresis, ii. Gel electrophoresis, iii. Capillary electrophoresis, iv. Zone electrophoresis, v. Moving boundary electrophoresis, vi. Iso-electric focusing.

b. **X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

c. **Radio Immunological Assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.

d. **Potentiometry:**

i. Principle, working, Ion selective Electrodes and Application of potentiometry.

ii. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation, advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

Thermal gravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

References:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F.James Holler, Timothy A.Nieman,5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edition, P.S/Kalsi, Wiley Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K. A.Connors, 3rd Edition, John Wiley & Sons, 1982.

QUALITY MANAGEMENT SYSTEMS (MQA 102T)

Scope:
This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Objectives:
At completion of this course it is expected that students will be able to understand:
- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of Drug and Drug substances
- Statistical approaches for quality

Course outcomes:
Upon completion of the course, the student shall be able to

CO1: Explain the salient contributions of Quality Gurus like Deming, Juran and Crosby.

CO2: Discuss about quality management systems and its implementation in a pharmaceutical Industry.

CO3: Comprehend the ISO standards and able to conduct an internal quality audit.

CO4: Express their knowledge on regulation and phases of quality certification system.

CO5: Discuss the stability testing as per ICH guidelines of drug substances and drug products.

CO6: Demonstrate the capability of making quality process for the selected process by using statistical charts.

CO7: Identify deviation and reduce errors by performing corrective and preventive action.

CO8: Identify the key aspects of the quality improvement cycle and to select and use appropriate tools and techniques for controlling, improving and measuring quality.

Theory **60 hrs**

1. Introduction to Quality: **12 hrs**

Evolution of Quality, Definition of Quality, Dimensions of Quality.
Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality.
Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers.

Case studies.
Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimizing costs, preventing cost of quality.

2. Pharmaceutical quality Management: 12 hrs

Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

3. Six System Inspection model: 12 hrs

Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection.
Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS),Out of Trend(OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

4. Drug Stability: 12 hrs

ICH guidelines for stability testing of Drug substances and Drug products. Study of ICH Q8, Quality by Design and Process development report.
Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

5. a. Statistical Process control (SPC): 12 hrs

Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

b. Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking:

Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

References:

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000.
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002.
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report by Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001.
4. Corporate Culture and the Quality Organization by James W. Fairfield- Sonn, Quorum Books, 2001.

5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997.
6. The Quality Toolbox, 2nd edition, Nancy R. Tague, ASQ Publications.
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications.
8. Root Cause Analysis- The Core of Problem Solving and Corrective Action. Duke Okes, 2009, ASQ Publications.

QUALITY CONTROL AND QUALITY ASSURANCE (MQA 103T)

Scope:

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives:

Upon completion of this course the student should be able to:

- Understand the cGMP aspects in a pharmaceutical industry.
- To appreciate the importance of documentation.
- To understand the scope of quality certifications applicable to Pharmaceutical industries.
- To understand the responsibilities of QA & QC departments.

Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Acquire knowledge about Good Laboratory Practice, GMP and ICH Guidelines with special emphasis on Q series guidelines.

CO2: Illustrate the protocol for conduct of non clinical testing and control on animal house in Good Laboratory Practices.

CO3: Describe the Good Warehousing Practice with respect to organization and personnel responsibilities.

CO4: Understand the cGMP guidelines according to schedule M and USFDA, Pharmaceutical Inspection Convention (PIC), WHO and EMEA.

CO5: Describe the In process and finished quality control products quality control of various pharmaceuticals.

CO6: Explain the importance of three tier documentation and records in quality management system.

CO7: Detail the various aspects of manufacturing operations and controls in pharmaceutical industry.

CO8: Acquire knowledge of intellectual property rights, concept of trade mark, copyright and patents.

Theory **60 hrs**

1. Introduction: 12 hrs

Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q- series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of nonclinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, Drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

12 hrs

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials.

In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products.

4. Documentation in pharmaceutical industry: 12 hrs

Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents.

Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.

5. Manufacturing operations and controls: 12 hrs

Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, Drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.

Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

References:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rdrevised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – Vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines.
8. ISO 9000 and total quality management.
9. The Drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, 6th edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Textbook of Pharmaceutical Packaging Technology by Atul Kaushik,Bhaskar Chaurasia,Virendra Dhakar, Published by CBS Publishers & Distributors Pvt. Ltd., New Delhi.
15. Schedule M and Schedule N. http://www.cdsco.nic.in/writereaddata/ScheduleM(GMP)6.pdf& https://www.irs.gov/pub/irs-pdf/f990sn.pd

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)

Scope:

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods,required following candidate Drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Objectives:

Upon completion of this course the student should be able to:

- To understand the new product development process.
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D.
- To elucidate necessary information to transfer technology of existing products between various manufacturing places.

Course outcomes:

Upon completion of the course, the student shall be able to:

CO1.Explain the different stages of drug discovery and development process.

CO2. Explain the role of the Food and Drug Administration (FDA) in the drug development and review process in the United States

CO3. Classify clinical trials and explain the stages of clinical trials from phase zero to phase IV.

CO4. Describe the essential documents related to IND, NDA and ANDA Submission to FDA.

CO5. Discuss bioequivalence and its ratings specified in the Orange book.

CO6. Discuss the primary objective of post marketing studies and to develop information about drug effects under customary conditions of drug use.

CO7. Explain the physical characteristics of drug and its compatibility with common excipients.

CO8. Discuss polymorphism and describe the techniques used in the study of the properties of crystals during preformulation studies.

CO9. Explain the concept of pilot plant scale up study

CO10. Analyse the stability and quality control testing of solids, liquids, semisolids and parenteral dosage forms.

CO11. Evaluate and perform the QC testing of Pharmaceutical packaging materials.

CO12. Describe the qualitative and quantitative technology models

CO13. Identify, Analyse and solve the problems during technology transfer implementation

CO14. Explain how Technology transfer can be effectively performed from R & D to production.

.

Theory **60 hrs**

1. Principles of Drug discovery and development: **12 hrs**

Introduction,Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

2. Pre-formulation studies: **12 hrs**

Introduction/concept,organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of drugs: Surfactants & its importance, co-solvency. Techniques for the study of crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.

3. Pilot plant scale up: **12 hrs**

Concept, significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

4. Pharmaceutical packaging: 12 hrs

Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.

Quality control test: Containers, closures and secondary packing materials.

5. Technology transfer: 12 hrs

Development of technology by R &D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.

Documentation in technology transfer: Development report, technology transfer plan and exhibit.

References:

1. The process of new Drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989), Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V.Patrevale, John I. Disouza, Maharukh T. Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19thedition (1995)Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way ‘Pure and applied Pharmacy’ by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1stedition(Reprint 2006). Taylor and Francis. London and New York.

PHARMACEUTICALQUALITY ASSURANCE PRACTICAL - I (MQA 105P)

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer.
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry.
3. Experiments based on HPLC.
4. Experiments based on Gas Chromatography.
5. Estimation of Riboflavin/Quinine sulphate by fluorimetry.
6. Estimation of sodium/potassium by flame photometry or AAS.
7. Case studies on

- Total Quality Management
- Six Sigma
- Change Management/ Change control.
- Out of Specifications (OOS)
- Out of Trend (OOT)
- Corrective & Preventive Actions (CAPA)
- Deviations

8. Development of Stability study protocol.
9. Estimation of process capability.
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs.
12. Testing of related and foreign substances in Drugs and raw materials.
13. To carry out pre-formulation study for tablets, parenterals (2 experiments).
14. To study the effect of pH on the solubility of Drugs, (1 experiment).
15. Quality control tests for Primary and secondary packaging materials.
16. Accelerated stability studies (1 experiment).
17. Improved solubility of Drugs using surfactant systems (1 experiment).
18. Improved solubility of Drugs using co-solvency method (1 experiment).
19. Determination of pKa and Log P of Drugs.

SEMESTER - II
HAZARDS AND SAFETY MANAGEMENT (MQA 201T)

Scope:

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provide the principle based approach to solve the complex tribulations.

Objectives:

At completion of this course it is expected that students will be able to:

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry.
- Provide comprehensive knowledge on the safety management.
- Empower ideas to clear mechanism and management in different kinds of hazard management system.
- Teach the method of Hazard assessment, procedure, methodology to provide safe industrial atmosphere.

Course outcomes:

Upon completion of the course, student shall be able to:

CO1: Acquire knowledge about the nature and degree of pollution from various sources in environment.

CO2: Describe the various Natural Resources and efforts on recovery of ecosystems.

CO3: Identify and control environmental hazards based on air, water, soil and radioisotopes.

CO4: Understand basic firefighting concepts and risk management approach.

CO5: Classify different classes of fires and identify appropriate fire extinguisher for each class of fire.

CO6: Describe sources of chemical based hazards and control measures as per regulations.

CO7: Elaborate the management of toxic gases, oxygen displacing gases and over-Exposure to chemicals.

CO8: Identify and detail all the possible **hazards** which include mechanical electrical, thermal and process hazards.

CO9: Understand the theory of preventive and protective management from fires and explosion.

CO10: Get knowledge of Preliminary Hazard Analysis and assessment in pharmaceutical industry.

Theory **60hrs**

1. Multidisciplinary nature of environmental studies: **12 hrs**

Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems.

a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources.

Ecosystems: Concept of an ecosystem and structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

2. Air based hazards: **12 hrs**

Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

3. Chemical based hazards: **12 hrs**

Sources of chemical hazards, Hazards of organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-exposure to chemicals and TLV concept.

4. Fire and Explosion: **12 hrs**

Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

5. Hazard and risk management: 12 hrs

Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools, Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

References:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad 380013, India.
4. Hazardous Chemicals: Safety Management and Global Regulations,T.S.S.Dikshith, CRC press.

PHARMACEUTICAL VALIDATION (MQA 202T)

Scope:

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives:

At completion of this course, it is expected that students will be able to understand:

- The concepts of calibration, qualification and validation.
- The qualification of various equipments and instruments.
- Process validation of different dosage forms.
- Validation of analytical method for estimation of drugs.
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals.

Course outcomes:

Upon completion of this topic, students should be able to

CO1: Explain the aspect of validation
CO2: Carryout the validation of manufacturing processes
CO3: Apply the knowledge of validation to instruments and equipments
CO4: Validate the manufacturing facilities
CO5: Prepare User Requirement Specification
CO6: Describe the requirements concerning Factory Acceptance Test) and Site Acceptance Test
CO7: Carry out the Qualification of Manufacturing Equipments and Laboratory equipments
CO8: Prepare Validation Master Plan and Validation Protocol
CO9: Prepare Qualification protocol
CO10: Document Qualification report
CO11: Carry out the Qualification of Analytical Instruments and calibration of Glasswares
CO12: Perform validation of Utility systems
CO13: Perform cleaning Validation
CO14: Carry out cleaning Method development and Validation

CO15: Perform validation of analytical method used in cleaning.
CO16: Perform cleaning of Equipment, cleaning of Facilities.
CO17: Define the parameters used for analytical method validation,
CO18: Understand the purpose of analytical method validation and the principles of measurement uncertainty.
CO19: Perform the Validation of analytical method as per ICH guidelines and USP
CO20: Describe the important aspects of Electronic records and digital significance
CO21: Describe the GAMP guidelines
CO22: Understand current and emerging issues relating to the intellectual property protection
CO23: Understand the various types of IPR, including patents, Copyright and Trademark
CO24: File a patent application

Theory **60 hrs**

1. Introduction to validation: **10 hrs**

Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.
Qualification:User requirement specification, Design qualification, Factory Acceptance Test (FAT) / Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).

2. Qualification of manufacturing equipment: **10 hrs**

Dry Powder Mixers, Fluid Bed and Tray Dryers, Tablet Compression (Machine), Dry heat sterilization / Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.
Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

3. Qualification of laboratory equipments: **10 hrs**

Hardness tester, Friability test apparatus, Tap density tester, Disintegration tester, Dissolution test apparatus.
Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

4. Process Validation& Cleaning Validation: **20 hrs**

a. Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.
b. Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).
Validation of facilities in sterile and non-sterile plant. Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP.

5. General Principles of Intellectual Property: 10 hrs

Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines.Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

References:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco,
5. (Marcel Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd edition, Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider.
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press.
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare.
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press.
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press.

AUDITS AND REGULATORY COMPLIANCE (MQA 203T)

Scope:

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives:

Upon completion of this course the student should be able to:

- To understand the importance of auditing.
- To understand the methodology of auditing.
- To carry out the audit process.

- To prepare the auditing report.
- To prepare the check list for auditing.

Course outcomes:
Upon completion of the course, the student shall be able to:

CO1: Explain why external audits and other types of assurance services are conducted.

CO2: Discuss the duties of auditors and other assurance providers.

CO3: List out the procedures for auditing in a microbiology laboratory.

CO4: Prepare the checklist for vendor audit, bulk pharmaceuticals and production processes.

CO5: Organize the checklist for auditing engineering departments like HVAC and ETP plant.

CO6: Perform an internal quality audit in a pharmaceutical environment.

Theory **60 hrs**

1. Introduction: **12 hrs**

Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies.

2. Role of quality systems and audits in pharmaceutical manufacturing environment: **12hrs**

cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for Drug industries.

3. Auditing of vendors and production department: **12 hrs**

Bulk Pharmaceutical Chemicals and packaging material Vendor audit Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

4. Auditing of Microbiological laboratory: **12 hrs**

Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

5. Auditing of Quality Assurance and engineering department: **12 hrs**

Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

References:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, NormanA. Hodges, Stephen P. Denyar. CRC Press. 2000.

4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca- Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T)

Scope:

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives:

At completion of this course it is expected that students will be able to understand:

- The common practice in the pharmaceutical industry developments, plant layout and production planning.
- Will be familiar with the principles and practices of aseptic process technology, nonsterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing.

Course Outcomes:

Upon completion of the course the student shall be able to:

CO1: Understand the common practice in the pharmaceutical industry developments with respect to legal requirements and licensing process.

CO2: Explicate Pharmaceutical industry developments with respect to plant layout and factors influencing plant layout and production planning of API and Formulation Industry.

CO3: Understand and explain Aseptic process technology and Advanced sterile product manufacturing technology

CO4: Understand the Process automation in sterile manufacturing and lyophillization technology in Pharmaceutical industry

CO5: Understand and Explain the concept of Non sterile manufacturing process technology, Advance non-sterile solid product manufacturing technology and coating technology and.

CO6: Acquire knowledge of various containers and closures used in pharmaceuticals and their evaluation procedures

CO7: Explain the concept and importance of Quality by design (QbD) in pharmaceutical industry

CO8: Explain the concept and importance of process analytical technology (PAT) in pharmaceutical manufacturing.

Theory **60 hrs**

1. Pharmaceutical industry developments: **12 hrs**

Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing.

Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.

Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

2. Aseptic process technology: 12 hrs

Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).

Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

Process Automation in Pharmaceutical Industry: With specificreference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP),Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).

Lyophilization technology: Principles, process, equipment.

3. Non sterile manufacturing process technology: 12 hrs

Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).

Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production:Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating technology: Process, equipments, particle coating, fluidized bed coating, and application techniques. Problems encountered.

4. Containers and closures for pharmaceuticals: 12 hrs

Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.

