## FACULTY OF PHARMACY KARPAGAM ACADEMY OF HIGHER EDUCATION

Deemed to be University
(Established Under Section 3 of UGC Act 1956)
Eachanari Post, Pollachi Main Road, Coimbatore – 641021.

# PHARM.D DEGREE COURSE (2022-2023) (DOCTOR OF PHARMACY)



## REGULATIONS 2022 COURSE OF STUDY AND SCHEME OF EXAMINATION

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**SYLLABUS** 

#### **CHAPTER-I**

#### 1. Short title and commencement

- (1) These regulations may be called the Pharm.D Regulations 2022.
- (2) They shall come into force from the date of their publication in the official Gazette.
- **2.** Pharm.D shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

#### **CHAPTER-II**

#### 3. Duration of the course:

- a) Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases
  - Phase I consisting of First, Second, Third, Fourth and Fifth academic year.

    Phase II consisting of internship or residency training during sixth year involving posting in specialty units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.
- b) Pharm.D (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases:
  - Phase I consisting of First and Second academic year.
  - Phase II consisting of Internship or residency training during third year involving posting in specialty units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.

#### 4. Minimum qualification for admission to:

- a) Pharm.D Part-I Course A pass in any of the following examinations:
  - (1) 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following subjects: Mathematics or Biology.
  - (2) A pass in D. Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.
  - (3) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

Provided that a student should complete the age of 17 years on or before 31<sup>st</sup> December of the year of admission to the course.

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.

b) Pharm.D. (Post Baccalaureate) Course –

A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

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.

- **5.** Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below:
  - i) Pharm.D. Programme 30 students
  - ii) Pharm.D. (Post Baccalaureate) Programme 10 students
- **6.** Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D programme. Pharm.D (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. Programme.

#### 7. Attendance and progress:

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

#### 8. Program / Course credit structure:

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, 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.

#### **Credit assignment:**

#### Theory and Laboratory courses:

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 theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

#### Minimum credit requirements:

The minimum credit points required for award of a Pharm.D degree is 160. These credits are divided into Theory courses, Tutorials, Practical, Clerkship and Project over the duration of six years. The credits are distributed year-wise as shown in Table VI. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the year-wise schedule of courses given in the syllabus.

#### 9. Academic work:

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses.

## 10. Course of study:

The course of study for Pharm.D shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns below.

TABLES
TABLE I : FIRST YEAR

Course Code	Name of Subject	No. of hours	Tutorial	Credit points
22PD101T	Human Anatomy and Physiology Theory	3	1	4
22PD102T	Pharmaceutics Theory	2	1	3
22PD103T	Medicinal Biochemistry Theory	3	1	4
22PD104T	Pharmaceutical Organic Chemistry Theory	3	1	4
22PD105T	Pharmaceutical Inorganic Chemistry Theory			3
22PD106RMT / 22PD106RBT	Remedial Mathematics**/ Remedial Biology Theory**	3	1	4
22PD107P	Human Anatomy and Physiology Practical	3	-	2
22PD108P	Pharmaceutics Practical	3	-	2
22PD109P	Medicinal Biochemistry Practical	3	-	2
22PD110P	Pharmaceutical Organic Chemistry Practical	3	-	2
22PD111P	Pharmaceutical Inorganic Chemistry Practical	3	-	2
22PD112RBP	Remedial Biology Practical**	3*	-	2*
	Total Hours	31/34*	6	32/34*

<sup>\*</sup> For Remedial Biology Practical

## **TABLE II: SECOND YEAR**

Course	Name of Subject	No. of	Tutorial	Credit
Code		hours		points
22PD201T	Pathophysiology Theory	3	1	4
22PD202T	Pharmaceutical Microbiology Theory	3	1	4
22PD203T	Pharmacognosy & Phytopharmaceuticals	3	1	4
	Theory			
22PD204T	Pharmacology-I Theory	3	1	4
22PD205T	Community Pharmacy Theory	2	1	3
22PD206T	Pharmacotherapeutics-I Theory	3	1	4
22PD207P	Pharmaceutical Microbiology Practical	3	-	2
22PD208P	Pharmacognosy & Phytopharmaceuticals	3	-	2
	Practical			
22PD209P	Pharmacotherapeutics-I Practical	3	-	2
	Total Hours	26	6	29

<sup>\*\*</sup> For Remedial Mathematics / Remedial Biology (Non University Exam)

## TABLE III: THIRD YEAR

Course	Name of Subject	No. of hours	Tutorial	Credit points
Code				
22PD301T	Pharmacology-II Theory	3	1	4
22PD302T	Pharmaceutical Analysis Theory	3	1	4
22PD303T	Pharmacotherapeutics-II Theory	3	1	4
22PD304T	Pharmaceutical Jurisprudence Theory	2	-	2
22PD305T	Medicinal Chemistry Theory	3	1	4
22PD306T	Pharmaceutical Formulations Theory	2	1	3
22PD307P	Pharmacology-II Practical	3	-	2
22PD308P	Pharmaceutical Analysis Practical	3	-	2
22PD309P	Pharmacotherapeutics-II Practical	3	-	2
22PD310P	Medicinal Chemistry Practical	3	-	2
22PD311P	Pharmaceutical Formulations Practical	3	-	2
	Total hours	31	5	31

## **TABLE IV : FOURTH YEAR**

Course Code	Name of Subject	No. of hours	Tutorial	Credit points
22PD401T	Pharmacotherapeutics-III Theory	3	1	4
22PD402T	Hospital Pharmacy Theory	2	1	3
22PD403T	Clinical Pharmacy Theory	3	1	4
22PD404T	Biostatistics & Research Methodology Theory	2	1	3
	Biopharmaceutics & Pharmacokinetics			4
22PD405T	Theory	3	1	
22PD406T	Clinical Toxicology Theory	2	1	3
22PD407P	Pharmacotherapeutics-III Practical	3	-	2
22PD408P	Hospital Pharmacy Practical	3	-	2
22PD409P	Clinical Pharmacy Practical	3	-	2
22PD410P	Biopharmaceutics & Pharmacokinetics	3	-	2
	Practical			
	Total Hours	27	6	29

## TABLE V: FIFTH YEAR

Course	Name of Subject	No. of hours	Seminar	Credit points
Code				
22PD501T	Clinical Research Theory	3	1	4
22PD502T	Pharmacoepidemiology and Pharmacoeconomics Theory	3	1	4
22PD503T	Clinical Pharmacokinetics & Pharmacotherapeutics Drug Monitoring Theory	2	1	3
22PD504S	Clerkship *	-	1	1
22PD505P	Project work (Six Months)	20	-	10
	Total hours	28	4	22

<sup>\*</sup> Attending ward rounds on daily basis

#### **SIXTH YEAR**

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

- (i) Six months in General Medicine department, and
- (ii) Two months each in three other speciality departments

TABLE VI: YEAR WISE CREDITS DISTRIBUTION

Year	Credit Points
I	32/34*
II	29
III	31
IV	29
V	22
VI	15
Total credit points for the program	158/160*

#### 11. Syllabus:

The syllabus for each subject of study in the said Tables shall be as specified in **Chapter-IV** to these regulations.

#### 12. Approval of the authority conducting the course of study:

- (1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D (Post Baccalaureate) programme without the prior approval of the Pharmacy Council of India.
  - a. Any person or pharmacy college for the purpose of obtaining permission under subsection (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.
  - b. The scheme referred to in sub-regulation
- (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs, equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.

## 13. Examination:

- (1) Every year there shall be an examination to examine the students.
- (2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.
- (3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below:

TABLES
TABLE VII: FIRST YEAR EXAMINATION

Course Code	Name of Subject		ernal ssment	Exami	Total	
Course Code	Name of Subject	Marks	Duration	Marks	Duration	Marks
22PD101T	Human Anatomy and Physiology Theory	30	1 Hr	70	3 Hrs	100
22PD102T	Pharmaceutics Theory	30	1 Hr	70	3 Hrs	100
22PD103T	Medicinal Biochemistry Theory	30	1 Hr	70	3 Hrs	100
22PD104T	Pharmaceutical Organic Chemistry Theory	30	1 Hr	70	3 Hrs	100
22PD105T	Pharmaceutical Inorganic Chemistry Theory	30	1 Hr	70	3 Hrs	100
22PD106RMT / 22PD106RBT	Remedial Mathematics Theory*/ Remedial Biology Theory*	30	1 Hr	70	3 Hrs	100
22PD107P	Human Anatomy and Physiology Practical	30	3 Hrs	70	3 Hrs	100
22PD108P	Pharmaceutics Practical	30	3 Hrs	70	3 Hrs	100
22PD109P	Medicinal Biochemistry Practical	30	3 Hrs	70	3 Hrs	100
22PD110P	Pharmaceutical Organic Chemistry Practical	30	3 Hrs	70	3 Hrs	100
22PD111P	Pharmaceutical Inorganic Chemistry Practical	30	3 Hrs	70	3 Hrs	100
22PD112RBP	Remedial Biology Practical*	30*	3 Hrs	70*	3 Hrs	100*
	Total	360	24 Hrs	840	36 Hrs	1200

<sup>\*</sup> For Biology

## TABLE VIII: SECOND YEAR EXAMINATION

Course Code	Name of Subject		Internal Assessment		Examination	
004200 0040	1 (dans 01 Sasjeet	Marks	Duration	Marks	Duration	Marks
22PD201T	Pathophysiology Theory	30	1 Hr	70	3 Hrs	100
22PD202T	Pharmaceutical Microbiology Theory	30	1 Hr	70	3 Hrs	100
22PD203T	Pharmacognosy & Phytopharmaceuticals Theory	30	1 Hr	70	3 Hrs	100
22PD204T	Pharmacology-I Theory	30	1 Hr	70	3 Hrs	100
22PD205T	Community Pharmacy Theory	30	1 Hr	70	3 Hrs	100
22PD206T	Pharmacotherapeutics-I Theory	30	1 Hr	70	3 Hrs	100
22PD207P	Pharmaceutical Microbiology Practical	30	3 Hrs	70	3 Hrs	100
22PD208P	Pharmacognosy & Phytopharmaceuticals Practical	30	3 Hrs	70	3 Hrs	100
22PD209P	Pharmacotherapeutics-I Practical	30	3 Hrs	70	3 Hrs	100
	Total	270	15 Hrs	630	27 Hrs	900

## TABLE IX: THIRD YEAR EXAMINATION

Course Code	Name of Subject	Internal Assessment		Examination		Total
Course Coue	Traine of Subject	Marks	Duration	Marks	Duration	Marks
22PD301T	Pharmacology-II Theory	30	1 Hr	70	3 Hrs	100
22PD302T	Pharmaceutical Analysis Theory	30	1 Hr	70	3 Hrs	100
22PD303T	Pharmacotherapeutics-II Theory	30	1 Hr	70	3 Hrs	100
22PD304T	Pharmaceutical Jurisprudence Theory	30	1 Hr	70	3 Hrs	100
22PD305T	Medicinal Chemistry Theory	30	1 Hr	70	3 Hrs	100
22PD306T	Pharmaceutical Formulations Theory	30	1 Hr	70	3 Hrs	100
22PD307P	Pharmacology-II Practical	30	3 Hrs	70	3 Hrs	100
22PD308P	Pharmaceutical Analysis Practical	30	3 Hrs	70	3 Hrs	100
22PD309P	Pharmacotherapeutics-II Practical	30	3 Hrs	70	3 Hrs	100
22PD310P	Medicinal Chemistry Practical	30	3 Hrs	70	3 Hrs	100
22PD311P	Pharmaceutical Formulations Practical	30	3 Hrs	70	3 Hrs	100
	Total	330	21 Hrs	770	33 Hrs	1100

## **TABLE X: FOURTH YEAR EXAMINATION**

<b>Course Code</b>	Name of Subject	Internal A	Assessment	Exam	ination	Total
		Marks	Duration	Marks	Duration	Marks
22PD401T	Pharmacotherapeutics-III Theory	30	1 Hr	70	3 Hrs	100
22PD402T	Hospital Pharmacy Theory	30	1 Hr	70	3 Hrs	100
22PD403T	Clinical Pharmacy Theory	30	1 Hr	70	3 Hrs	100
22PD404T	Biostatistics & Research Methodology Theory	30	1 Hr	70	3 Hrs	100
22PD405T	Biopharmaceutics & Pharmacokinetics Theory	30	1 Hr	70	3 Hrs	100
22PD406T	Clinical Toxicology Theory	30	1 Hr	70	3 Hrs	100
22PD407P	Pharmacotherapeutics-III Practical	30	3 Hrs	70	3 Hrs	100
22PD408P	Hospital Pharmacy Practical	30	3 Hrs	70	3 Hrs	100
22PD409P	Clinical Pharmacy Practical	30	3 Hrs	70	3 Hrs	100
22PD410P	Biopharmaceutics & Pharmacokinetics Practical	30	3 Hrs	70	3 Hrs	100
	Total	300	18 Hrs	700	30 Hrs	1000

## **TABLE XI: FIFTH YEAR EXAMINATION**

<b>Course Code</b>	Name of Subject	Internal A	Internal Assessment		ination	Total
		Marks	Duration	Marks	Duration	Marks
22PD501T	Clinical Research Theory	30	1 Hr	70	3 Hrs	100
22PD502T	Pharmacoepidemiology and	30	1 Hr	70	3 Hrs	100
	Pharmacoeconomics Theory					
22PD503T	Clinical Pharmacokinetics &	30	1 Hr	70	3 Hrs	100
	Pharmacotherapeutics Drug					
	Monitoring Theory					
22PD504S	Clerkship *	30	1 Hr	70	3 Hrs	100
22PD505P	Project work** (Six Months)	-	-	100	-	100
	Total	120	4 Hrs	380	12 Hrs	500

<sup>\*</sup>Attending ward rounds on daily basis.