5. Quality by design (QbD) and process analytical technology (PAT): 12 hrs

Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for Drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a Driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

References:

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of Industrial pharmacy, 3rd edition, Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5thedition, B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: Tablets Vol. I-III, 2nd edition, CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th edition, Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA, NewYork.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL – II (MQA 205P)

1. Organic contaminants residue analysis by HPLC.
2. Estimation of Metallic contaminants by Flame photometer.
3. Identification of antibiotic residue by TLC.
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO2 using Colorimetric method.
7. Qualification of following Pharma equipment
    a. Autoclave
    b. Hot air oven
    c. Powder Mixer (Dry)
    d. Tablet Compression Machine
8. Validation of an analytical method for a Drug.
9. Validation of a processing area.
10. Qualification of at least two analytical instruments.
11. Cleaning validation of one equipment.
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester).
13. Check list for Bulk Pharmaceutical Chemicals vendors.
14. Check list for tableting production.
15. Check list for sterile production area.
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile.
18. Case study on application of QbD.
19. Case study on application of PAT.

M.PHARM PHARMACOGNOSY (MPG)

PROGRAM OUTCOMES:

Upon completion of the Program, the student shall be able to:

PO1: Demonstrate comprehension of Good Agricultural Practices with reference to Medicinal Plant Cultivation and of Phytochemical finger printing, spectral structural elucidation techniques and essential modern pharmaceutical analytical techniques for quality control of natural products.

PO2: Be competent in methods of isolation, purification, phytochemical and pharmacological profile as well as pharmacovigilance of essential marine/phytopharmaceuticals and nutraceuticals

PO3: Understand the history of natural product drug development through biogenetic pathway radio tracing, extraction and phytochemical processing techniques upto significance of herbal drug clinical trials and the protocols for the same

PO4: List the essential infrastructural and regulatory requirements and protocols for establishing a herbal drug production unit and the concept of quality management systems with respect to herbals

PO5: Explain National and International Patent laws, Constitutional differences among various herbal drug pharmacopoeias, Export-Import Policy and Global marketing strategies applicable to herbal drugs

PO6: Show how comprehensive knowledge on various medicinal plant biotechnological techniques applicable to culture, elicitation and harvest of secondary metabolites

PO7: Be competent in the know how pertaining to Ethnobotany, Ethnopharmacology, toxicity of herbal remedies and their adulteration as well as methods of detection inclusive of development of analytical profiles and screening for bioactivity

PO8: Will have a fundamental grasp of the principles of Ayurveda, Siddha and Unani systems of medicine along with familiarity of the practice of Aromatherapy, Naturopathy and Yoga

PO9: Show how techniques of herbal drug formulation development as per various systems of medicine.

PO10: Understand components and sections of the Drugs and Cosmetics act such as Schedule T that govern herbal drug manufacture and control,background of various national initiatives such as TKDL and Bills pertaining to herbal drug regulations in India

SEMESTER - I
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPG 101T)

Scope:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of Drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives:

Upon completion of course, the student shall be able to know:

- The analysis ofchemicals and excipients.
- The analysis of various Drugs in single and combination dosage forms.
- Theoretical and practical skills of the instruments.

Course outcomes:

Upon completion of the course, the student shall be able to :

CO1: Select the method for the analysis of drugs and chemicals.

CO2: Understand the principle and theory involved in the various instrumental techniques.

CO3: Know the various chromatographic techniques involved in the analysis of excipients and drugs.

CO4: Acquire the knowledge and practical skills required to analyse drugs.

CO5: Interpret the data obtained in various spectroscopic methods.

CO6: Explain the applications of instrumental techniques in various fields.

CO7: Apply instrumental and non-instrumental techniques in the analysis of different formulations.

CO8: Perform qualitative and quantitative analysis of pharmaceuticals using various analytical techniques.

Theory **60 hrs**

1. a. **UV-Visible spectroscopy**: **10 hrs**

Introduction, Theory, Laws, and Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect, Applications of UV-Visible spectroscopy, Difference / Derivative spectroscopy.

b. **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of Drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy **10 hrs**

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR, Applications of NMR spectroscopy.

3. Mass Spectroscopy **10 hrs**

Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

4. Chromatography **10 hrs**

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of Drug from excipients, data interpretation and applications of the following:

a. Paper Chromatography
b. Thin Layer chromatography
c. High Performance Thin Layer Chromatography
d. Ion exchange chromatography
e. Column chromatography
f. Gas chromatography
g. High Performance Liquid chromatography
h. Ultra High Performance Liquid chromatography
i. Affinity chromatography
j. Gel Chromatography

5. a**. Electrophoresis:** **20 hrs**

Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

i. Paper electrophoresis, ii. Gel electrophoresis, iii. Capillary electrophoresis, iv. Zone electrophoresis, v. Moving boundary electrophoresis, vi. Iso-electric focusing.

b. **X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

c. **Radio Immunological Assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.

d. **Potentiometry:**

i. Principle, working, Ion selective Electrodes and Application of potentiometry.

ii.Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation, advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

Thermal gravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

References:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rdedition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edition, P.S/Kalsi, Wiley EasternLtd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOGNOSY – I (MPG 102T)

Scope:

To learn and understand the advances in the field of cultivation , isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals ,medicinal uses and their health benefits.

Objectives:

Upon completion of the course, the student shall be able to know the:

- Advances in the cultivation and production of drugs.
- Various phyto-pharmaceuticals and their source, utilization and medicinal value.
- Various nutraceuticals/herbs and their health benefits.
- Drugs of marine origin.
- Pharmacovigilance of drugs from natural origin.

Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Understand about Good agricultural practices of medicinal plants

CO2: Explain exsitu and insitu conservation of medicinal plants

CO3: Explain the different methods of isolation and purification of drugs of marine origin

CO4: Recognize taxonomical identification and chemical screening of marine natural products

CO5: Explain health benefits of various nutraceuticals including their regulatory aspects

CO6: Describe the health benefits of various phytopharmaceuticals including their source utilization & medicinal value

CO7: Explain the WHO & AYUSH guidelines for safety monitoring of natural medicine

CO8: Recognize Drug-Drug & Drug-food interactions

CO9: Perform different methods of extraction of crude drugs

CO10: Develop fingerprint of different selected medicinal plant extracts

Theory **60 hrs**

1. Plant Drug Cultivation: **12 hrs**

General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation practices,

Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and In- situ conservation of medicinal plants.

2. Marine Natural Products: 12 hrs

General methods of isolation and purification, Study of Marine toxins, Recent advances in research on marine Drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.

3. Nutraceuticals: 12 hrs

Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibers, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following:

i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.

4. Phytopharmaceuticals: 12 hrs

Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
b) Limonoids – i) d-Limonene ii) α – Terpineol
c) Saponins – i) Shatavarins
d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
e) Phenolic acids- Ellagic acid
f) Vitamins - Tocotrienols and Tocopherols
g) Miscellaneous - Andrographolide, Glycolipids, Guggulipids, Withanolides, Vasocine, Taxol

5. Pharmacovigilance of Drugsof Natural Origin: 12 hrs

WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio Drug adverse reactions, bio Drug-Drug and bio Drug-food interactions with suitable examples.

References (Latest Editions of):

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy-Tyler, Brady, Robbers.
3. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II.
4. Text Book of Pharmacognosy by T.E. Wallis.
5. Marine Natural Products-Ernesto Fattorusso, ,William H. GerwickOrazio Taglialatela- Scafati, Springer Netherlands, 2012.
6. Natural products: A lab guide by Raphael Ikan, Academic Press 1991.
7. Glimpses of Indian Ethanopharmacology, P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products- Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.

12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor.
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu.University Press, 2001. 237.
14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998.
15. Recent Advances in Phytochemistry- Vol.1&4: Scikel Runeckles- Appleton Centurycrofts.
16. Text book of Pharmacognosy, C.K. Kokate, Purohit, Ghokhale, Nirali Prakashan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.
18. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
19. Clinical Dietitics and Nutrition, F.P. Antia, Oxford University Press, Delhi.
20. Nutraceutical and Functional Food Regulations in the United States and around the world edited by Debasis Bagchi,Academic Press, Elseveir, 2008.
21. Functional foods and Nutraceuticals, Rotimi E. Aluko, Springer, NewYork.
22. Functional Foods and Dietary Supplements: Processing Effects and Health Benefitsedited by Athapol Noomhorm, Imran Ahmad, Anil K. Anal, John Wiley & Sons, 2014.
23. Handbook of Nutraceuticals Volume I: Ingredients, Formulations and Applications edited by Yashwant Vishnupant Pathak, CRC Press, London, 2009.
24. Nutraceuticals: Efficacy, Safety and Toxicityedited by Ramesh C. Gupta, Elsevier, London, 2016.
25. Phytomedicine Journal - Elsevier.
26. Phytotherapy Research Journal - Elsevier.
27. Planta Medica – International Journal

PHYTOCHEMISTRY (MPG 103T)

Scope:

Students shall be equipped with the knowledge of natural product drug discovery and will be able to extract, isolate, and identify the Phytoconstituents

Objectives:

Upon completion of the course, the student shall be able to know the:

- Different classes of Phytoconstituents, their biosynthetic pathways, their properties, extraction and
  general process of natural product drug discovery.
- Phytochemical fingerprinting and structure elucidation of Phytoconstituents.

Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Enumerate the biosynthetic pathways

CO2: Classify the phyto constituents and their properties.

CO3: Explain the phytochemical fingerprinting

CO4: Illustrate the structure elucidation of phytoconstituents

CO5: Discuss about Drug discovery and development

CO6: Classify the different techniques involved in extraction

Theory **60 hrs**

1. Biosynthetic Pathways and Radio Tracing Techniques: **12hrs**

Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals.

a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vinca alkoloids.
b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercetin.
c) Steroids: Hecogenin, guggulosterone and withanolides.
d) Coumarin: Umbelliferone.
e) Terpenoids:Cucurbitacins.

2. Drug discovery and development: **12hrs**

History of herbs as source of Drugs and Drug discovery, the lead structure selection process, structure development, product discovery process and Drug registration, Selection and optimization of lead compounds with suitable examples from the following sources:
Artemesinin and Andrographolides.Clinical studies emphasizing on phases of clinical trials, protocol design for lead molecules.

3. Extraction and phytochemical studies: **12 hrs**

Recent advances in extractions with emphasis on selection of method ,choice of solvent for extraction, successive and exhaustive extraction. Other methods of extraction commonly used like microwave assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, Supercritical fluid extraction (SFE) techniques including preparative HPLC and Flash column chromatography, Counter current Column chromatography.

4. Phytochemical finger printing: **12 hrs**

HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents.

5. Structure elucidation of the following compounds by spectroscopic techniques: **12 hrs**

UV, IR, MS, NMR (^{1}H, ^{13}C)

a. Carvone, Citral, Menthol
b. Luteolin, Kaempferol
c. Nicotine, Caffeine
d. Glycyrrhizin.

References (Latest Editions of):

1. Organic Chemistry by I.L. Finar Vol.II.
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of Drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvolds text book of OrganicMedicinal and Pharmaceutical Chemistry by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edition 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui
10. Organic Chemistry of Natural Products, Vol. 1& 2. Gurdeep R Chatwal.

11. Chemistry of Natural Products- Vol. 1 onwards IUPAC.
12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley &Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Interceptt Ltd., New York, 1999.
16. A Guide to Modern Techniques of Plant Analysis by Jeffrey B. Harborne.
17. Chemistry of Natural Products, By Sujata V. Bhat, B.A. Nagasampagi, Meenakshi Sivakumar, Springer, India, 2005.
18. Introduction to Natural Products Chemistry, edited by Rensheng Xu, Yang Ye, Weimin Zhao, Science Press, Beijing, 2010.
19. Natural Products Chemistry: Sources, Separations and Structures, By Raymond Cooper, George Nicola, CRC Press, 2015.
20. Drug Discovery from Natural Products, edited by Ana Martinez, Olga Genilloud, Francisca Vicente, RSC Publishing, 2012.
21. Natural Products: Drug Discovery and Therapeutic Medicine, edited by Lixin Zhang, Arnold L. Demain, Humana Press, New Jersy, 2005.
22. Case Studies in Modern Drug Discovery and Development, edited by Xianhai Huang, Robert G. Aslanian, John Wiley & Sons, New Jersey, 2012.
23. Discovery and Development of Antidiabetic Agents from Natural Products, By Goutam Brahmachari, Elsevier.
24. The Journal of Ethnopharmacology.
25. The Journal of Phytopharmacology.
26. The Journal of Phytopharmacy.

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG 104T)

Scope:

To understand the Industrial and commercial potential of Drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and Drugs of natural origin.

Objectives:

Upon completion of the course, the student shall be able to know:

- The requirements for setting up the herbal/natural Drug industry.
- The guidelines for quality of herbal/natural medicines and regulatory issues.
- The patenting/IPR of herbals/natural Drugs and trade of raw and finished materials.

Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Explain the requirements for setting up the herbal/natural Drug industry.

CO2: Describe the guidelines for quality of herbal/natural medicines and regulatory issues.

CO3: Explain the procedure involved in patenting/IPR of herbals/natural Drugs and trade of raw and finished materials.

CO4: Explain various parameters of monographs of herbal drugs as per Pharmacopoeial methods.

CO5: Identify bioactive compounds from plant extracts.

CO6: Perform monograph of herbal drugs as various pharmacopeial methods viz. IP, USP, Ayurveda, Siddha & Unani Pharmacopoeia.

CO7: Formulate different dosage forms and their standardization.

CO8: Explain stability testing of natural products.

Theory **60 hrs**

1. Herbal Drug Industry: **12 hrs**

Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management of herbals.

2. Regulatory Requirements for Setting Herbal Drug Industry: **12hrs**

Global marketing management,Indian and International patent law as applicable to herbal drugs and natural products.
Export - Import (EXIM) policy, TRIPS.
Quality assurance in herbal/natural drug products.
Concepts of TQM, GMP, GLP, ISO-9000.

3. Monographs of Herbal Drugs: **12 hrs**

General parameters of monographs of herbal Drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

4. Testing of Natural Products and Drugs: **12 hrs**

Herbal medicines - Clinical laboratory testing. Stability testing of natural products, protocols.

5. Patents: **12hrs**

Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non- obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.

References (Latest Editions of):

1. Herbal Drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), 1st Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal Drugs by Pulok K Mukarjee (2002), Business HorizonsPharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.

7. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
8. Plant Drug analysis by H. Wagner and S.Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.
11. Herbal Medicine. Expanded Commission E Monographs by M. Blumenthal, (2004), IST Edition.
12. Drug Formulation Manual by D.P.S. Kohli and D.H.Shah (1998), Eastern Publisher, NewDelhi.
13. The Ayurvedic Pharmacopoeia of India part – I volume – IX Government of India.Ministryof Ayush 2016 published by pharmacopoeia commission for Indian medicine & Homoeopathy, Ghaziabad. 2016.
14. The Siddha Pharmacopoeia of India part – I volume – I, 1st edition Government of India Ministry of health and family welfare department of Ayurveda, yoga & naturopathy, Unani,Siddha and homoeopathy (Ayush).
15. American Herbal Pharmacopoeia3051 Browns Lane Soquel, CA 95073.
16. British Herbal Pharmacopoeia.
17. WHO Human Resources Management (HRD) World Health Organization Avenue Appia 20. CH - 1211, Geneva 27, Switzerland.
18. Chinese Journal of Integrative Medicine.