70 marks – Thesis work

CIA	1320/1350#/1380*	ESE	3180/3250#/3320*	<b>Grand Total</b>	4500/4600#/4700*	
# for Remedial Mathematics *for Remedial Biology						

<sup>\*\*30</sup> marks – viva-voce (oral)

#### 14. Eligibility for appearing Examination:

Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D or as the case may be, the Pharm.D (Post Baccalaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.

#### 15. Mode of examinations:

- (1) Theory examination shall be of three hours and practical examination shall be of three hours duration.
- (2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.
- (3) Practical examination shall also consist of a viva –voce (Oral) examination.
- (4) Clerkship examination Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. 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.

#### 16. Award of sessional marks and maintenance of records:

- (1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post Baccalaureate) course, 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 as sessional. There shall be at least two periodic sessional examinations during each academic year and the average marks of at least two sessional exams shall be computed for internal assessment. The sessional marks in practicals shall be allotted on the following basis:-
  - (i) Actual performance in the sessional examination (20 marks)
  - (ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc. (10 marks)

#### **Minimum marks for passing examination:**

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 sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt.

#### **Question paper pattern for Theory Sessional examinations**

#### For 30 marks paper

I. Long Answers (Answer 1 out of 2) = 
$$1 \times 15 = 15$$
  
II. Short Answers (Answer 3 out of 4) =  $3 \times 5 = 15$   
Total = 30 marks

## **Question paper pattern for Practical Sessional examinations**

#### For 30 marks paper

Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

#### **Question paper pattern for Theory Examinations**

#### For 70 marks paper

I. Long Essay (Answer 2 out of 3) = 
$$2 \times 15 = 30$$
  
II. Short Essay (Answer 6 out of 8) =  $6 \times 5 = 30$   
III. Short Answers (Answer 5 out of 7) =  $5 \times 2 = 10$   
Total =  $70$  marks

#### **Question paper pattern for Practical Examinations**

## For 70 marks paper

I. Synopsis = 15

II. Experiments = 40 (25+15)

IV.Viva voce = 15

Total = **70 marks** 

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## 17. Grading of performances

### 17.1. 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 - XII.

Table XII: LETTER GRADES AND GRADE POINTS EQUIVALENT TO PERCENTAGE

OF MARKS AND PERFORMANCES

Letter Grade	Marks Range	Grade Point	Description
0	91 – 100	10	OUTSTANDING
A+	81 – 90	9	EXCELLENT
A	71-80	8	VERY GOOD
B+	66-70	7	GOOD
В	61-65	6	ABOVE AVERAGE
С	55-60	5	AVERAGE
D	50-54	4	PASS
RA	<50	0	REAPPEARANCE
AB		0	ABSENT

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.

#### 18. Grade Sheet

After results are declared, Grade sheet will be issued to each student which will contain the following details:

- i. The list of courses enrolled during the year and the grade scored,
- ii. The Grade Point Average(GPA) for the year and

iii. The Cumulative Grade Point Average (CGPA) of all courses enrolled from first

years onwards.

iv. The Cumulative Grade point Average (GPA) of all course enrolled from first year

onwards.

GPA is ratio of the sum of the products of the number of credits © of courses enrolled and the

Grade Points(GP) corresponding to the grades scored in those courses, taken for all the courses

to the sum of the number of credits of all the courses in the year.

 $GPA = Sum of [C \times GP]$ 

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Sum of C

CGPA will be calculated in a similar manner, considering all the courses enrolled from First

year. RA grade and value added course will be excluded for calculating GPA and CGPA.

19. Revaluation

Revaluation and Re-totaling is allowed on representation. A candidate can apply for revaluation

of his/her semester Examination answer paper in a theory course, within 2 weeks from the

declaration of results, on payment of a prescribed fee through proper application to the

Controller of Examinations through the Head of the Department and Dean. A candidate can

apply for revaluation of answer scripts for not exceeding 4 subjects at a time. The Controller of

Examinations will arrange for the revaluation and the results will be intimated to the candidate

through the Head of the Department and Dean. Revaluation is not permitted for Supplementary

Examinations, Practical Examinations, Technical Seminars, In-plant Training and Project Work.

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = 8 and above

First Class = 6.50 to 7.99

Second Class = 5.00 to 6.49

#### 21. Eligibility for promotion to next year :

All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.

#### 22. Internship:

- (1) 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.
- (2) Every student has to undergo one year internship as per Appendix-C to these regulations.

#### **23.** Approval of examinations:

Examinations mentioned in regulations 10 to 12 and 14 shall be held by the examining authority hereinafter referred to as the university, which shall be approved by the Pharmacy Council of India under sub-section (2) of section 12 of the Pharmacy Act, 1948. Such approval shall be granted only if the examining authority concerned fulfills the conditions as specified in Appendix–D to these regulations.

#### 24. Certificate of passing examination:

Every student who has passed the examinations for the Pharm.D (Doctor of Pharmacy) or Pharm.D (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.

#### **CHAPTER-III**

#### PRACTICAL TRAINING

#### 25. Hospital posting:

Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. 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.

#### 26. Project work:

- (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.

#### 27. 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; and
- (ii) develop the students in data collection, analysis and reporting and interpretation skills.

#### 28. 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 authorised 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 utilisation 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; and
- (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.

#### 29. 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 authorised 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 authorised teacher with font size 14.
- (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

#### **30. 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	g items: Marks
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)

**Total** (70 marks)

(17.5)

(17.5)

#### Explanation:

c) Communication skills

d) Question and answer skills

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.

#### 31. a. Online Course

Students shall study at least one online course from SWAYAM/ NPTEL/ MOOC in any one of the first five years for which examination shall be conducted at the end of the course by the respective organizations. The student can register to the courses which are approved by the Department. The student shall produce a pass certificate from the respective organizations before the end of the fifth year. The credit(s) earned by the students will be considered as additional credit(s) over and above the required credits earned from programme concerned.