PHARMACOGNOSY PRACTICAL I (MPG I05P)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Visible Spectrophotometer.
2. Analysis of recorded spectra of simple Phytoconstituents.
3. Experiments based on Gas Chromatography.
4. Estimation of sodium/potassium by flame photometry.
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal Drugindustry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
6. Methods of extraction.
7. Phytochemical screening.
8. Demonstration of HPLC- Estimation of glycyrrhizin.
9. Monograph analysis of clove oil.
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts.
12. Formulation of different dosage forms and their standardization.

SEMESTER - II
MEDICINAL PLANT BIOTECHNOLOGY (MPG 201T)

Scope:

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

Objectives:

Upon completion of the course, the student shall be able to:

- Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
- Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants.

Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Demonstrate knowledge on development of plant biotechnology as a source of medicinal agents

CO2: Apply various biotechnological tools suitable for Pharmaceutical sciences

CO3: Explain different tissue culture techniques for micropropagation and secondary metabolite production from medicinal & aromatic plants.

CO4: Apply biotechnological techniques for obtaining and improving the quality of natural products

CO5: Explain the process of genetic engineering in medicinal plants for higher yield of phytopharmaceutics.

Theory **60 hrs**

1. Introduction to plant biotechnology: **12 hrs**

Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology.

2. Different Tissue Culture Techniques: **15 hrs**

Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root ,multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants.

Sterilization methods involved in tissue culture, gene transfer in plants and their applications.

3. Immobilisation techniques & Secondary Metabolite Production: **15 hrs**

Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents.

Precursors and elicitors on production of secondary metabolites.

4. Biotransformation and Transgenesis: **13 hrs**

Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

5. Fermentation Technology: 5hrs

Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest.

References (Latest Editions of):

1. Plant tissue culture, Bhojwani, Vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985.
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham.
15. International Journal of Traditional & Herbal Medicine.

ADVANCED PHARMACOGNOSY –II (MPG 202T)

Scope:

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening.

Objectives:

Upon completion of the course, the student shall be able to know the:

- Validation of herbal remedies.
- Methods of detection of adulteration and evaluation techniques for the herbal drugs.
- Methods of screening of herbals for various biological properties.

Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Explain the validation of herbal remedies.

CO2: Demonstrate the methods of detection of adulteration and evaluation techniques for the herbal Drugs.

CO3: Explain the methods of screening of herbals/formulations for various biological properties.

CO4: Demonstrate the toxicity studies of herbal drugs/formulations as per OECD guidelines

Theory 60 hrs

1. Herbal remedies – toxicity and regulations: 12 hrs

Herbals vs. Conventional Drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues.

2. Adulteration and Deterioration: 12 hrs

Introduction,Types of Adulteration / Substitution of Herbal Drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of Drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations.

3. Ethnobotany and ethnopharmacology: 12 hrs

Ethnobotany in herbal Drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for Drug discovery, Role of Ethnopharmacology in Drug evaluation, Reverse Pharmacology.

4. Analytical profiles of herbal Drugs: 12 hrs

Andrographis paniculata, Boswellia serrata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia.

5. Biological Screening of Herbal Drugs: 12 hrs

Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products, *In vitro* evaluation techniques for Antioxidants, Antimicrobial and Anticancer Drugs*. In vivo* evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.

References (Latest Editions of):

1. Glimpses of Indian Ethno Pharmacology by P. Pushpangadan. Ulf Nyman. V.George Tropical Botanical Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K. Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal Drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II, Career Publication, Nasik, India.
12. Plant Drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publishers, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M. Blumenthal.
15. Herbal Drug Technology by S.S. Agarwal 4M Paridhavi, second Edition 2012, University Press, Hyderabad.
16. Pharmacognosy and Phytochemistry – A Comprehensive Approach by S.L. Deore S.S. Khadabadi&B.A. Baviskar, 2014, Pharma med press, Hyderabad.

17. Drug discovery and Evaluation, Pharmacological assays, Vogel, Hans, 3rd edtion, Springer.
18. Indian Journal of Tradional Knowledge.
19. International journal of Ayurvedic Medicine

INDIAN SYSTEMS OF MEDICINE (MPG 203T)

Scope:

To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani; also, focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

Objectives:

Upon completion of the course, the student shall be able to:

- Understand the basic principles of various Indian systems of medicine
- Know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

Course outcomes:

Upon completion of the course, the student will be able to:

CO1: Describe the basic principles of various Indian systems of medicinelike Ayurveda, Siddha, Homeopathy and Unani

CO2: Prepare and evaluate the formulations of Indian systems of medicine

CO3: Discuss about the clinical research of traditional medicines

CO4: Explain about current good manufacturing practice of Indian systems of medicine and their formulations.

CO5: Confer about quality assurance and challenges in monitoring the safety of herbal medicines.

Theory **60 hrs**

1. **Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine, Different dosage forms of the ISM.**

12 hrs

Ayurveda:

Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude Drugs with references to: Identity, purity and quality.

Siddha:

Gunapadam (Siddha Pharmacology), raw Drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).

2. Naturopathy, Yoga and Aromatherapy practices **12 hrs**

a) Naturopathy - Introduction, basic principles and treatment modalities.

b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama,Meditations and Relaxation techniques.

c) Aromatherapy – Introduction, aroma oils for common problems,carrier oils.

3. Formulation development of various systems of medicine **12 hrs**

Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts.

Standardization, Shelf life and Stability studies of ISM formulations.

4. Schedule T – Good Manufacturing Practice of Indian systems of Medicine **12 hrs**

Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

Quality assurance in ISM formulation industry - GAP, GMP and GLP. Preparation of documents for new drug application and export registration.

Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias.

5. TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU**.** **12 hrs**

References (Latest Editions of):

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, NewDelhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, NewDelhi.
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, SriSatguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
6. Homeopathic Pharmacy: An introduction & Hand book, Steven B. Kayne,Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, British Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine,Pulok K Mukharjee, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Yoga - The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.
12. The Siddha Pharmacopoeia of India part – I volume – I, 1st edition Government of India.
13. Ministry of health and family welfare department of Ayurveda, yoga & naturopathy, Unani, Siddha and homoeopathy (Ayush).
14. Anonymous, 2007, Standardization of single Drugs of Unani Medicine, Part III, 1st editionCentral Council for Research in Unani Medicine (CCRUM), New Delhi.
15. Anonymous, The Unani Pharmacopoeia of India, Part I, Vol I, Department of AYUSH, Ministry of Health and Family Welfare, New Delhi.
16. Medicinal and Aromatic Plants Abstracts.
17. Pharmacological Research.

HERBAL COSMETICS (MPG 204T)

Scope:

This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals.

Objectives:

Upon completion of the course, the student shall be able to:

- Understand the basic principles of various herbal/natural cosmetic preparations.
- Current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities.

Course outcomes:

Upon completion of the course, the student shall be able to:

CO1: Describe the basic principles of various herbal/natural cosmetic preparations

CO2: Enumerate the Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

CO3: List out the herbal cosmetics and their preparations.

CO4: Explain the Cosmeceuticals of herbal and natural origin

CO5: Write down the analysis of Cosmetics, Toxicity screening and test methods

Theory **60 hrs**

1. Introduction: **12 hrs**

Herbal / natural cosmetics, Classification & Economic aspects. Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal / natural cosmetics, Industries involved in the production of Herbal / natural cosmetics.

2. Commonly used herbal cosmetics: **12 hrs**

Raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulations.

3. Herbal Cosmetics: **12 hrs**

Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following: Tonic, Bleaches, Dentifrices,Mouth washes & Tooth Pastes, Cosmetics for Nails.

4. Cosmeceuticals of herbal and natural origin: **12 hrs**

Hair growth formulations-Shampoos, Conditioners, Colorants & hair oils,

Fairness formulations-varnishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants.

5. Analysis of Cosmetics, Toxicity screening and test methods: **12 hrs**

Quality control and toxicity studies as per Drug and Cosmetics Act.

References (Latest Editions of):

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.
9. Drugs and cosmetic act, central Drugs Standard and Control Organization, Director General of Health Services, Ministry of Health and Family Welfare, Government of India.
10. Hand book of Skin diseases by DR. Isidor Neumann.
11. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems, World Health Organization, Geneva, 2004.
12. Phytochemicals and Phytopharmaceuticalsedited by Fereidoon Shahidi, Chi-Tang Ho, AOCS Press, Illinois, 1999.
13. Natural Product Sciences - Journal
14. Medical Herbalism - The Science Principles and Practices Of Herbal Medicine, by David Hoffmann.
15. Journal of Herbal Medicine.
16. Journal of the Science of Food and Agriculture.

PHARMACOGNOSY PRACTICAL II (MPG 205P)

1. Isolation of nucleic acid from cauliflower heads.
2. Isolation of RNA from yeast.
3. Quantitative estimation of DNA.
4. Immobilization technique.
5. Establishment of callus culture.
6. Establishment of suspension culture.
7. Estimation of aldehyde contents of volatile oils.
8. Estimation of total phenolic content in herbal raw materials.
9. Estimation of total alkaloid content in herbal raw materials.
10. Estimation of total flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary.
12. Preparation of certain Aromatherapy formulations.
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products.
14. Evaluation of herbal tablets and capsules.

15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup.

M.PHARM PHARMACEUTICAL ANALYSIS (MPA)

PROGRAM OUTCOMES:

Upon Completion of the Program, the candidate shall be able to:

PO1: Utilize various advanced instrumental techniques for identification, characterization, and quantification of drugs.

PO2: Detect the impurities in pharmaceutical formulations and perform impurity profiling, stability testing of phytopharmceuticals, and their protocol development

PO3: Develop and implement plans and organize work to meet deadlines.

PO4: Understand quality assurance aspects of pharmaceutical industries such as CGMP, Documentations, certifications, GLP, and other regulatory affairs

PO5: Possess knowledge on various hyphenated analytical instrumental techniques for identification, characterization, and quantification of drugs

PO6: Analyze food constituents, finished food products, food additives, pesticides and recognize the regulations of food and legislations of food products

PO7: Perform extraction, separation of drugs from biological samples using different techniques and apply the guidelines for analytical methods

PO8: Plan and conduct analytical experiments for effective quality control and quality assurance system.

PO9: Use knowledge to solve problem in pharmaceutical quality system.

PO10: Relate scientific knowledge, exposure, risk assessment and policy in total quality management system.

PO11: Demonstrate the ability to work in team by combining individual strength, team dynamics and emotional intelligence.

SEMESTER - I
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

Scope:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of Drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives:

After completion of course, the student is able to know:

- The analysis of chemicals and excipients.

- The analysis of various Drugs in single and combination dosage forms.
- Theoretical and practical skills of the instruments.

Course Outcomes:

Upon completion of the course, the student shall be able to:

CO1: Select the method for the analysis of drugs and chemicals.

CO2: Understand the principle and theory involved in the various instrumental techniques.

CO3: Know the various chromatographic techniques involved in the analysis of excipients and drugs.

CO4: Acquire the knowledge and practical skills required to analyse drugs.

CO5: Interpret the data obtained in various spectroscopic methods.

CO6: Explain the applications of instrumental techniques in various fields.

CO7: Apply instrumental and non-instrumental techniques in the analysis of different formulations.

CO8: Perform qualitative and quantitative analysis of pharmaceuticals using various analytical techniques.

Theory **60 hrs**

1. a. **UV-Visible spectroscopy**: **10 hrs**

Introduction, Theory, Laws, and Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect, Applications of UV-Visible spectroscopy, Difference / Derivative spectroscopy.

b. **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. **Flame emission spectroscopy and Atomic absorption spectroscopy**: -Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy **10 hrs**

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR, Applications of NMR spectroscopy.

3. Mass Spectroscopy **10 hrs**

Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

4. Chromatography **10 hrs**

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of Drug from excipients, data interpretation and applications of the following:

a. Paper Chromatography
b. Thin Layer Chromatography
c. High Performance Thin Layer Chromatography
d. Ion Exchange Chromatography
e. Column Chromatography
f. Gas Chromatography
g. High Performance Liquid Chromatography
h. Ultra High Performance Liquid Chromatography
i. Affinity chromatography
j. Gel Chromatography

5. a**. Electrophoresis:** **20 hrs**

Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

i. Paper electrophoresis, ii. Gel electrophoresis, iii. Capillary electrophoresis, iv. Zone electrophoresis, v. Moving boundary electrophoresis, vi. Iso-electric focusing.

b. **X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

c. **Radio Immunological Assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.

d. **Potentiometry:**

i. Principle, working, Ion selective Electrodes and Application of potentiometry.

ii.Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation, advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

Thermal Gravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

References:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley &Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series.
8. Spectroscopy of Organic Compounds, 2nd edition, P.S.Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K. A.Connors, 3rd edition, John Wiley & Sons, 1982.

ADVANCED PHARMACEUTICAL ANALYSIS (MPA 102T)

Scope:

This subject deals with the various aspects of Impurity, Impurities in new Drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective:

Upon completion of the course, the students shall able to know:

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in Drugs, residual solvents and stability studies of Drugs and biological products.

Course Outcomes:

Upon completion of the course, the students shall be able to:

CO 1: Define and classify the impurities in drug substances as per ICH guidelines
CO 2: Summarize the concepts of degradation products and its reporting.
CO 3: Compile the scope, general principles and limits of residual solvents.
CO 4: Describe the instrument and procedure to analyze C, H, N, and S.
CO 5: Discuss the Stability testing protocols for the API and finished products.
CO 6: Discuss ICH stability guidelines for biological products.
CO 7: Describe the HPTLC finger printing for phytopharmaceuticals and its limitation.
CO 8: Reveal the techniques involved in the separation of bound and unbound drug.
CO 9: Brief the concept of radioimmunoassay and elaborate its applications.

Theory **60 hrs**

1. Impurity and stability studies: **10 hrs**

Definition, classification of impurities in Drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.

Impurities in new Drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products.

Impurities in residual solvents: General principles, classification of residual solvents, Analyticalprocedures, limits of residual solvents, reporting levels of residualsolvents.

2. Elemental impurities: 10 hrs

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis.

Stability testing protocols:

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. with practical considerations.

3. Impurity profiling and degradent characterization: 10 hrs

Method development, Stability studies and concepts of validation, accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products.

4. Stability testing of phytopharmaceuticals: 10 hrs

Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

5. a. Immunoassays (IA) 20 hrs

Basic principles, Production of antibodies, Separation of bound and unbound Drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

b. Biological tests and assays of the following:

a. Adsorbed tetanus vaccine, b. Adsorbed diphtheria vaccine, c. Human anti-haemophilic vaccine, d. Rabies vaccine, e.Tetanus anti-toxin, f.Tetanus anti serum, g.Oxytocin, h. Heparin sodium IP, i. Antivenom.

PCR: PCR studies for gene regulation, instrumentation (Principle and Procedures).

References:

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd edition, Wiley –Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd edition, CBS Publishers New Delhi, 1997.

6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - DC Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I, II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of Drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005.
12. Analytical Profiles of Drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of Drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

PHARMACEUTICAL VALIDATION (MPA 103T)

Scope:

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives:

Upon completion of the subject student shall be able to:

- Explain the aspect of validation.
- Carryout validation of manufacturing processes.
- Apply the knowledge of validation to instruments and equipments.
- Validate the manufacturing facilities.

Course Outcomes:

Upon completion of the course, the students shall be able to;

CO1: Explain the aspect of validation.
CO2: Carryout the validation of manufacturing processes.
CO3: Apply the knowledge of validation to instruments and equipments.
CO4: Validate the manufacturing facilities.
CO5: Prepare User Requirement Specification.
CO6: Describe the requirements concerning Factory Acceptance Test) and Site Acceptance Test.
CO7: Carry out the Qualification of Manufacturing Equipments and Laboratory equipments.
CO8: Prepare the Validation Master Plan and Validation Protocol.
CO9: Prepare Qualification protocol.
CO10: Document Qualification report.
CO11: Carry out the Qualification of Analytical Instruments and calibration of Glasswares.
CO12: Perform validation of Utility systems.
CO13: Perform cleaning validation.
CO14: Carry out cleaning Method development and Validation
CO15: Perform validation of analytical method used in cleaning.

CO16: Perform cleaning of Equipment, cleaning of Facilities.
CO17: Define the parameters used for analytical method validation.
CO18: Understand the purpose of analytical method validation and the principles of measurement uncertainty.
CO19: Perform the Validation of analytical method as per ICH guidelines and USP.
CO20: Describe the important aspects of Electronic records and digital significance.
CO21: Describe the GAMP guidelines.
CO22: Understand current and emerging issues relating to the intellectual property protection.
CO23: Understand the various types of IPR, including patents, Copyright and Trademark.
CO24: File patent applications.

Theory **60 hrs**

1. Introduction: **12 hrs**

Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.
Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re-qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

2. Qualification of analytical instruments: **12 hrs**

Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, Pipette, Measuring Cylinder, Beakers and Burette.

3.Validation of Utility systems: **12 hrs**

Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

4. Analytical method validation: **12 hrs**

General principles, Validation of analytical method as per ICH guidelines and USP.
Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP.

5. General Principles of Intellectual Property: **12 hrs**

Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

References:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd edition, Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157,2nd edition, Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider.
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press.
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2ndedition.
9. Analytical Method Validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

QUALITY CONTROL AND QUALITY ASSURANCE (MPA 104T)

Scope:

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives:

At the completion of this subject it is expected that the student shall be able to know:

- The cGMP aspects in a pharmaceutical industry.
- To appreciate the importance of documentation.
- To understand the scope of quality certifications applicable to Pharmaceutical industries.
- To understand the responsibilities of QA & QC departments.

Course Outcomes:

Upon completion of the course, the student shall be able to:

CO1: Acquire knowledge about Good Laboratory Practice, GMP and ICH Guidelines with special emphasis on Q series guidelines.

CO2: Illustrate the protocol for conduct of non clinical testing and control on animal house in Good Laboratory Practices.

CO3: Describe the Good Warehousing Practice with respect to organization and personnel responsibilities.

CO4: Understand the cGMP guidelines according to schedule M and USFDA, Pharmaceutical Inspection Convention (PIC), WHO and EMEA.

CO5: Describe the In process and finished quality control products quality control of various pharmaceuticals.

CO6: Explain the importance of three tier documentation and records in quality management system.
CO7: Detail the various aspects of manufacturing operations and controls in pharmaceutical industry.
CO8: Get knowledge of intellectual property rights, concept of trade mark, copyright and patents.

Theory **60 hrs**

1. Concept and Evolution of Quality Control and Quality Assurance **12 hrs**
Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation.

2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, Drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.
12 hrs

3. Analysis of raw materials, finished products, packaging materials, in process qualitycontrol(IPQC), Developing specification (ICH Q6 and Q3), Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

4. Documentation in pharmaceutical industry: **12 hrs**
Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

5. Manufacturing operations and controls: **12 hrs**
Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, Drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

References:
1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rdrevised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.

3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines.
8. ISO 9000 and total quality management.
9. The Drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, 6th edition, (Volume 1- with checklists and software package), Taylor &Francis, 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Textbook of Pharmaceutical Packaging Technology by Kaushik Atul, published by CBS Publishers & Distributors Pvt. Ltd., New Delhi
15. Schedule M - Central Drugs Standard Control Organization. www.cdsco.nic.in/writereaddata/Schedule M(GMP)6.pdf
16. Schedule N - India health service. Indian healthservices.in/schedules/Schedule_N.pd

PHARMACEUTICAL ANALYSIS PRACTICAL I (MPA 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Visible spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry.
3. Experiments based on HPLC.
4. Experiments based on Gas Chromatography.
5. Estimation of riboflavin/quinine sulphate by fluorimetry.
6. Estimation of sodium/potassium by flame photometry.
7. Assay of official compounds by different titrations.
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group.
11. Colorimetric determination of Drugs by using different reagents.
12. Impurity profiling of Drugs.
13. Calibration of glasswares.
14. Calibration of pH meter.
15. Calibration of UV-Visible spectrophotometer.
16. Calibration of FTIR spectrophotometer.
17. Calibration of GC instrument.
18. Calibration of HPLC instrument.

19. Cleaning validation of any one equipment.
20. In process and finished product quality control tests for tablets, capsules, parenterals and creams.
21. Quality control tests for Primary and secondary packing materials.
22. Assay of raw materials as per official monographs.
23. Testing of related and foreign substances in Drugs and raw materials.
24. Preparation of Master Formula Record.
25. Preparation of Batch Manufacturing Record.

SEMESTER - II
ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)

Scope:

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Objectives:

Upon completion ofthe course, student will be able to know:

- Interpretation of the NMR, Mass and IR spectra of various organic compounds.
- Theoretical and practical skills of the hyphenated instruments.
- Identification of organic compounds.

Course Outcomes:

Upon completion of the course, the student shall be able to

CO1: Acquire the cognitive, technical and creative skills and apply established knowledge and practice concerning modern analytical hyphenated instrumentation and measurement techniques to a range of situations.
CO2: Investigate and solve qualitative and quantitative problems in the analytical / pharmaceutical sciences, both individually and in teams**.**
CO3: Formulate hypotheses, proposals and design experiments and projects in a safe and responsible manner.
CO4: Interpret NMR (Proton and carbon), Mass and IR spectra of various organic compounds.
CO5: Record, analyse, interpret and critically evaluate the research findings individually.
CO6: Justify and interpret theoretical propositions, methodologies, conclusions and professional decisions regarding analytical instrumentation to specialist and non-specialist audiences.
CO7: Develop a capacity for independent and self-directed work.
CO8: Describe the operating principles of the various column and channel separation techniques, including HPLC - Nano, UPLC, gas chromatography, HPTLC, supercritical fluid chromatography and capillary electrophoresis.
CO9: Describe the instrumentation required for the various separation techniques and their associated operating principles.
CO10: Select the operating conditions (mobile phase, temperature, flow rate, program rate, etc.) for the various separation techniques.
CO11: Write a critical review of a research paper reporting the use of any column or channel separation technique.

CO12: Discuss the significance, quality and limitations of the results produced by the various separation techniques.

Theory **60 hrs**

1. HPLC: **12 hrs**

Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

2. Biochromatography: **12 hrs**

Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

3. Super critical fluid chromatography: **12 hrs**

Principles, instrumentation, pharmaceutical applications.

Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and methoddevelopment in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

4. Mass spectrometry: **12 hrs**

Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrapole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.

5. NMR spectroscopy: **12 hrs**

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to^{13}CNMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

R**eferences:**

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley
&Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - PD Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

Scope:

This subject is designed to provide detailed knowledge about the importance of analysis of Drugs in biological matrices.

Objectives:

Upon completion of the course, the student shall be able to understand:

- Extraction of drugs from biological samples.
- Separation of drugs from biological samples using different techniques.
- Guidelines for BA/BE studies.

Course Outcomes:

Upon completion of Course, the students shall be able to :

CO1: Exhibit the knowledge of analysing the drugs in biological matrices and bio analytical method validation.
CO2: Separate the drug from Biological samples using modern instrumentation techniques.
CO3: Explain the regulatory guidelines like USFDA and EMEA to conduct bioequivalence study.
CO4: Demonstrate the various sophisticated instruments used in bio analytical laboratory.
CO5: Categorize the Pharmacokinetics and toxico kinetics evaluation in Preclinical study
CO6: Explain the various cell culture techniques and their applications.
CO7: Describe the Concept of MTT assay and flow Cytometry.
CO8: Identify the *in-vitro* techniques involved in the estimation of drug metabolites.
CO9: Design a Study Protocol for Bioequivalence study.
CO10: Perform the evaluation of Bio similar drug products using various study design in Bio analytical study.

Theory **60 hrs**

1. Extraction of drugs and metabolites from biological matrices: **12 hrs**

General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach.
Bioanalytical method validation: USFDA and EMEA guidelines.

2. Biopharmaceutical Consideration: **12hrs**

Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, *In Vitro*: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models,

Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: *In-vitro, in-situ and In-vivo* methods.

3. Pharmacokinetics and Toxicokinetics: 12 hrs

Basic consideration, Drug interaction (PK-PD interactions), the effect of protein-binding interactions, the effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics - Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

4. Cell culture techniques 12 hrs

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

5. Metabolite identification: 12 hrs

In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met–ID. (Regulatory perspectives).
In-vitro assay of drug metabolites &Drug metabolizing enzymes.
Drugproduct performance, *In vivo*: Bioavailability and Bioequivalence:
Drugproduct performance, Purpose of bioavailability studies, Relative and Absolute Availability. Methods for assessing bioavailability, Bioequivalence studies, Design and evaluation of bioequivalence studies, Study designs, Crossover study designs, Generic biologics (Biosimilar drug products), Clinical significance of bioequivalence studies.

References:

1. Analysis of Drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork,1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A.Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4.Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2ndEdition, John Wiley & Sons, New Jersey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA, 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker,
John Wiley & Sons, New Jercy, USA, 2007.
8. Good Laboratory Practice Regulations, 2ndEdition, Sandy Weinberg Vol.69, Marcel Dekker Series,1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series,1989.
10.ICH, USFDA & CDSCO Guidelines.

FOOD ANALYSIS (MPA 203T)

Scope:

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives:

At completion of this course student shall be able to understand various analytical techniques in the determination of:

- Food constituents.
- Food additives.
- Finished food products.
- Pesticides in food.
- The student shall also have the knowledge on food regulations and legislations.

Course Outcomes:

Upon completion of Course, the students shall be able to:

CO1: Understand and perform the various analytical techniques for the determination of carbohydrates in food and food products

CO2: Understand and perform the various analytical techniques for the determination of proteins in food and food products

CO3: Understand and perform the various analytical techniques for the determination of lipids in food and food products

CO4: Understand and perform the various analytical techniques for the determination of vitamins in food and food products

CO5: Perform the analysis of food additives like preservatives, antioxidants, artificial sweeteners, flavors, stabilizers and thickening agents

CO6: Understand and perform various analytical techniques in the determination of milk and milk products

CO7: Understand and perform various analytical techniques in the determination of fermentation products

CO8: Understand the concept of analyzing pesticide residues in fruits, vegetables and milk products

CO9: Acquire knowledge on pigments and synthetic dyes and their method of detection

CO10: Acquire knowledge on food regulations and legislation

Theory **60 Hrs**

1. Carbohydrates: **12 hrs**

Classification and properties of food Carbohydrates, General methods of analysis of food Carbohydrates,Changes in food Carbohydrates during processing, Digestion, absorption and metabolism of Carbohydrates, Dietary fibre, Crude fibre and application of food Carbohydrates.

Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

2. Lipids: **12 hrs**

Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, various methods used for measurement of spoilage of fats and fatty foods.

Vitamins:Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

3. Food additives: **12 hrs**

Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

4. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar. **12 hrs**

5. Pesticide analysis: **12 hrs**

Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.

Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

References:

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976.
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, 6thedition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

HERBAL AND COSMETIC ANALYSIS (MPA 204T)

Scope:

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal Drug interaction andmonographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives:

At completion of this course student shall be able to understand:

- Determination of herbal remedies and regulations.
- Analysis of natural products and monographs.
- Determination of Herbal Drug-Drug interaction.
- Principles of performance evaluation of cosmetic products.

Course Outcomes:

Upon completion of the course, the students shall be able to:

CO 1: Describe herbal drug standardization as per WHO guidelines.

CO 2: Compare the natural product monograph from different herbal pharmacopoeias.

CO 3: Discuss regulatory requirements for setting up a herbal drug industry.

CO 4: Apply DNA finger printing technique for the identification of drugs of natural origin

CO 5: Summarize the types, causes and measures of adulteration.

CO 6: Determine the Herbal Drug-Drug interaction.

CO 7: Explain the principles of performance evaluation of cosmetic products.

Theory **60 hrs**

1. Herbal remedies - Toxicity and Regulations: **12 hrs**

Herbals vs. Conventional Drugs, Efficacy of herbal medicinal products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal Drug standardization: WHO and AYUSH guidelines.

2. Adulteration and Deterioration: **12 hrs**

Introduction, types of adulteration/substitution of herbal Drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of Drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.

Regulatory requirements for setting up of a herbal drug industry: Global marketing management, Indian and international patent law as applicable to herbal drugs and natural products and its protocol.

3. Testing of natural products and Drugs: **12 hrs**

Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products and its protocol.

Monographs of Herbal Drugs: Study of monographs of herbal drugs and comparative study in IP, USP, AyurvedicPharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

4.Herbal Drug-Drug interaction: **12 hrs**

WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

5. Evaluation of cosmetic products: **12 hrs**

Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks, hair products and skin creams by the Bureau Indian Standards (BIS).

References

1. Pharmacognosy by Trease and Evans.
2. Pharmacognosy by Kokate, Purohit and Gokhale.
3. Quality Control Methods for Medicinal Plant, WHO, Geneva.
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar.
5. Essential of Pharmacognosy by DR.S.H. Ansari.
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi.
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition.
10. Suppliers catalogue on specialized cosmetic excipients.
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps.
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition.
13. Herbal Drug technology by S S Agarwal.
14. Quality control of herbal Drugs by DR.Pulok K. Muckherjee.

PHARMACEUTICAL ANALYSIS PRACTICAL - II (MPA 205P)

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule.
2. Interpretation of organic compounds by FT-IR.
3. Interpretation of organic compounds by NMR.
4. Interpretation of organic compounds by MS.
5. Determination of purity by DSC in pharmaceuticals.
6. Identification of organic compounds using FT-IR, NMR, ^{13}CNMR and Mass spectra.
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Biomolecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. Quantitative analysis of rancidity in lipsticks and hair oil.
13. Determination of aryl amine content and Developer in hair dye.
14 Determination of foam height and SLS content of Shampoo.
15. Determination of total fatty matter in creams (Soap, skin and hair creams).
16. Determination of acid value and saponification value.
17. Determination of calcium thioglycolate in depilatories.
18. Determination of total reducing sugar.
19. Determination of proteins.
20. Determination of saponification value, Iodine value, Peroxide value, Acid value infood products.
21. Determination of fat content and rancidity in food products.
22. Analysis of natural and synthetic colors in food.
23. Determination of preservatives in food.
24. Determination of pesticide residue in food products.
25. Analysis of vitamin content in food products.