#### 31. b. Online Course Co-ordinator

To help students in planning their online courses and for general advice on online courses, the HOD shall nominate a co-ordinator for the online courses. The Online course co-ordinator shall identify the courses which students can select for their programme from the available online courses offered by the different agencies periodically and inform the same to the students. Further, the co-ordinator shall advice the students regarding the online courses and monitors their course.

#### 32. Award of Ranks

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

#### 33. Award of degree

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

#### 34. 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 have to pass within the said period, otherwise they have to get fresh registration.

#### 35. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

No condonation is allowed for the candidate who has more than 2 years of breakup period and he/she has to rejoin the program by paying the required fees.

## FACULTY OF PHARMACY PHARM.D PROGRAMME

**(2021–2022 Batch and onwards)** 

	PEOs				week	Credit(s)	Maximum Marks			
		POs	L	Т	P	Cre	CIA	ESE	Total	
	F						30	70	100	
·	T	Т	1		1	1	T	1		
Human Anatomy and Physiology Theory	2	k	3	1	-	4	30	70	100	
Pharmaceutics Theory	3	a	2	1	-	3	30	70	100	
Medicinal Biochemistry Theory	2	a,k	3	1	-	4	30	70	100	
Pharmaceutical Organic	3	a	3	1	-	4	30	70	100	
Pharmaceutical Inorganic Chemistry Theory	2	a	2	1	-	3	30	70	100	
Remedial Mathematics**/	6	c/a	3	1	-	4	30	70	100	
Remedial Biology** Theory										
Human Anatomy and Physiology Practical	2	b	-	-	3	2	30	70	100	
Pharmaceutics Practical	3	a,b	-	-	3	2	30	70	100	
Medicinal Biochemistry Practical	2	b,k	-	-	3	2	30	70	100	
Pharmaceutical Organic Chemistry Practical	2	b	-	-	3	2	30	70	100	
Pharmaceutical Inorganic Chemistry Practical	2	b	-	-	3	2	30	70	100	
Remedial Biology Practical**	2	b	-	-	3*	2*	30	70	100	
Total			16	6	15/ 18*	32/ 34*	360	840	1200	
	Medicinal Biochemistry Theory Pharmaceutical Organic Chemistry Theory Pharmaceutical Inorganic Chemistry Theory Remedial Mathematics**/ Remedial Biology** Theory  Human Anatomy and Physiology Practical Pharmaceutics Practical Medicinal Biochemistry Practical Pharmaceutical Organic Chemistry Practical Pharmaceutical Inorganic Chemistry Practical Remedial Biology Practical**  Total	Medicinal Biochemistry Theory Pharmaceutical Organic Chemistry Theory Pharmaceutical Inorganic Chemistry Theory Remedial Mathematics**/ Remedial Biology** Theory Human Anatomy and Physiology Practical Pharmaceutics Practical Pharmaceutical Organic Chemistry Practical Pharmaceutical Inorganic Chemistry Practical Pharmaceutical Inorganic Chemistry Practical Remedial Biology Practical*  Remedial Biology Practical*  2 Total	Medicinal Biochemistry Theory Pharmaceutical Organic Chemistry Theory Pharmaceutical Inorganic Chemistry Theory Remedial Mathematics**/ Remedial Biology** Theory Human Anatomy and Physiology Practical Pharmaceutics Practical Pharmaceutical Organic Chemistry Practical Pharmaceutical Organic Chemistry Practical Pharmaceutical Inorganic Chemistry Practical Pharmaceutical Inorganic Chemistry Practical Remedial Biology Practical**  Total	Medicinal Biochemistry Theory Pharmaceutical Organic Chemistry Theory Pharmaceutical Inorganic Chemistry Theory Remedial Mathematics**/ Remedial Biology** Theory  Human Anatomy and Physiology Practical Pharmaceutics Practical Pharmaceutical Organic Chemistry Practical Pharmaceutical Inorganic Chemistry Practical Pharmaceutical Inorganic Chemistry Practical Pharmaceutical Inorganic Chemistry Practical Remedial Biology Practical**  2 a 2  2 b -	Medicinal Biochemistry Theory Pharmaceutical Organic Chemistry Theory Pharmaceutical Inorganic Chemistry Theory Remedial Mathematics**/ Remedial Biology** Theory  Human Anatomy and Physiology Practical Pharmaceutical Organic Chemistry Practical Pharmaceutical Organic Chemistry Practical Pharmaceutical Inorganic Chemistry Practical Pharmaceutical Inorganic Chemistry Practical Remedial Biology Practical*  Total  2	Medicinal Biochemistry   2	Medicinal Biochemistry   2	Medicinal Biochemistry   2	Medicinal Biochemistry         2         a,k         3         1         -         4         30         70           Pharmaceutical Organic         3         a         3         1         -         4         30         70           Chemistry Theory         2         a         2         1         -         3         30         70           Remedial Mathematics**/ Remedial Biology** Theory         6         c/a         3         1         -         4         30         70           Human Anatomy and Physiology Practical         2         b         -         -         3         2         30         70           Medicinal Biochemistry Practical         2         b,k         -         -         3         2         30         70           Pharmaceutical Organic Chemistry Practical         2         b         -         -         3         2         30         70           Remedial Biology Practical         2         b         -         -         3         2         30         70           Total         16         6         15/ 18*         34*         360         840	

	Pharmacognosy & Phytopharmaceuticals Practical	2	a.b	-	-	3	2	30	70	100
22PD209P	Pharmacotherapeutics-I Practical	3	b,c,g	-	-	3	2	30	70	100
	Total			17	6	9	29	270	630	900