26. Determination of density and specific gravity of foods.
27. Determination of food additives.

M.PHARM PHARMACOLOGY (MPL)

PROGRAM OUTCOMES:

Upon completion of the course, student shall be able to:

PO1: Explain mechanism of drug action at organ system/sub cellular/ macromolecular levels.
PO2: Demonstrate cellular and organismal function of drug into key stages in preclinical and clinical research studies.
PO3: Establish pharmacokinetic/pharmacodynamic (PK/PD), efficacy and toxicology related studiesfor any new drug candidate and to apply these towards the advancement of clinical development.
PO4: Discuss strategic approaches for progression from early drug discovery screening to preclinical development, including use of biomarkers.
PO5: Describe the pros and cons of different models and select relevant animal models for drug screening.
PO6: Optimize animal models for reliability and predictability and translate the preclinical results to clinical studies.
PO7: Describe the regulations, ethical requirement and good laboratory practices in conducting efficacy and toxicity studies, maintenance and handling of experimental Animals.
PO8: Apply knowledge of pharmacological principle to design and conduct experiments, as well as to analyze and interpret data.
PO9: Explain cell-based and molecular assays to characterize therapeutic responses.
PO10: Describe the genomic regulation of drug action and application of recombinant DNA technology.
PO11: Explain the Proteomics-based biomarker discovery for clinical diagnosis, disease staging/stratification, and understanding drug effects and other biological mechanisms.
PO12: Demonstrate the role of genomics, proteomics and bioinformatics in drug discovery.
PO13: Demonstrate the properties of drugs and their actions, including the interactions between drug molecules and drug receptors and how these interactions elicit an effect.
PO14: Describe and demonstrate the regulatory, ethical requirements for conducting, monitoring and reporting clinical trial
PO15: Explain the principles, roles and responsibilities of Pharmacovigilance

SEMESTER - I
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

Scope:
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of Drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives:

After completion of the course, student shall be able to know about:

- The analysis of chemicals and excipients.
- The analysis of various Drugs in single and combination dosage forms.
- Theoretical and practical skills of the instruments.

Course outcomes:

Upon completion of the course, the student shall be able to

CO1: Select the method for the analysis of drugs and chemicals.

CO2: Understand the principle and theory involved in the various instrumental techniques.

CO3: Know the various chromatographic techniques involved in the analysis of excipients and drugs.

CO4: Acquire the knowledge and practical skills required to analyse drugs.

CO5: Interpret the data obtained in various spectroscopic methods.

CO6: Explain the applications of instrumental techniques in various fields.

CO7: Apply instrumental and non-instrumental techniques in the analysis of different formulations.

CO8: Perform qualitative and quantitative analysis of pharmaceuticals using various analytical techniques.

Theory **60 hrs**

1. a. **UV-Visible spectroscopy**: **10 hrs**

Introduction, Theory, Laws, and Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect, Applications of UV-Visible spectroscopy, Difference / Derivative spectroscopy.

b. **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of Drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy **10 hrs**

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR, Applications of NMR spectroscopy.

3. Mass Spectroscopy **10 hrs**

Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

4. Chromatography **10 hrs**

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of Drug from excipients, data interpretation and applications of the following:

a. Paper Chromatography
b. Thin Layer chromatography
c. High Performance Thin Layer Chromatography
d. Ion exchange chromatography
e. Column chromatography
f. Gas chromatography
g. High Performance Liquid chromatography
h. Ultra High Performance Liquid chromatography
i. Affinity chromatography
j. Gel Chromatography

5. a**. Electrophoresis: 20 hrs**

Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

i. Paper electrophoresis, ii. Gel electrophoresis, iii. Capillary electrophoresis, iv. Zone electrophoresis, v. Moving boundary electrophoresis, vi. Iso-electric focusing.

b. **X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

c. **Radio Immunological Assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.

d. **Potentiometry:**

i. Principle, working, Ion selective Electrodes and Application of potentiometry.

ii. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation, advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

Thermal gravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

References:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rdedition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, MarcelDekker Series.
8. Spectroscopy of Organic Compounds, 2nd edition. P. S. Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOLOGY - I (MPL 102T)

Scope:

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the Drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of Drug action and mechanisms involved

Objectives:

Upon completion of the course the student shall be able to:

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of Drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

Course outcomes:

Upon completion of the Course the student will be able to:

CO1: Discuss the pathophysiology and pharmacotherapy of certain diseases.

CO2: Explain the mechanism of actions at cellular and molecular level for the drugs acting on cardiovascular system and central nervous system.

CO3: Explain the concepts of linear and non-linear compartment models.

CO4: Discuss the physiological and pathological role of Autocoids.

CO5: Describe the general aspects of receptor pharmacology.

CO6: Explain the general aspects and steps involved in neurotransmission.

CO7: Explain the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

Theory **60 hrs**

1. General Pharmacology **12 hrs**

a. Pharmacokinetics: The dynamics of Drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

b. Pharmacodynamics: Mechanism of Drug action and the relationship between Drug concentration and effect. Receptors,structural and functionalfamilies of receptors, quantization of Drug receptors interaction and elicited effects.

2. Neurotransmission **12 hrs**

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Nor-adrenaline, Adrenaline and Acetylcholine).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].

d. Non-adrenergic non cholinergic transmission (NANC). Co- transmission.

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel Drugs used in the following systems.

Autonomic Pharmacology.

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affectingneuromuscular junction.

3. Central nervous system Pharmacology **12 hrs**

General and local anesthetics.

Sedatives and hypnotics, Drugs used to treat anxiety.

Depression, psychosis, mania, epilepsy, neurodegenerative diseases.

Narcotic and non-narcotic analgesics.

4. Cardiovascular Pharmacology **12 hrs**

Diuretics, antihypertensives, anti-ischemics, anti-arrhythmics, Drugs for heart failure and hyperlipidemia.

Hematinics, coagulants, anticoagulants, fibrinolytics and anti- platelet drugs.

5. Autocoid Pharmacology **12 hrs**

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids.

Pharmacology of antihistamines, 5HT antagonists.

References:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's.
2. Principles of Pharmacology. The Pathophysiologic basis of Drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung.
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery's Drug Treatment.
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9thedition. (Robbins Pathology).
11. A Complete Textbook of Medical Pharmacology by DR. S.K Srivastava published by APC Avichal Publishing Company.
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.

14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications – Malcolm Rowland and Thomas N. Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I (MPL 103T)

Scope:

This subject is designed to impart the knowledge on preclinical evaluation of Drugs and recent experimental techniques in the Drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro* and *in-vivo* preclinical evaluation processes

Objectives:

Upon completion of the course the student shall be able to:

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the Drug discovery process and good laboratory practices in maintenance and handling of experimental animals.
- Describe the various newer screening methods involved in the Drug discovery process.
- Appreciate and correlate the preclinical data to humans.

Course outcomes:

Upon completion of the Course the student will be able to:

CO1: Appraise the regulations and ethical requirement for the usage of experimental animals.

CO2: Describe the various animals used in the Drug discovery process and good laboratory

practices in maintenance and handling of experimental animals.

CO3: Describe the various newer screening methods involved in the Drug discovery process.

CO4: Explain the Limitation of animal experimentation.

CO5: Describe the Alternative models to animal experiments.

CO6: Explain the new testing strategies for toxicological evaluation of compounds.

CO7: Explain the General principles of immunoassay and the evaluation methods of Immunoassay.

CO8: Appreciate and correlate the preclinical data to humans.

Theory **60 hrs**

1. Laboratory Animals **12 hrs**

Common laboratory animals: Description, handling and applications of different species and strains of animals.

Transgenic animals: Production, maintenance and applications

Transgenic animals: Production, maintenance and applications.
Anaesthesia and euthanasia of experimental animals.
Maintenance and breeding of laboratory animals.
CPCSEA guidelines to conduct experiments on animals.
Good laboratory practice.
Bioassay-Principle, scope, limitations and methods.

2. Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro*, and other possible animal alternative models. 12 hrs

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, antiepileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

3. Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro*, and other possible animal alternative models. 12 hrs

Respiratory Pharmacology: anti-asthmatics, Drugs for COPD and anti-allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents. Gastrointestinal Drugs: antiulcer, anti -emetic, anti- diarrheal and laxatives.

4. Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro*, and other possible animal alternative models. 12 hrs

Cardiovascular Pharmacology: antihypertensives, antiarrhythmics,antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

5. Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro*, and other possible animal alternative models. 12 hrs

Immunomodulators, Immunosuppressants and immunostimulants.
General principles of immunoassay:theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay: methods, evaluation, protocol outline, objectives and preparation. Immunoassay for digoxin and insulin.
Limitations of animal experimentation and alternate animal experiments.
Extrapolation of *in vitro* data to preclinical and preclinical to humans.

References:

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
2. Screening methods in Pharmacology by Robert Turner. A.
3. Evaluation of Drugs activities by Laurence and Bachrach.
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N. Ghosh.
6. Pharmacological experiment on intact preparations by Churchill Livingstone.
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new Drugs by S.K. Guta.

10. Handbook of Experimental Pharmacology, S. K.Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy, S. K. Kulkarni, 3rd edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A. Turner.
14. Rodents for Pharmacological Experiments, DR. Tapan Kumar Chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author).

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with Drugs. This information will further help the student to apply the knowledge in Drug discovery process.

Objectives:

Upon completion of the course, the student shall be able to:

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by Drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology.

Course outcomes:

Upon completion of the Course the student will be able to:

CO1: Explain the receptor signal transduction processes.

CO2: Explain the molecular pathways affected by Drugs.

CO3: Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.

CO4: Demonstrate molecular biology techniques as applicable for pharmacology.

CO5: Describe the key steps that lead to the change in gene regulation.

CO6: Explain the principles and applications of genomic and proteomic tools.

CO7: Enumerate the basics of cell culture techniques.

Theory **60 hrs**

1. Cell biology **12 hrs**

Structure and functions of cell and its organelles.

Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing.

Cell cycles and its regulation.

Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

2. Cell signaling **12 hrs**

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP_3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

3. Principles and applications of genomic and proteomic tools **12 hrs**

DNA electrophoresis, PCR (reverse transcription and real time),Gene sequencing, microarray technique, SDS page, ELISA and Western blotting.

Recombinant DNA technology and gene therapy:

Basic principles of recombinant DNA technology - Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.

Gene therapy- Various types of gene transfer techniques,clinical applications and recent advances in gene therapy.

4. Pharmacogenomics **12 hrs**

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology.

Polymorphisms affecting Drug metabolism.

Genetic variation in Drug transporters.

Genetic variation in G protein coupled receptors.

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics.

Immunotherapeutic s- Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice.

5. a. Cell culture techniques **12 hrs**

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures, isolationof cells, subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays.

Principles and applications of flow cytometry.

b. Biosimilars.

References:

1. The Cell- A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M. L. Wong.
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al.
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al.
5. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Miller.
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor).

7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor).
8. Current protocols in molecular biology Vol I to VI edited by Frederick M.Ausuvel et la.

PHARMACOLOGY PRACTICAL I (MPL 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Visible spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry.
3. Experiments based on HPLC.
4. Experiments based on Gas Chromatography.
5. Estimation of riboflavin/quinine sulphate by fluorimetry.
6. Estimation of sodium/potassium by flame photometry.

Handling of laboratory animals.

1. Various routes of Drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test).
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion,Goat liver).
10. Isolation of RNA from yeast.
11. Estimation of proteins by Bradford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy.
13. Gene amplification by PCR.
14. Protein quantification byWestern Blotting.
15. Enzyme based *in-vitro* assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of Drugs given by different routes of administration using softwares.
21. Enzyme inhibition and induction activity.
22. Extraction of Drug from various biological samples and estimation of Drugs in biological fluids using different analytical techniques (UV).
23. Extraction of Drug from various biological samples and estimation of Drugs in biological fluids using different analytical techniques (HPLC).

References:

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines
2. Fundamentals of experimental Pharmacology by M.N. Ghosh.
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.

5. Spectrometric Identification of Organic compounds - Robert M Silverstein.
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman.
7. Vogel's Text book of quantitative chemical analysis-Jeffery, Basset, Mendham, Denney.
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille.
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor).
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor).
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee Brothers medical publishers Pvt. Ltd.

SEMESTER - II
ADVANCED PHARMACOLOGY - II (MPL 201T)

Scope:

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

Objectives:

Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level.
- Discuss the pathophysiology and pharmacotherapy of certain diseases.
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

Course outcomes:

Upon completion of the Course the student will be able to:

CO1: Discuss the pathophysiology and pharmacotherapy of certain diseases.

CO2: Describe molecular and cellular mechanism of action of hormones.

CO3: Enumerate cellular and biochemical mediators of inflammation and immune response.

CO4: Explain the applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer.

CO5: Elucidate the role of free radicals in etiopathology of various diseases.

CO6: Explain the Chemotherapy of cancer.

Theory **60 hrs**

1. Endocrine Pharmacology **12 hrs**

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones.

Anti-thyroid Drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation.

2. Chemotherapy **12 hrs**

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB Drugs.

3. Chemotherapy **12 hrs**

Drugs used in Protozoal Infections.
Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immuneresponse. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.
Immunosuppressants and Immunostimulants.

4. GIT Pharmacology **12 hrs**

Antiulcer Drugs, Prokinetics, antiemetics, anti-diarrhoeals and Drugs for constipation and irritable bowel syndrome.
Chronopharmacology.
Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer.

5. Free radicals Pharmacology **12 hrs**

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant.
Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus.

References:

1. The Pharmacological basis of therapeutics- Goodman and Gillman's.
2. Principles of Pharmacology. The Pathophysiologic basis of Drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G. Katzung.
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, Drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
9. Robbins & Cortan Pathologic Basis of Disease, 9th edition. (Robbins Pathology).
10. A Complete Textbook of Medical Pharmacology by DR. S.K.Srivastava published by APC Avichal Publishing Company.
11. K. D.Tripathi. Essentials of Medical Pharmacology.
12. Principles of Pharmacology. The Pathophysiologic basis of Drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL 202T)

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of Drug & new chemical entity.This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

Upon completion of the course, the student shall be able to:

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Course outcomes:

Upon completion of the Course the student will be able to:

CO1 Appreciate the importance of ethical and regulatory requirements for toxicity studies.

CO2: Demonstrate the practical skills required to conduct the preclinical toxicity studies.

CO3: Explain the acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.

CO4: Explain the *in-vitro* and *in-vivo* models for carrying out Genotoxicity and Carcinogenicity studies.

CO5: Discuss the importance and steps in submission of application for Investigational New Drug (IND).

CO6: Describe the origin, concepts and importance of safety pharmacology.

CO7: Discuss the importance and applications of toxicokinetic studies.

CO8: Enumerate the alternative methods to animal toxicity testing.

Theory **60 hrs**

1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)

12 hrs

Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y.

OECD principles of Good laboratory practice (GLP): History, concept and its importance in Drug development.

2. Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.

12 hrs

Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.

Test item characterization - importance and methods in regulatory toxicology studies.

3. Reproductive toxicology studies: **12 hrs**

Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II).

Genotoxicity studies (Ames Test, *in-vitro and in-vivo* Micronucleus and Chromosomal aberrations studies).