		and	ectives l out mes	h	truct ours week	:/	(8)	Max	Maximum Marks			
Course code	Name of the course	PEOs	PEOs POs		Т	P	Credit(s)	CIA	ESE	Total		
								30	70	100		
YEAR - III								_				
22PD301T	Pharmacology-II Theory	3	a,d,k	3	1	-	4	30	70	100		
22PD302T	Pharmaceutical Analysis Theory	2	c	3	1	-	4	30	70	100		
22PD303T	Pharmacotherapeutics-II Theory	3	a,f,k	3	1	-	4	30	70	100		
22PD304T	Pharmaceutical Jurisprudence Theory	5	a,e,g	2	-	-	2	30	70	100		
22PD305T	Medicinal Chemistry Theory	2	a.k	3	1	-	4	30	70	100		
22PD306T	Pharmaceutical Formulations Theory	4	a,c,k	2	1	-	3	30	70	100		
22PD307P	Pharmacology-II Practical	3	a,d,k			3	2	30	70	100		
22PD308P	Pharmaceutical Analysis Practical	2	c	-	-	3	2	30	70	100		
22PD309P	Pharmacotherapeutics-II Practical	3	a,f,k	-	-	3	2	30	70	100		
22PD310P	Medicinal Chemistry Practical	2	a,b	-	-	3	2	30	70	100		
22PD311P	Pharmaceutical Formulations Practical	4	a,c	-	-	3	2	30	70	100		
	Total			16	6	15	31	330	770	1100		
YEAR - IV												
22PD401T	Pharmacotherapeutics-III Theory	3	a,f,k	3		1 -	4	1 30	70	100		
22PD402T	Hospital Pharmacy Theory	1,6	a,f,g,i, k	2		1 -	(1)	30	70	100		
22PD403T	Clinical Pharmacy Theory	1,6	a,f,g,i, k	3		1 -	4	30	70	100		
22PD404T	Biostatistics & Research Methodology Theory	2	b,c,d,k	2		1 -		30	70	100		
22PD405T	Biopharmaceutics & Pharmacokinetics Theory	5	a,c,k	3		1 -	4	30	70	100		
22PD406T	Clinical Toxicology Theory	3	a,g,k,i	2		1	3	30	70	100		
22PD407P	Pharmacotherapeutics-III Practical	3	a,f,k	-		- 3	1 2	2 30	70	100		
22PD408P	Hospital Pharmacy Practical	1,6	a,f,g,i, k	-		- 3	2	2 30	70	100		
22PD409P	Clinical Pharmacy Practical	6	a,f,g,i, k	-	-	- 3	1 2	2 30	70	100		
22PD410P	Biopharmaceutics & Pharmacokinetics Practical	3,5	a,c,k	-		- 3			70	100		
	Total			10	5	5 1	2 2	9 300	700	1000		

Course code	Name of the course	•	tives and comes		ruct ours week	/	Credit(s)	Maximum Marks			
Course code		PEOs	POs	L	Т	P	Cr	CIA	ESE	Total	
					_	_		30	70	100	
YEAR V											
22PD501T	Clinical Research Theory	1,4,6	a,f,i,g,k	3	1	-	4	30	70	100	
22PD502T	Pharmacoepidemiology and Pharmacoeconomics Theory	3,6	a,d,j	3	1	-	4	30	70	100	
22PD503T	Clinical Pharmacokinetics & Pharmacotherapeutics Drug Monitoring Theory	3,5	a,c,k	2	1	-	3	30	70	100	
22PD504S	Clerkship *	1,3,5,6	c,e,f,g,h, i,k	ı	1	-	1	30	70	100	
22PD505P	Project work (Six Months)	1,3,5,6	a,b,c,d,e, f,g,h,i,j,k	1	-	20	10	-	100**	100	
	Total			8	4	20	22	120	380	500	

<sup>\*</sup>Attending ward rounds on daily basis

#### **YEAR VI**

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

- (i) Six months in General Medicine department, and
- (ii) Two months each in three other speciality departments.

<sup>\*\* 30</sup> marks – Viva- Voice (oral)

<sup>70</sup> marks – Thesis work

#### PROGRAM OUTCOMES (PO's)

- a. Pharmacy Knowledge: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and practice of pharmacy.
- b. **Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
- c. Problem analysis: Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
- d. **Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
- e. **Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and wellbeing.
- f. **Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
- g. **Pharmaceutical Ethics:** Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
- h. **Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
- i. **The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.

- j. **Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
- k. **Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

#### PROGRAM SPECIFIC OUTCOMES (PSOs)

**PSO I:** Understand different classes of drugs, their mechanism of action, dynamics, kinetics, structure activity relationships, pathophysiology and pharmacotherapeutics of various diseases, ability to synthesize, develop and/or evaluate various pharmaceuticals and their formulations and cosmeceuticals products.

**PSO m:**Develop skills in qualitative and quantitative analysis of various pharmaceuticals. Acquire technical knowledge and hands on training on equipments, instruments and software used in the field of pharmaceutical sciences.

**PSO n:** To inculcate the practice of pharmacyand train pharmacists to play an important role in patient care, health and wellness and population-based care as members of the health care team

**PSO o:** To exhibit behaviors and values that are consistent with the trust given to the profession, professionalism in interactions with patients, professionalism in interactions with other healthcare providers, professionalism in interactions with society

**PSO p**: To strengthen the professional and ethical attitude, effective communication skills, teamwork skills, multidisciplinary approach, and an ability to relate pharmaceutical sciences issues to broader social context.

**PSO** q: To stream a lifelong career of personal and practicing professional growth with ethical codes and self-esteem.

#### PROGRAM EDUCATIONAL OBJECTIVES (PEOs)

**PEO 1:** Synthesize population-based drug information to address patient medication adherence, prescribing patterns, and treatment protocol adherence to document issues, alert prescribers, design interventions, and assess intervention effectiveness.

- **PEO 2:** To provide students with a strong and well defined concepts in the various fields of pharmaceutical sciences viz., pharmaceutics, pharmaceutical chemistry, pharmacology and pharmacognosy according to the requirement of pharmaceutical industries, community and hospital pharmacy and also to develop a sense of teamwork and awareness amongst students towards the importance of interdisciplinary approach for developing competence in solving complex problems in the area of Pharmaceutical Sciences.
- **PEO 3:** Identify physicochemical properties of drug substances that affect solubility, pharmacodynamic and pharmacokinetic properties, pharmacologic actions, and stability when designing patient-specific care plans.
- **PEO 4:** Formulate and implement a care plan in cooperation with patients and other healthcare providers based on established, evidence-based standards of practice; provide medication therapy management services for patients with acute & chronic health problems.
- **PEO 5:** Integrate knowledge of chemical, physical, and biopharmaceutical principles to preparesafe and effective prescriptions (sterile and non-sterile) in conformity with all applicable federal and state laws and regulations.
- **PEO 6:** Provide health care information regarding nutrition, lifestyle, and other non-drug measures that promote health or prevent the progression of a disease or medical condition. Demonstrate a comprehensive approach to practice and care, includes problem solving, educator, patient advocacy, interprofessional collaboration, cultural sensitivity, communication.

#### **MAPPING**

PO	a	b	c	d	e	f	g	h	i	j	k	PSO 1	PSO m	PSO n	PSO o	PSO p	PSO q
PEO 1	X	X		X	X	X	X	X	X		X	X		X	X	X	X
PEO 2	X		X				X				X	X	X			X	X
PEO 3	X	X	X			X			X		X	X	X				
PEO 4	X	X	X			X	X	X		X	X			X	X	X	X
PEO 5	X						X	X	X	X	X		X		X		
PEO 6	X		X			X	X	X	X	X	X			X	X	X	X

22PD101T FIRST YEAR

#### HUMAN ANATOMY AND PHYSIOLOGY THEORY 4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

#### Theory: 4 Hrs / Week

#### **Course 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 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.
- To appreciate coordinated working pattern of different organs of each system; and
- To understand the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

#### **Course Outcome (CO's):**

- 1. Describe the structure (gross and histology) and functions of various organs of the human body;
- 2. Describe the various homeostatic mechanisms and their imbalances of various systems;
- 3. Discuss the various tissues and organs of the different systems in the human body;
- 4. Perform the hematological tests and also record blood pressure, heart rate, pulse and respiratory volumes;
- 5. Illustrate the coordinated working pattern of different organs of each system; and
- 6. Illustrate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

#### **Course Content:**

#### **UNIT I**

- Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)
- Structure of cell its components and their functions.
- Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics

#### **UNIT II**

• Osseous system - structure, composition and functions of the skeleton

 Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

#### **UNIT III**

#### **Haemopoetic System**

- Composition and functions of blood
- Haemopoesis and disorders of blood components (definition of disorder)
- Blood groups
- Clotting factors and mechanism
- Platelets and disorders of coagulation

#### Lymph

- Lymph and lymphatic system, composition, formation and circulation.
- Spleen: structure and functions, Disorders
- Disorders of lymphatic system (definition only)

#### **UNIT IV**

#### Cardiovascular system

- Anatomy and functions of heart
- Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
- Electrocardiogram (ECG)
- Cardiac cycle and heart sounds
- Blood pressure its maintenance and regulation
- Definition of the following disorders
- Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina,
   Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

#### **Respiratory system**

- Anatomy of respiratory organs and functions
- Mechanism / physiology of respiration and regulation of respiration
- Transport of respiratory gases
- Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia,
   Dybarism, Oxygen therapy and resuscitation.

#### **UNIT V**

#### **Digestive system**

• Anatomy and physiology of GIT

- Anatomy and functions of accessory glands of GIT
- Digestion and absorption
- Disorders of GIT (definitions only)

#### **UNIT VI**

#### Nervous system

- Definition and classification of nervous system
- Anatomy, physiology and functional areas of cerebrum
- Anatomy and physiology of cerebellum
- Anatomy and physiology of mid brain
- Thalamus, hypothalamus and Basal Ganglia
- Spinal cord: Structure & reflexes mono-poly-planter
- Cranial nerves names and functions
- ANS Anatomy & functions of sympathetic & parasympathetic N.S.

#### **UNIT VII**

## **Urinary system**

- Anatomy and physiology of urinary system
- Formation of urine
- Renin Angiotensin system Juxtaglomerular apparatus acid base Balance
- Clearance tests and micturition

## **Endocrine system**

- Pituitary gland
- Adrenal gland
- Thyroid and Parathyroid glands
- Pancreas and gonads

#### **UNIT VIII**

#### **Reproductive system**

- Male and female reproductive system
- Their hormones Physiology of menstruation
- Spermatogenesis & Oogenesis
- Sex determination (genetic basis)
- Pregnancy and maintenance and parturition
- Contraceptive devices

#### **UNIT IX**

#### Sense organs

- Eye
- Ear
- Skin
- Tongue & Nose

#### **Skeletal muscles**

- Histology
- Physiology of Muscle contraction
- Physiological properties of skeletal muscle and their disorders (definitions)

#### **UNIT X**

#### **Sports physiology**

- Muscles in exercise, Effect of athletic training on muscles and muscle performance,
- Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
- Drugs and athletics

#### **Suggested Readings:**

- 1. Tortora Gerard J. and Nicholas P. Principles of Anatomy and Physiology Publisher Harpercollins College New York.
- 2. Wilson, K.J.W. Ross and Wilson's foundations of Anatomy and Physiology Publisher: Churchill Livingstone, Edinburg.

#### **Reference Books (Latest Editions):**

- 1. Guyton Arthur, C. Physiology of human body. Publisher: Holtsaunders.
- 2. Chatterjee C C. Human physiology. Volume 1&11. Publisher: Medical Allied Agency, Calcutta.
- 3. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
- 4. Gray's Anatomy. Publisher: Churchill Livingstone, London.

22PD107P FIRST YEAR

#### HUMAN ANATOMY AND PHYSIOLOGY PRACTICAL 3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

## Practical: 3 Hrs/Week

#### **Course Objectives:**

- Practical physiology is complimentary to the theoretical discussions in physiology.
- Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings.
- To Identify epithelial, connective tissue, muscular, nervous tissues Microscopically and the axial, appendicular bones.
- Know about the bleeding time and clotting time.
- Know to Record the heart rate, pulse rate, blood pressure.
- Understand the WBC count and RBC count

Course Outcomes (CO's): On successful completion of the course the student will

- 1. Identify different types of tissues under microscope
- 2. Identify different types of bones
- 3. Identify different types of organs
- 4. Demonstration of blood analysis.
- 5. Demonstration of BP/heart rate/pulse rate
- 6. Explain different family planning techniques.

**General Requirements:** Dissection box, Laboratory Napkin, muslin cloth, record, Observation book (100pages), Stationary items, Blood lancet.

#### **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.

#### **Suggested Readings:**

1. 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

- 1. Ranade VG, Text Book of Practical Physiology, Latest Edition, Publisher: PVG, Pune.
- 2. Anderson Experimental Physiology, Latest Edition, Publisher: NA

22PD102T

PHARMACEUTICS THEORY

FIRST YEAR **3H 3C** 

Instruction hours/ week: L: 2 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

#### Theory: 3 Hrs/Week

#### **Course Objectives:**

- This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.
- Students can Understand the history of profession of pharmacy
- To know the basics of different dosage forms.
- To Understand the professional way of handling the prescription
- Students will know how to Prepare various conventional dosage forms
- Students will develop a clear idea about Pharmaceutical incompatibility and different pharmaceutical calculations in pharmacy.

## Course Outcomes (CO's): On successful completion of the course the student will

- 1. Understand the history of profession of pharmacy
- 2. Understand the basics of different dosage forms.
- 3. Understand the professional way of handling the prescription
- 4. Prepare various conventional dosage forms
- 5. Develop a clear idea about Pharmaceutical incompatibility and different pharmaceutical calculations in pharmacy.
- 6. Predict the instability problems in semi sold dosage forms

#### **Course Content:**

#### **UNIT I**

- Introduction to dosage forms classification and definitions
- Prescription: definition, parts and handling

#### **UNIT II**

Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.

#### **UNIT III**

Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.

#### **UNIT IV**

• Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.

 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.

#### **UNIT V**

**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.

#### **UNIT VI**

**Monophasic Dosage forms:** Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavors with examples. Study of Monophonic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

#### **UNIT VII**

**Biphasic dosage forms:** Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.

#### **UNIT VIII**

- Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
- Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.