In-vivo carcinogenicity studies.

4. IND enabling studies (IND studies): 12 hrs

Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.

Safety pharmacology studies - origin, concepts and importance of safety pharmacology.

Tier 1 - CVS, CNS and respiratory safety pharmacology, HERG assay. Tier 2- GI, renal and other studies.

5. Toxicokinetics 12 hrs

Toxicokinetic evaluation in preclinical studies, saturation kinetics. Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.

References:

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tDR/publications/documents/glp- handbook.pdf).
2. Schedule Y Guideline: Drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi.
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan.
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3 (R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals.

(http://www.fda.gov/downloads/Drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf).

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

Scope:

The subject imparts basic knowledge of Drug discovery process. This information will make the student competent in Drug discovery process

Objectives:

Upon completion of the course, the student shall be able to:

- Explain the various stages of Drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery.
- Explain various targets for Drug discovery.
- Explain various lead seeking method and lead optimization.
- Appreciate the importance of the role of computer aided Drug design in drug discovery.

Course outcomes:

Upon completion of the Course the student will be able to:

CO1: Explain the various stages of Drug discovery.

CO2: Discuss the importance of the role of genomics, proteomics and bioinformatics in drug discovery.

CO3: Explain various lead seeking method and lead optimization.

CO4: Discuss the importance of combinatorial chemistry and high throughput screening in drug discovery.

CO5: Describe the concepts of Rational Drug Design.

CO6: Enumerate Virtual Screening techniques.

CO7: Explain the Docking based screening.

CO8: Discuss the importance of the role of computer aided Drug design in drug discovery.

CO9: Explain the principles of Quantitative analysis of Structure Activity Relationship.

CO10: Describe the rationale and practical consideration of prodrug design.

CO11: Explain the QSAR Statistical methods

Theory **60 hrs**

1. An overview of modern Drug discovery process: **12 hrs**

Target identification, target validation, lead identification and lead Optimization.
Economics of drug discovery.
Target discovery and validation-Role of Genomics, Proteomics and Bioinformatics.
Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins.
Role of transgenic animals in target validation.

2. Lead Identification: **12 hrs**

Combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.
Protein structure: Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction.

3. Rational Drug Design: **12 hrs**

Traditional vs. rational Drug design, Methods followed in traditional Drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches.
Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening.

4. Molecular docking: **12 hrs**

Rigid docking, flexible docking, manual docking; Docking based screening. De novo Drug design. Quantitative analysis of Structure Activity Relationship.
History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

5. QSAR Statistical methods: 12 hrs

Regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA.

Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

References:

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markel In. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer, New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.
6. Abby L. Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society:Washington, DC, 1999.
7. J. Rick Turner. New Drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing Drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

Upon completion of the course, the student shall be able to:

- Explain the regulatory requirements for conducting clinical trial.
- Demonstrate the types of clinical trial designs.
- Explain the responsibilities of key players involved in clinical trials.
- Execute safety monitoring, reporting and close-out activities.
- Explain the principles of Pharmacovigilance.
- Detect new adverse Drug reactions and their assessment.
- Perform the adverse Drug reaction reporting systems and communication in Pharmacovigilance.

Course outcomes:

Upon completion of the Course the student will be able to:

CO1: Describe the regulatory and ethical requirements for conducting clinical trial.

CO2: Conduct the clinical trial activities.

CO3: Describe the safety monitoring and reporting in clinical trials.

CO4: Explain the principles, roles and responsibilities of Pharmacovigilance.

CO5: Detect and assess adverse Drug reactions.

CO6: Manage the trial coordination process.

CO7: Explain the statistical methods for evaluating medication safety data.

Theory **60 hrs**

1. Regulatory Perspectives of Clinical Trials: **12 hrs**

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR

Informed Consent Process: Structure and content of an Informed Consent Process, Ethical principles governing informed consent process.

2. Clinical Trials: **12 hrs**

Types and Design Experimental Study- RCT and Non-RCT.

Observation Study: Cohort, Case Control, Cross sectional.

Clinical Trial Study Team.

Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

3. Clinical Trial Documentation: **12 hrs**

Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT

Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse Drug reactions; Terminologies of ADR.

4. Basic aspects, terminologies and establishment of Pharmacovigilance: **12 hrs**

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international Drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

5. a. Methods, ADR reporting and tools used in Pharmacovigilance: **12 hrs**

International classification of diseases, International Non- proprietary names for Drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

b. Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

References:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice, E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000, Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. 2nd edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

PHARMACOLOGY PRACTICAL II (MPL 205P)

1. To record the DRC of agonist using suitable isolated tissue preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine the strength of unknown sample by matching bioassay using suitable tissue preparation.
4. To determine the strength of unknown sample by interpolation bioassay using suitable tissue preparation.
5. To determine the strength of unknown sample by bracketing bioassay using suitable tissue preparation.
6. To determine the strength of unknown sample by multiple point bioassay using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various Drugs on isolated heart preparations.
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG.
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, hematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial (3 Nos.).

17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting.

References:

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh.
2. Hand book of Experimental Pharmacology-S.K.Kulakarni.
3. Text book of in-vitro practical Pharmacology by Ian Kitchen.
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal Choudhary and William Thomsen.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

M.PHARM PHARMACEUTICAL CHEMISTRY (MPC)
SEMESTER - I
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPC101T)

Scope:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of Drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives:

After completion of the course, student shall be able to know about:

- The analysis of chemicals and excipients.
- The analysis of various Drugs in single and combination dosage forms.
- Theoretical and practical skills of the instruments.

Theory **60 hrs**

1. a. **UV-Visible spectroscopy**: **10 hrs**

Introduction, Theory, Laws and Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect, Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

b. **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of Drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy **10 hrs**

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR, Applications of NMR spectroscopy.

3. Mass Spectroscopy **10 hrs**

Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

4. Chromatography **10 hrs**

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of Drug from excipients, data interpretation and applications of the following:

a. Paper Chromatography
b. Thin Layer chromatography
c. High Performance Thin Layer Chromatography
d. Ion Exchange Chromatography
e. Column Chromatography
f. Gas Chromatography
g. High Performance Liquid chromatography
h. Ultra High Performance Liquid chromatography
i. Affinity Chromatography
j. Gel Chromatography

5. a**. Electrophoresis:** **20 hrs**

Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

i. Paper electrophoresis, ii. Gel electrophoresis, iii. Capillary electrophoresis, iv. Zone electrophoresis, v. Moving boundary electrophoresis, vi. Iso-electric focusing.

b. **X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

c. **Radio Immunological Assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.

d. **Potentiometry:**

i. Principle, working, Ion selective Electrodes and Application of potentiometry.

ii. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation, advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

Thermal Gravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

References:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, TimothyA.Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel.Dekker Series.
8. Spectroscopy of Organic Compounds, 2nd edition, P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd edition, John Wiley & Sons, 1982.

ADVANCED ORGANIC CHEMISTRY- I (MPC102T)

Scope:

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as Drug discovery.

Objectives:

Upon completion of course, the student shall be to understand:

- The principles and applications ofreterosynthesis.
- The mechanism & applications of various namedreactions.
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organicreactions.
- The chemistry of heterocycliccompounds.

Theory **60hrs**

1. Basic Aspects of Organic Chemistry: **12 hrs**

1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes, their method of formation, stability and synthetic applications.
2. Types of reaction mechanisms and methods of determining them.
3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity andorientations.

Addition reactions

a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2).
b) Elimination reactions (E1 & E2; Hoffman &Saytzeff's rule).
c) Rearrangementreaction.

2. Study of mechanism and synthetic applications of following named Reactions:12 hrs

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack

Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction.

3. Synthetic Reagents & Applications: 12 hrs

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexyl carbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenyl phosphine, (Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protectinggroups

a. Role of protection in organicsynthesis.
b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates,cyclic acetals & ketals.
c. Protection for the Carbonyl Group: Acetals andKetals.
d. Protection for the Carboxyl Group: amides and hydrazides, esters.
e. Protection for the Amino Group and Amino acids: carbamates andamides.

4. Heterocyclic Chemistry: 12 hrs

Organic Name reactions with their respective mechanism and application involved in synthesis of Drugs containing five, six membered and fused hetrocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing theheterocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene,Sulfamerazine,Trimethoprim,Hydroxychloroquine,
Quinine,Chloroquine,Quinacrine,Amsacrine,Prochlorpherazine,Promazine,
Chlorpromazine,Theophylline, Mercaptopurine andThioguanine.

5. Synthon approach and retrosynthesis applications 12 hrs

i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI andFGA).

ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds.

iii. Strategies for synthesis of three, four, five and six-membered ring.

References:

1. Advanced Organic chemistry, Reaction, Mechanisms and Structure by J March, John Wiley and Sons, NewYork.
2. Mechanism and Structure in Organic Chemistry by ES Gould, Hold Rinchart and Winston, NewYork.
3. Organic Chemistry by Clayden, Greeves, Warren and Woihers, Oxford University Press 2001.
4. Organic Chemistry, Vol I and II by I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley India) Pvt.Ltd.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, NewDelhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. Combinatorial Chemistry – Synthesis and applications – Stephen R Wilson& Anthony W Czarnik, Wiley –Blackwell.

8. Carey, Organic Chemistry, 5thedition (Viva Books Pvt.Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, WilyIndia.
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, NarosaPublishers.
12. Organic Reaction Mechanisms 4th edition, VK Ahluwalia and RK Parashar, Narosa Publishers.

ADVANCED MEDICINAL CHEMISTRY (MPC103T)

Scope:

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Objectives:

At completion of this course it is expected that students will be able to understand:

- Different stages of drug discovery.
- Role of medicinal chemistry in drug research.
- Different techniques for drug discovery.
- Various strategies to design and develop new srug like molecules for biological targets.
- Peptidomimetics.

Theory **60hrs**

1. Drug discovery: **12 hrs**

Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs. antagonists, artificial enzymes.

2. ProDrug Design and Analog design: **12 hrs**

a.Prodrug design: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, drug solubility, drug absorption and distribution, site specific drugdelivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrugdesign.

b.Combatingdrug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.

c.Analog design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

3. Medicinal chemistry aspects of the following class of drugs **12 hrs**

Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:

a.Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic& Cholinergic agents, Antineoplastic and Antiviral agents.

b.Stereochemistry and drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in Drug adsorption, metabolism, distribution andelimination.

4. Rational Design of Enzyme Inhibitors **12 hrs**

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

5. Peptidomimetics **12 hrs**

Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.

References:

1. Medicinal Chemistry by Burger, Vol I–VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12thedition, Lippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, NewDelhi.
3. Comprehensive Medicinal Chemistry – Corwin andHansch.
4. Computational and structural approaches to Drug design edited by Robert M Stroud and Janet. F Moore.
5. Introduction to Quantitative Drug Design by Y.C.Martin.
6. Principles of Medicinal Chemistry by William Foye, 7thedition, Lippincott Williams & Wilkins, Wolter Kluwer (India) Pvt.Ltd, NewDelhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh.
8. Principles of Drug Design bySmith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, NewDelhi.
10. An Introduction to Medicinal Chemistry, Graham L. Patrick, III Edition, Oxford University Press,USA.
11. Biopharmaceutics and pharmacokinetics, D. M.Brahmankar, Sunil B. Jaiswal 2nd edition, 2014, Vallabh Prakashan, NewDelhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley Publishers.

CHEMISTRY OF NATURAL PRODUCTS (MPC104T)

Scope:

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives:

At completion of this course it is expected that students will be able to understand:

- Different types of natural compounds and their chemistry and medicinal importance.
- The importance of natural compounds as lead molecules for new drug discovery.
- The concept of renal technology tool for new drug discovery.
- General methods of structural elucidation of compounds of natural origin.

- Isolation, purification and characterization of simple chemical constituents from natural source.

Theory **60hrs**

1. Study of Natural products as leads for new pharmaceuticals for the following class of Drugs: **12 hrs**

a) Drugs Affecting the Central Nervous System: Morphine Alkaloids.
b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide.
c) Cardiovascular Drugs: Lovastatin, Teprotide andDicoumarol.
d) Neuromuscular Blocking Drugs: Curarealkaloids.
e) Anti-malarial drugs andanalogues.
f) Chemistry of macrolide antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins andCarbapenem).

2. a). Alkaloids : **12 hrs**

General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

b) **Flavonoids:**

Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

c) **Steroids:**

General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).

3. a). Terpenoids: **12 hrs**

Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of Drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene, Ginsenoside) carotinoids (β carotene).

b). Vitamins.

Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

4. a). Recombinant DNA technology and Drug discovery: **12 hrs**

rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation.

b).Active constituent of certain crude Drugs used in Indigenous system Diabetic therapy– Gymnema *sylvestre*, Salacia *reticulate,* Pterocarpus*marsupiam,* Swertia*chirata,* Trigonella*foenumgraccum;* Liver dysfunction – Phyllanthus*niruri;* Antitumor – Curcuma *longa* Linn.

5. Structural Characterization of natural compounds: **12 hrs**

Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

References:

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Reinhld.
3. Recent advances in Phytochemistry Vol. I to IV – ScikelRuneckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwardsIWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" – Raphael Ikan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, AcademicPress.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya PublishingHouse.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, KrishanPrakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson Education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi vPublishers.
13. Pharmaceutical Biotechnology by S.P. Vyas and V.K.Dixit, CBSPublishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13thedition.
15. Phytochemical methods, Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

PHARMACEUTICAL CHEMISTRY PRACTICAL I (MPC 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Visible spectrophotometer, RNA & DNA estimation.
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry.
3. Experiments based on Column chromatography.
4. Experiments based on HPLC.
5. Experiments based on Gas Chromatography.
6. Estimation of riboflavin/quinine sulphate by fluorimetry.
7. Estimation of sodium/potassium by flame photometry.

To perform the following reactions of synthetic importance

1. Purification of organic solvents, column chromatography.
2. Claisen-schimidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction.
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments).
8. Estimation of elements and functional groups in organic natural compounds.

9. Isolation, characterization like melting point, mixed melting point, molecular weight. determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents.

SEMESTER - II
ADVANCED SPECTRAL ANALYSIS (MPC 201T)

Scope:
This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of Drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives:
At completion of this course it is expected that students will be able to understand:
- Interpretation of the NMR, Mass and IR spectra of various organic compounds.
- Theoretical and practical skills of the hyphenated instruments.
- Identification of organic compounds.

Theory **60hrs**

1. UV and IR spectroscopy: **12 hrs**
Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

2. NMR spectroscopy: **12 hrs**
1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATEtechniques, Interpretation of organic compounds.

3. Mass Spectroscopy **12 hrs**
Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

4. Chromatography: **12 hrs**
Principle, Instrumentation and Applications of the following:
a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE- MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography.

5. a)Thermal methods of analysis: **12 hrs**
Introduction, principle, instrumentation and application of DSC, DTA and TGA.
b). Raman Spectroscopy:
Introduction, Principle, Instrumentation and Applications.
c). Radio immuno assay:
Biological standardization, bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

References:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6thedition, John Wiley & Sons,2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore,1998.
3. Instrumental methods of analysis – Willards, 7thedition, CBSpublishers.
4. Organic Spectroscopy - William Kemp, 3rdedition, ELBS,1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - PD Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rdedition, CBS Publishers, New Delhi,1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson,Volume 11, Marcel DekkerSeries.

ADVANCED ORGANIC CHEMISTRY- II (MPC 202T)

Scope:

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives:

Upon completion of course, the student shall able to understand:

- The principles and applications of Green chemistry.
- The concept of peptide chemistry.
- The various catalysts used in organic reactions.
- The concept of stereochemistry and asymmetric synthesis.

Theory **60hrs**

1. Green Chemistry: **12 hrs**

a.Introduction, principles of green chemistry.

b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis.

c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications.

d. Continuous flow reactors: Working principle, advantages and synthetic applications.

2. Chemistry of peptides **12 hrs**

a. Coupling reactions in peptide synthesis.

b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides.

c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies.

d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over- activation and side reactions of individual amino acids.

3. Photochemical Reactions **12 hrs**

Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.

Pericyclic reactions.

Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples.

4. Catalysis: **12 hrs**

a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages

b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of Drugs.

c.Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of Drugs.

d. Transition-metal and Organo-catalysis in organic synthesis:Metal-catalyzed reactions.

e.Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.

f. Phase transfer catalysis - theory and applications.

5. Stereochemistry and Asymmetric Synthesis: **12 hrs**

a.Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.

b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

References:

1. Advanced Organic chemistry, Reaction, mechanisms and structure by J March, John Wiley and sons, NewYork.
2. Mechanism and structure in organic chemistry by ES Gould, Hold Rinchart andWinston,New York.
3. Organic Chemistry by Clayden, Greeves, Warren and Woihers, Oxford University Press 2001.
4. Organic Chemistry, Vol I and II by I.L. Finar. ELBS, 6th edition, 1995.
5. Carey, Organic chemistry, 5thedition (Viva Books Pvt. Ltd.).
6. Organic synthesis-the disconnection approach, S. Warren, WilyIndia.
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelsonthorns.
8. Organic synthesis- Special techniques by VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edition, by VK Ahluwalia and RK Parashar, Narosa Publishers.

COMPUTER AIDED DRUG DESIGN (MPC203T)

Scope:

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted Drug design.

Objectives:

At completion of this course it is expected that students will be able to understand:

- Role of CADD in Drug discovery.
- Different CADD techniques and their applications.
- Various strategies to design and develop new druglike molecules.
- Working with molecular modeling softwares to design new drug molecules
- I*n silico* virtual screening protocols.

Theory **60hrs**

1. Introduction to Computer Aided Drug Design(CADD): **12 hrs**

History, different techniques and applications.

Quantitative Structure Activity Relationships: Basics.

History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

2. Quantitative Structure Activity Relationships: **12 hrs**

Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.

3D-QSAR approaches and contour map analysis.

Statistical methods used in QSAR analysis and importance of statistical parameters.

3. Molecular Modeling and Docking: **12 hrs**

a) Molecular and Quantum Mechanics in Drug design.

b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation.

c)Molecular docking and Drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase andHIV protease, choline esterase (AchE&BchE).

4. Molecular Properties and Drug Design: **12 hrs**

a). Prediction and analysis of ADMET properties of new molecules and its importance in Drugdesign.

b).De novo Drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based Drug design.

c). Homology modeling and generation of 3D-structure of protein.

5. Pharmacophore MappingandVirtualScreening: 12 hrs

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques.

Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

References:

1. Computational and structural approaches to Drug discovery, Robert M Stroud and Janet. F Moore, RCSPublishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor& Francisgroup.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, ElsevierPublishers.
6. Medicinal Chemistry by Burger, Wiley PublishingCo.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford UniversityPress.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams &Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to Drug design edited by Robert M Stroud and Janet. F Moore.

PHARMACEUTICAL PROCESS CHEMISTRY (MPC 204T)

Scope:

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the Drugdevelopment phase.

Objectives:

At completion of this course it is expected that students will be able to understand:

- The strategies of scale up process of APIs and intermediates.
- The various unit operations and various reactions in process chemistry.

Theory 60hrs

1. Process chemistry: 12 hrs

Introduction, Synthetic strategy.

Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process.

Case studies of some scale up process of APIs.

Impurities in API, types and their sources including genotoxic impurities.

2. Unit operations: **12 hrs**

a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.

b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,

c) Distillation: azeotropic and steam distillation.

d) Evaporation: Types of evaporators, factors affecting evaporation.

e) Crystallization: Crystallization from aqueous, non- aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

3. Unit Processes-I: **12 hrs**

a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,

b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenations process.

c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2, sodium hypochlorite, Oxygen gas,ozonolysis.

4. Unit Processes-II: **12 hrs**

a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.

b) Fermentation: Aerobic and anaerobic fermentation.

Production of

i. Antibiotics; Penicillin and Streptomycin,
ii. Vitamins: B2 andB12
iii. Statins: Lovastatin, Simvastatin

c) Reaction progress kinetic analysis

i. Streamlining reaction steps, route selection,
ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

5. Industrial Safety: **12 hrs**

a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment(PPE).

b) Fire hazards, types of fire &fire extinguishers.

c) Occupational Health &Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management.

References:

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever- Changing Climate- An Overview; K. Gadamasetti, CRCPress.
2. Pharmaceutical Manufacturing Encyclopedia, 3rdedition, Volume2.
3. Medicinal Chemistry by Burger, 6thedition, Volume1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGrawHill.
5. Polymorphism in Pharmaceutical Solids. Dekker Series Volume 95thedition: H G Britain (1999).
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis

7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up.
8. P.H.Groggins: Unit processes in organic synthesis (MGH).
9. F.A.Henglein: Chemical Technology (Pergamon).
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press.
11. Clausen, Mattson: Principle of Industrial Chemistry, Wiley PublishingCo.
12. Lowenheim& M.K. Moran: IndustrialChemicals.
13. S.D. Shukla& G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas PublishingHouse.
14. J.K. Stille: Industrial Organic Chemistry (PH).
15. Shreve: Chemical Process, McGrawhill.
16. B.K.Sharma: Industrial Chemistry, Goel PublishingHouse.
17. ICHGuidelines.
18. United States Food and Drug Administration official websitewww.fda.gov.

PHARMACEUTICAL CHEMISTRY PRACTICAL II (MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments).
   a) Oxidation
   b) Reduction/hydrogenation
   c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments).
3. Assignments on regulatory requirements in API (2 experiments).
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule.
5. Interpretation of organic compounds by FT-IR.
6. Interpretation of organic compounds by NMR.
7. Interpretation of organic compounds by MS.
8. Determination of purity by DSC in pharmaceuticals.
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra.
10. To carry out the preparation of following organic compounds.

a. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
b. Preparation of 4-iodotolene from p-toluidine.
c. NaBH4 reduction of vanillin to vanillyl alcohol.
d. Preparation of umbelliferone by Pechhman reaction.
e. Preparation of triphenyl imidazole.

11. To perform the Microwave irradiated reactions of synthetic importance (Any two).
12. Determination of log P, MR, hydrogen bond donors and acceptors of selected Drugs using softwares.
13. Calculation of ADMET properties of Drug molecules and its analysis using softwares Pharmacophore modeling.
14. 2D-QSAR based experiments.
15. 3D-QSAR based experiments.
16. Docking study based experiment.
17. Virtual screening based experiment.

M.PHARM PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

PROGRAM OUTCOMES:

Upon completion of this programme it is expected that students will be able to:

PO1: Provide quality inputs in the area of Pharmaceutical Regulatory Affairs.

PO2: Develop documentation / research writing expertise in the field of Pharmaceutical Regulatory Affairs.

PO3: Make available a pool of competent professionals in the area of Pharmaceutical Regulatory Affairs.

PO4: Prepare students to be masters in the field of global regulatory affairs and enable existing regulatory affairs professionals to refine and update their knowledge of global regulatory affairs statutes and practices.

SEMESTER - I
GOOD REGULATORY PRACTICES (MRA 101T)

Scope:

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Objectives:

At completion of this course it is expected that students will be able to understand:

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- the check lists and SOPs for various Good Regulatory Practices.
- Good Regulatory Practices in the Healthcare and related Industries.
- the readiness and conduct of audits and inspections.

Course outcomes:

Upon completion of this course it is expected that students will be able to:

CO1: Explain the key elements of current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, Good Documentation Practices and Good Regulatory Practices.

CO2: Prepare and implement the check lists for various Good Regulatory Practices.

CO3: Prepare and implement the SOPs for various Good Regulatory Practices.

CO4: Implement Good Regulatory Practices in the Healthcare and related Industries.

CO5: Conduct audit and inspect the Pharmaceutical Industries.

Theory **60 hrs**

1. Current Good Manufacturing Practices: **12 hrs**

Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines.

GAMP-5; Medical device and IVDs Global Harmonization TaskForce (GHTF) Guidance docs.

2. Good Laboratory Practices: 12 hrs

Introduction, USFDA GLP Regulations (Sub part A to Sub part K), Controlling the GLP Inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant Island Quality Council of India (QCI) Standards.

3. Good Automated Laboratory Practices: 12 hrs

Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

4. Good Distribution Practices: 12 hrs

Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards.

5. Quality management systems: 12 hrs

Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of Drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

References:

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168.
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press.
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs& Cosmetics Act, Rules & Amendments.

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Scope:

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Objectives:

Upon completion of the course the student shall be able to:

- Know the various documents pertaining to drugs in pharmaceutical industry.

- Understand the basics of regulatory compilation.
- Understand the regulation submission as per the requirements of agencies.
- Understand the submissions and post approval of document requirements.

Course outcomes:

Upon completion of this course it is expected that students will be able to:
CO1: Explain the various documents pertaining to drugs in pharmaceutical industry.
CO2: Explain the basics of regulatory compilation.
CO3: Create and assemble the regulation submission as per the requirements of agencies.
CO4: Follow up the submissions and post approval document requirements.

Theory **60 hrs**

1. Documentation in pharmaceutical industry: **12 hrs**

Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

2. Dossier preparation and submission: **12 hrs**

Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non-eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

3. Audits: **12 hrs**

Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document.ISO 13485.

4. Inspections: **12 hrs**

Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of Drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).

5. Product life cycle management: **12 hrs**

Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard.

References:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press, 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al EnDRes, Wiley, 2000.
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases,

By Jiju Antony; David Preece, Routledge, 2002.

7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report by Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001.
8. Corporate Culture and the Quality Organization by James W. Fairfield- Sonn, Quorum Books, 2001.
9. The Quality Management Sourcebook: An International Guide to Materials and Resources by Christine Avery; Diane Zabel, Routledge, 1997.
10. The Quality Toolbox, 2nd Edition, Nancy R. Tague. ASQ Publications.
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and JosephA. De Feo, ASQ Publications.
12. Root Cause Analysis- The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.
13. International Medical Device Regulators Forum (IMDRF). Medical Device Single Audit Program (MDSAP).

CLINICAL RESEARCH REGULATIONS (MRA 103T)

Scope:

This course is designed to impart the fundamental knowledge on the clinical development process of Drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Objectives:

Upon completion of the course, the student shall be able to (know, do and appreciate):

- History, origin and ethics of clinical and biomedical research and evaluation.
- Clinical drug, medical device development process and different types and phases of clinical trials.
- Regulatory requirements and guidance for conduct of clinical trials and research.

Course Outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain the history, origin and ethics of clinical and biomedical research and evaluation.

CO2: Explain the clinical drug, medical device development process and its types.

CO3: Explain the regulatory requirements and guidance for conducting the clinical trials and research.

Theory **60 hrs**

1. Clinical Drug Development Process: **12 hrs**

Different types of Clinical Studies.

Phases of clinical trials, Clinical Trial protocol.

Phase 0 studies.

Phase I and sub type studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, Drug – Drug interaction, PK end points.

Phase II studies (proof of concept or principle studies to establish efficacy).

Phase III studies (Multi ethnicity, global clinical trial, registration studies).

Phase IV studies (Post Marketing Studies; PSUR).

Clinical Investigation and Evaluation of Medical Devices & IVDs.

Different Types of Studies.

Key Concepts of Medical Device Clinical Evaluation Key concepts of Clinical Investigation.

2. Ethics in Clinical Research: **12 hrs**

Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki.

Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.

The ethics of randomized clinical trials

The role of placebo in clinical trials.

Ethics of clinical research in special population.

Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data.

Data safety monitoring boards.

Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research.

Ethical principles governing informed consent process.

Patient Information Sheet and Informed Consent Form.

The informed consent process and documentation.

3. Regulations governing Clinical Trials: **12 hrs**

India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance.

USA: Regulations to conduct Drug studies in USA (FDA).

NDA 505(b)(1) of the FD&C Act (Application for approval of a new Drug).

NDA 505(b)(2) of the FD&C Act (Application for approval of a new Drug that relies, at least in part,

on data not developed by the applicant).

ANDA 505(j) of the FD&C Act (Application for approval of a generic Drug product).

FDA Guidance for Industry - Acceptance of Foreign Clinical Studies.

FDA Clinical Trials Guidance Document: Good Clinical Practice.

EU: Clinical Research regulations in European Union (EMA).

4. Clinical Research Related Guidelines: **12 hrs**

Good Clinical Practice Guidelines (ICH GCP E6).
Indian GCP Guidelines.
ICMR Ethical Guidelines for Biomedical Research.
CDSCO guidelines.
GHTF study group 5 guidance documents.

Regulatory Guidance on Efficacy and Safety ICH Guidance:

E4 – Dose Response Information to support Drug Registration.
E7 – Studies in support of General Population: Geriatrics.
E8 – General Considerations of Clinical Trials.
E10 – Choice of Control Groups and Related Issues in Clinical Trials,
E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population.
General biostatistic principles applied in clinical research.

5. USA & EU Guidance: **12 hrs**

USA: FDA Guidance

- CFR 21Part 50: Protection of Human Subjects.
- CFR 21Part 54: Financial Disclosure by Clinical Investigators.
- CFR 21Part 312: IND Application.
- CFR 21Part 314: Application for FDA Approval to Market a New Drug.
- CFR21Part320: Bioavailability and bioequivalence requirements.
- CFR 21Part 812: Investigational Device Exemptions.
- CFR 21Part 822: Post-market surveillance.
- FDA Safety Reporting Requirements for INDs and BA/BE Studies.
- FDA Med Watch.
- Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.

European Union: EMA Guidance

- EU Directives 2001.
- EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use.
- EU Annual Safety Report (ASR).
- Volume 9A – Pharmacovigilance for Medicinal Products for Human Use.
- EU MDD with respect to clinical research.
- ISO 14155.

References:

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams.
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide by Mark Barnes, JD, LLM and Jennifer Kulynych, JD, Ph.D.
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene.
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie
A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.

6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription Drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA.
8. Country Specific Guidelines from official websites.
9. Drugs& Cosmetics Act & Rules and Amendments.

Recommended websites:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf.
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh /cfdocs/cfcfr/cfrsearch.cfm.
3. Guidelines of International Conference on Harmonization: http://www.ich.org/products/guidelines.html.
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm.
5. FDA New Drug Application.
6. http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmetic ActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm.
7. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk
8. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf.
9. ICMR Ethical Guidelines for Biomedical Research:http://icmr.nic.in /ethical_guidelines.pdf.