#### **UNIT IX**

- Pharmaceutical calculations.
- Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.

#### **UNIT X**

Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

## **Suggested Readings:**

- 1. Cooper and Gunn's Dispensing for pharmacy students.
- 2. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

#### **Reference Books (Latest Editions):**

- 1. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- 2. Remington's Pharmaceutical Sciences. Register of General Pharmacy by Cooper and Gunn.
- 3. General Pharmacy by M.L.Schroff.

22PD108P FIRST YEAR

#### PHARMACEUTICS PRACTICAL

3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

## Practical: 3 Hrs./Week

#### **Course Objectives:**

- To know various internal liquid dosage forms preparations.
- To know various external liquid dosage forms.
- To prepare various solid dosage forms.
- To Perform quality control tests for various dosage forms
- To know various formulations for body cavities.
- Pharmaceutical calculations in pharmacy.

#### Course Outcomes (CO's): On successful completion of the course the student will

- 1. Prepare various internal liquid dosage forms
- 2. Prepare various solid dosage forms
- 3. Perform quality control tests for various dosage forms
- 4. Prepare various formulations for body cavities
- 5. Develop a clear idea about Pharmaceutical incompatibility and different pharmaceutical calculations in pharmacy.

## **List of Experiments:**

#### **Syrups**

- Simple Syrup I.P
- Syrup of Ephedrine Hcl NF
- Syrup Vasaka IP
- Syrup of ferrous Phosphate IP
- Orange Syrup

#### Elixir

- Piperizine citrate elixir BP
- Cascara elixir BPC
- Paracetamol elixir BPC

#### Linctus

- Simple Linctus BPC
- Pediatric simple Linctus BPC

#### **Solutions**

- Solution of cresol with soap IP
- Strong solution of ferric chloride BPC
- Aqueous Iodine Solution IP
- Strong solution of Iodine IP
- Strong solution of ammonium acetate IP

#### Liniments

- Liniment of turpentine IP\*
- Liniment of camphor IP

#### Suspensions\*

- Calamine lotion
- Magnesium Hydroxide mixture BP

#### **Emulsions\***

- Cod liver oil emulsion
- Liquid paraffin emulsion

## $\mathbf{Powders}^{\#}$

- Eutectic powder
- Explosive powder
- Dusting powder
- Insufflations

## **Suppositories**<sup>#</sup>

- Boric acid suppositories
- Chloral suppositories

#### **Incompatibilities**

- Mixtures with Physical
- Chemical & Therapeutic incompatibilities

#### **Suggested Readings:**

- 3. Cooper and Gunn's Dispensing for pharmacy students.
- 4. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

#### **Reference Books (Latest Editions):**

- 4. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- 5. Remington's Pharmaceutical Sciences. Register of General Pharmacy by Cooper and Gunn.
- 6. General Pharmacy by M.L.Schroff.

<sup>\*</sup> Colorless bottles required for dispensing

<sup>&</sup>lt;sup>#</sup> Paper envelope (white), butter paper and white paper required for dispensing.

22PD103T

FIRST YEAR

#### MEDICINAL BIOCHEMISTRY THEORY

4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

## Theory: 4 Hrs. /Week

#### **Course Objectives:**

- Medicinal 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.
- To understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- To know the metabolic process of biomolecules in health and illness (metabolic disorders);
- To understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- To know the biochemical principles of organ function tests of kidney, liver and endocrine gland

#### **Course Outcome (CO's):**

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

- 1. Understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- 2. Know the metabolic process of biomolecules in health and illness (metabolic disorders);
- 3. Understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- 4. Know the biochemical principles of organ function tests of kidney, liver and endocrine gland.
- 5. Perform the qualitative analysis and quantitative analysis of body fluids.
- 6. To understand the basic concepts of biological oxidation.

#### **Course content:**

#### UNIT I

• Introduction to biochemistry: Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.

• **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.

#### **UNIT II**

- 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, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.
- **Lipid metabolism:** Oxidation of saturated (β-oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolmiea).

#### **UNIT III**

**Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;

#### **UNIT IV**

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, porphoria, jaundice. Metabolic disorder of Amino acids.

#### **UNIT V**

**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.

#### **UNIT VI**

**Introduction to clinical chemistry: Cell**; composition; malfunction; Roll of the clinical chemistry laboratory.

#### **UNIT VII**

The kidney function tests: Role of kidney; Laboratory tests for normal function includes-

- Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
- Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)

- Urine concentration test
- Urinary tract calculi. (stones)

#### **UNIT VIII**

**Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.

- Test for hepatic dysfunction-Bile pigments metabolism.
- Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
- Dye tests of excretory function.
- Tests based upon abnormalities of serum proteins.

#### **UNIT IX**

- **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
- 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)

#### **UNIT X**

**Electrolytes:** Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

## **Suggested Readings:**

- 1. Harpers Review of Biochemistry Martin
- 2. Text book of Biochemistry D. Satyanarayana
- 3. Text book of Clinical Chemistry- Alex Kaplan & Laverve L.Szabo

- 1. Principles of Biochemistry -- Lehninger
- 2. Text book of Biochemistry -- Ramarao
- 3. Practical Biochemistry-David T.Plummer
- 4. Practical Biochemistry-Pattabhiraman

22PD109P FIRST YEAR

#### MEDICINAL BIOCHEMISTRY PRACTICAL 3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical: 3 Hrs./Week

## **Course Objectives:**

- To know the Qualitative analysis of the biomolecules.
- Will be able to Quantitatively analyze biochemical parameters and their importance in diagnosis of disease.
- To understand how to analyse the urine for abnormal constituents.
- Understand how to identify the biomolecules using chemical tests.
- To Determine the enzymatic activity.
- To Study the effect of physical parameters on the enzymatic activity.

## Course Outcomes (CO's): On successful completion of the course the student will

- 1. To perform the qualitatively analysis of biomolecules.
- 2. To perform the Quantitatively analysis of biomolecules in blood,urine and serum.
- 3. Quantitative analysis of biomolecules by colorimetric method.
- 4. Quantitative analysis of biomolecules by titrimetric method.
- 5. Determine the enzymatic activity.
- 6. Study the effect of physical parameters on the enzymatic activity.

#### **Title of the Experiment:**

- 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 Glucoseoxidase.\*\*
- 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.