REGULATIONS AND LEGISLATION FOR DRUGS& COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T)

Scope:

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs& Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs& Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives:

Upon the completion of the course the student shall be able to:

- Know different Acts and guidelines that regulate Drugs& Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
- Understand the approval process and regulatory requirements for Drugs& Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals.

Course Outcome:

Upon the completion of the course the student shall be able to:

CO1: Explain different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.

CO2: State the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals.

CO3: Discuss the Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards.

CO4: Differentiate IPR and Regulatory affairs.

Theory **60 hrs**

1. Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments): 12 hrs

1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA.
2. Other relevant provisions (rules schedules and guidelines for approval of Drugs, Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India.

Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.

2. Regulatory requirements and approval procedures for Drugs& Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals: 12 hrs

CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities.

- Rules, regulations, guidelines and standards for regulatory filing of Drugs& Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceutical
- Format and contents of Regulatory dossier filing.

Clinical trial/ investigations.

3. Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards 12 hrs

4. Bioavailability and Bioequivalence data (BA &BE), BCS ClassificationofDrugs, Regulatory Requirements for Bioequivalence study 12 hrs

Stability requirements: ICH and WHO.
Guidelines for Drug testing in animals/Preclinical Studies .
Animal testing: Rationale for conducting studies, CPCSEA Guidelines.
Ethical guidelines for human participants.
ICMR-DBT Guidelines for Stem Cell Research.

5. Intellectual Property Rights: 12 hrs

Patent, Trademark, Copyright, Industrial Designs and
Geographical Indications, Indian Patent Scenario. IPR vs. Regulatory Affairs.

References:

1. Manual of Patent Practice & Procedure, 3rdedition, by The Patent Office of India.
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer.
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee.
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New Delhi 2006.

5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for control and supervision on experiments on animals (CPCSEA).
6. ICH E6 Guideline — Good Clinical Practice‖ by ICH Harmonised Tripartite.
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation).
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO.
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO.
10. Guidelines from official website of CDSCO.

REGULATORY AFFAIRS PRACTICAL I (MRA 105P)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation).
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India.
7. Registration for conducting BA/ BE studies in India.
8. Import of Drugs for research and developmental activities.
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM.
10. Registering for different Intellectual Property Rights in India.
11. GMP Audit Requirements as per CDSCO.
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan.
20. Preparation of regulatory submission using eCTD software.
21. Preparation of Clinical Trial Application (CTA) for US submission.
22. Preparation of Clinical Trial Application (CTA) for EU submission.
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER - II

REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Scope:

This course is designed to impart the fundamental knowledge on the Drug development process, regulatory requirements for approval of new Drugs, Drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the Drug products and cosmetics in regulated and semi-regulated countries.

Objectives:

Upon completion of the course, the student shall be able to know:

- Process of Drug discovery and development and generic product development.
- Regulatory approval process and registration procedures for API and Drug products in US, EU.
- Cosmetics regulations in regulated and semi-regulated countries.
- A comparative study of India with other global regulated markets.

Course Outcome:

Upon completion of the course, the student shall be able to:

CO1: Explain the process of drug discovery and development and generic product development.

CO2: Discuss the regulatory approval process and registration procedures for API and drug products in US and EU.

CO3: Explain the cosmetics regulations in regulated and semi-regulated countries.

CO4: Compare the study in India with other global regulated markets.

Theory **60 hrs**

1. USA & CANADA: Organization structure and functions of FDA: **12 hrs**

Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan Drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.

2. European Union & Australia: **12 hrs**

Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

3. Japan: **12 hrs**

Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, Drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan.

4. Emerging Market: **12 hrs**

Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC).

WHO: WHO, GMP, Regulatory Requirements for registration of Drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana).

5. Brazil, ASEAN, CIS and GCC Countries: **12 hrs**

ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of Drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.

CIS (Commonwealth Independent States): Regulatory pre- requisites related to Marketing authorization requirements for Drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for Drugs and post approval requirements in Saudi Arabia and UAE.

Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.

References:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144.
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for Drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition by Rick Ng.
7. New Drug Development: A Regulatory Overview, Eighth Edition by Mark Mathieu.
8. Pharmaceutical Risk Management by Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko.
9. Preparation and Maintenance of the IND Application in eCTD Format by William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pd
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2.

13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981- 230-750-7.
14. Building a Future with Brics: The Next Decade for Off shoring, Mark Kobayashi-Hillary, Springer.
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman.
16. The World Bank, Washington, DC, ISBN: 0-8212-5896-0.
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World byFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139.
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010).
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9.
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Institute of South east Asian studies, Singapore.

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)

Scope:

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labeling of Biologics in India, USA and Europe. It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products.

Objectives:

Upon the completion of the course the student shall be able to:

- Know the regulatory Requirements for Biologics and Vaccines.
- Understand the regulation for newly developed biologics and biosimilars.
- Know the pre-clinical and clinical development considerations of biologics.
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements.

Course outcomes:

Upon the completion of the course the student shall be able to:

CO1: Explain the regulatory requirements for biologics and vaccines.

CO2: Discuss the regulation for newly developed biologics and biosimilars.

CO3: State the pre-clinical and clinical development considerations of biologics.

CO4: Explain the Regulatory Requirements of blood and/or its components including blood products and label requirements.

Theory **60 hrs**

1. India: **12 hrs**

Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

2. USA: **12 hrs**

Introductionto Biologics; biologics, biological and biosimilars, different biological products, difference between generic Drug and biosimilars, laws, regulations and guidance on biologics/biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labeling and packing of biologics.

3. European Union: 12 hrs

Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labeling and packing of biologics in EU.

4. Vaccine regulations in India, US and European Union: 12 hrs

Clinical evaluation, Marketing authorization, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilance Network).

5. Herbal Products: 12 hrs

Quality, safety and legislation for herbal products in India, USA and European Union.

References:

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano, David S. Mantus; Informa,2008.
2. Biological DrugProducts:Developmentand Strategies;Wei Wang, Manmohan Singh; Wiley,2013.
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh, Indresh K. Srivastava;Wiley, 2011.
4. www.who.int/biologicals/en.
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com.
7. www.isbtweb.org.
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India.
9. www.cdsco.nic.in.
10. www.ema.europa.eu › scientific guidelines › Biologicals.
11. www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation (Biologics).

REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Scope:

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the

harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Objectives:

Upon completion of the course, the student shall be able to know

- Basics of medical devices and IVDs, process of development, ethical and quality considerations.
- Harmonization initiatives for approval and marketing of medical devices and IVDs.
- Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN.
- Clinical evaluation and investigation of medical devices and IVDs.

Course Outcomes:

Upon completion of the course, the student shall be able to:

CO1: Discuss the basics of medical devices and IVDs, development process, ethical and quality considerations.

CO2: Explain the harmonization initiatives for approval and marketing of medical devices and IVDs.

CO3: Reiterate the regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN.

CO4: State the clinical evaluation and investigation of medical devices and IVDs.

Theory **60 hrs**

1. Medical Devices: **12 hrs**

Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.

IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

2. Ethics: **12 hrs**

Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device.

3. USA: **12 hrs**

Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of*In vitro* diagnostics, classification and approval process.

4. European Union: **12 hrs**

Introduction, Classification,Regulatory approval process for Medical Devices(Medical Device Directive, Active Implantable Medical Device Directive) and *In vitro* Diagnostics (*In Vitro* Diagnostics Directive), CE certification process.

Basics of *In vitro* diagnostics, classification and approval process.

5. ASEAN, China & Japan: **12 hrs**

Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation.

IMDRF study groups and guidance documents.

References:

1. FDA regulatory affairs: a guide for prescription Drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh.
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina.
5. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

Scope:

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe.

It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

Objectives:

Upon completion of the course, the student shall be able to:

- Know the regulatory Requirements for nutraceuticals.
- Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

Course Outcomes:

Upon completion of the course, the student shall be able to:

CO1: Explain the regulatory Requirements for nutraceuticals.

CO2: State the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

CO3: Explain the global aspects of manufacturing nutraceuticals including their standards and GMP.

Theory **60 Hrs**

1. Nutraceuticals: **12 hrs**

Introduction, History of Food and NutraceuticalRegulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

2. Global Aspects: **12 hrs**

WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food and Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.

3. India: **12 hrs**

Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

4. USA: **12 hrs**

US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labeling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S.

5. European Union: **12 hrs**

European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labeling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

References:

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library).
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier).
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL STU(2015)536324_EN.pdf.
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press).
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley).
7. Country Specific Guidelines from official websites.

REGULATORY AFFAIRS PRACTICAL II (MRA 205P)

Case studies on

1. Change Management/ Change control. Deviations.
2. Corrective & Preventive Actions (CAPA).
3. Documentation of raw materials analysis as per official monographs.
4. Preparation of audit checklist for various agencies.
5. Preparation of submission to FDA using eCTD software.
6. Preparation of submission to EMA using eCTD software.
7. Preparation of submission to MHRA using eCTD software.
8. Preparation of Biologics License Applications (BLA).
9. Preparation of documents required for Vaccine Product Approval.
10. Comparison of clinical trial application requirements of US, EU and India of Biologics.

11. Preparation of Checklist for Registration of Blood and Blood Products.
12. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization.
13. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization.
14. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization.
15. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization.
16. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization.
17. Checklists for 510k and PMA for US market.
18. Checklist for CE marking for various classes of devices for EU.
19. STED Application for Class III Devices.
20. Audit Checklist for Medical Device Facility.
21. Clinical Investigation Plan for Medical Devices.

SEMESTER - III
MRM 301T - RESEARCH METHODOLOGY & BIOSTATISTICS
(COMMON FOR ALL SPECIALIZATIONS)

Scope:
This course is designed to equip the students with the principles, methodologies and theory of statistics as applied in the life and health sciences research.

Course Outcomes:
Upon completion of the course the student shall be able to:

CO1: Explain the values of Ethics and their place in the conduct of medical research
CO2: Follow guidelines pertaining to the ethical conduct of research
CO3: Explain step wise protocol for framing a research proposal

Theory **60 hrs**

UNIT – I **12 hrs**

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II **12 hrs**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, Dropouts, statistical tests of significance, type of significance tests, parametric tests(students “t” test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III **12 hrs**

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV **12 hrs**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V **12 hrs**

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

RP304P - DISSERTATION (ORIENTATION REPORT FORMAT)

Title Page (For specializations other than Pharmacy Practice)

M.Pharmacy (Branch)

Orientation Report

Company logo

Company Name with Address

Submitted by

Name
M.Pharmacy - III Semester

Reg.No:

Faculty of Pharmacy
Sri Ramachandra Institute of Higher Education and Research
(Deemed to be University)
Porur, Chennai - 600 116

Month; Year

Certificate Page

Certificate

This is to certify that Mr/Ms ……, Registration No: …… M.Pharmacy (Branch), III semester, Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai-600116 has completed the Dissertation Orientation Programme during the period ……. under our guidance.

Industrial Guide

Institutional Guide

Principal

Declaration Page

DECLARATION

I hereby declare that this Orientation entitled "----------" in capital and bold submitted by me, in partial fulfillment of the requirements for the degree of Master of Pharmacy (Branch) to Sri Ramachandra Institute of Higher Education and Research (Deemed to be University) is the result of my original and independent research work carried out under the guidance of Institutional guide & Industrial/Clinical Guide to Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai – 600 116, during the year ……..

Date : Reg. No: Signature of the Candidate

Place :

Evaluated by :

Date of the Examination :

Signature of the Internal Examiner 1:

Signature of the Internal Examiner 2 :

M.Pharmacy (Branch)

Orientation Report

Submitted by

Name

M.Pharmacy - III Semester

Reg.No:

Faculty of Pharmacy
Sri Ramachandra Institute of Higher Education and Research
(Deemed to be University)
Porur, Chennai - 600 116

Month; Year

Orientation report should be presented under the following subtitles.

1. Content Page
2. Introduction
3. Literature Review
4. Aim and Objective
5. Plan of work (Inclusive of the Timeline of work)
6. Methodology
7. Conclusion
8. References
9. Appendices

SEMESTER IV

MRP402P – DISSERATION FORMAT
Title Page

TITLE

Dissertation submitted to

Sri Ramachandra Institute of Higher Education and Research
(Deemed to be University)
Porur, Chennai – 600 116

in Partial Fulfillment of the requirement for the degree examination of

MASTER OF PHARMACY (BRANCH)

Submitted by

Name of the Candidate (in capitals)
Registration Number

Faculty of Pharmacy
Sri Ramachandra Institute of Higher Education and Research
(Deemed to be University)
Porur,Chennai – 600 116

Under the guidance of

Guide Name in capitals (Institutional guide)
Industrial/ Clinical guide
With full details

Month & Year

Bonafdide Certificate page

Sri Ramachandra Institute of Higher Education and Research
(Deemed to be University)
Porur, Chennai – 600 116, INDIA

BONAFIDE CERTIFICATE

This is to certify that the dissertation work entitled “TITLE IN BOLD AND CAPITALS” is based on the bonafide work done by student’s Name in capitals, Registration No: ------, II year M.Pharmacy (Branch), during the academic year……...

Date :
Place :

Principal
Faculty of Pharmacy
Sri Ramachandra
Institute of Higher Education and Research
(Deemed to be University)
Porur, Chennai – 600 116.

Certificate Page

CERTIFICATE

This is to certify that this dissertation entitled “TITLE IN BOLD AND CAPITALS” is a bonafide work done by student Name in Capital, Registration No: ----------, in, Industry Name in Capital, Place, in small letters, under our guidance and is being submitted in partial fulfillment for the degree of M.Pharmacy (Branch) examination in (Month; Year).

Industrial /Clinical Guide

Institutional Guide

Date :

Place :

Declaration Page (For specializations other than Pharmacy Practice)

DECLARATION

I hereby declare that this dissertation entitled "---------- in capital and bold submitted by me, in partial fulfillment of the requirements for the degree of Master of Pharmacy (Branch) to Sri Ramachandra Institute of Higher Education and Research (Deemed to be University) is the result of my original and independent research work carried out under the guidance of Institutional guide & Industrial Guide to Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai – 600 116, during the year ……

Date : Reg. No: Signature of the Candidate

Place :

Evaluated by :

Date of the Examination :

Signature of the Internal Examiner :

Signature of the External Examiner :

Declaration Page (For Pharmacy Practice)

DECLARATION

I hereby declare that this dissertation entitled "---------- in capital and bold submitted by me, in partial fulfillment of the requirements for the degree of Master of Pharmacy (Pharmacy Practice) to Sri Ramachandra Institute of Higher Education and Research (Deemed to be University) is the result of my original and independent research work carried out under the guidance of Institutional guide & Clinical Guide to Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai – 600 116, during the year ……

Date : Reg. No: Signature of the Candidate

Place :

Evaluated by :

Date of the Examination :

Signature of the Internal Examiner :

Signature of the interdepartmental/Clinical Examiner :

Signature of the External Examiner :

Dissertation Report Format

Dissertation report should be presented under the following subtitles.

1. Content Page
2. Introduction
3. Literature Review
4. Aim and Objective
5. Plan of work (inclusive of timeline of work)
6. Methodology
7. Results
8. Discussion
9. Conclusion
10. References
11. Appendices