## **Suggested Readings:**

- 1. Harpers Review of Biochemistry Martin
- 2. Text book of Biochemistry D. Satyanarayana
- 3. Text book of Clinical Chemistry- Alex Kaplan & Laverve L.Szabo

- 1. Practical Biochemistry-David T.Plummer
- 2. Practical Biochemistry-Pattabhiraman

PHARMACEUTICAL ORGANIC CHEMISTRY THEORY

#### 22PD104 T

## FIRST YEAR **RY** 4H

**4C** 

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory: 4 Hrs. /Week

## **Course 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
- To know important medicinal uses of some important organic compounds.

## Course Outcomes (CO's): On successful completion of the course the student will

- 1. Understand the classification and nomenclature of organic compounds, and the concepts of isomerism.
- 2. Schematize the reaction/reaction mechanism.
- 3. Explain the orientation of reactions.
- 4. Account for reactivity/stability of compounds.
- 5. Discuss the various theory of resonance.
- 6. Illustrate the important named reactions in organic chemistry.

#### **UNIT I**

#### **Structures and Physical properties:**

- 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,
- Acids and bases, Lowry bronsted and Lewis theories
- Isomerism.

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.

Free radicals chain reactions of alkane: Mechanism, relative reactivity and stability

#### **UNIT II**

• Alicyclic compounds: Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.

• Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN2 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.

#### **UNIT III**

**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.

#### **UNIT IV**

Electrophillic 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, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, Halohydin 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.

#### **UNIT V**

- Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.
- Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation 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.

#### **UNIT VI**

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 halogination of alkyl benzene, resonance stabilization of benzyl radical.

#### **UNIT VII**

**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 caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution. 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.

#### **UNIT VIII**

• **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.

## **UNIT IX**

- **Nucleophilic aromatic substitution:** Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.
  - Oxidation reduction reaction.

#### **UNIT X**

 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.

## **Suggested Readings:**

- 1. T.R.Morrison and R. Boyd Organic chemistry
- 2. Bentley and Driver-Text book of Pharmaceutical chemistry
- 3. I.L.Finar- Organic chemistry, the fundamentals of chemistry

- 1. Organic chemistry J.M.Cram and D.J.Cram
- 2. Organic chemistry- Brown
- 3. Advanced organic chemistry- Jerry March, Wiley
- 4. Organic chemistry- Cram and Hammered, Pine Hendrickson

22PD110P FIRST YEAR

## PHARMACEUTICAL ORGANIC CHEMISTRY PRACTICAL 3H 2C

Instruction hours/ week: L: 0 T:0 P: 3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical: 3 Hrs./Week

#### **Course Objectives:**

- Students will able to perform qualitative analysis of unknown organic compounds.
- Will be able to detect special elements in an organic sample.
- Understand how to Confirm unknown compounds by m.p./b.p.
- Will be able to Prepare derivatives of organic compounds.
- To know how to prepare the solid derivatives from organic compounds.
- Able to Construct molecular models.

## Course Outcomes (CO's): On successful completion of the course the student will

- 1. Synthesis of compounds using acetylation, Benzoylation and coupling reactions.
- 2. Synthesis of compounds using Bromination, Nitration and condensation reactions.
- 3. Synthesis of compounds using Oxidation, reduction and Hydrolysis reactions.
- 4. Systematically perform qualitative analysis of unknown organic compounds.
- 5. Prepare derivatives of organic compounds.
- 6. Construct molecular models.

# Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

- 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 Antharaquinone (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-chlorobenzoic acid from O-chlorotolune
- 14. Preparation of cyclohexanone from cyclohexanol

## 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, nitrocompounds.

#### Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

## **Suggested Readings:**

- 1. T.R.Morrison and R. Boyd Organic chemistry
- 2. Bentley and Driver-Text book of Pharmaceutical chemistry
- 3. I.L.Finar- Organic chemistry, the fundamentals of chemistry

- 1. Organic chemistry J.M.Cram and D.J.Cram
- 2. Organic chemistry- Brown
- 3. Advanced organic chemistry- Jerry March, Wiley
- 4. Organic chemistry- Cram and Hammered, Pine Hendrickson

22PD105T FIRST YEAR

## PHARMACEUTICAL INORGANIC CHEMISTRY THEORY 3H 3C

Instruction hours/ week: L: 2 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory: 3 Hrs./Week

## **Course 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.
- This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs
- To Understand the basic concepts and Pharmacopeial standards of pharmaceutical analysis
- To Identify the errors in analysis
- To Understand the principles of volumetric analysis
- To Understand the principles of electrochemical analysis

## **Course Outcome (CO's):**

- 1. Understand the principles and procedures involved.
- 2. Know the analysis of the inorganic pharmaceuticals their applications; and
- 3. Appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.
- 4. Understand the principles of volumetric analysis and electrochemical analysis
- 5. Applications of volumetric analysis.

#### **UNIT I**

Errors

#### **UNIT II**

• Volumetric analysis

#### **UNIT III**

- Acid-base titrations
- Redox titrations

#### **UNIT IV**

• Non aqueous titrations

- Precipitation titrations
- Complexometric titrations

#### **UNIT V**

• Theory of indicators

#### **UNIT VI**

• Gravimetry

#### **UNIT VII**

• Limit tests

#### **UNIT VIII**

Medicinal gases

#### **UNIT IX**

- Acidifiers
- Antacids
- Cathartics
- Electrolyte replenishers
- Essential Trace elements
- Antimicrobials
- Pharmaceutical aids
- Dental Products
- Miscellaneous compounds

#### **UNIT X**

• Radio Pharmaceuticals

#### **Suggested Readings:**

- 1. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
- 2. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol -I & Vol-II
- 3. Inorganic Pharmaceutical Chemistry III-Edition P. Gundu Rao

- 1. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
- 2. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
- 3. Analytical Chemistry Principles by John H. Kennedy
- 4. I.P.1985 and 1996, Govt. of India, Ministry of Health

22PD111P FIRST YEAR

## PHARMACEUTICAL INORGANIC CHEMISTRY PRACTICAL 3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

## Practical: 3 Hrs./Week

#### **Course Objectives:**

- To analyze the limit test for samples.
- Understand how to prepare the solutions for volumetric and electro-analytical methods.
- To standardize the solutions by volumetric and electro-analytical methods.
- Know how to Perform the assay for chemical substances.
- To standardize the titrant used for the assay.
- To determine the strength of the solutions by electro-analytical methods.

## Course Outcomes (CO's): On successful completion of the course the student will

- 1. Analyze the limit test for samples.
- 2. Prepare the solutions for volumetric and electro-analytical methods.
- 3. Standardize the solutions by volumetric and electro-analytical methods.
- 4. Perform the assay for chemical substances.
- 5. Standardize the titrant used for the assay.
- 6. Determine the strength of the solutions by electro-analytical methods.

## **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

#### Assays (10 exercises)

- g. Ammonium chloride- Acid-base titration
- h. Ferrous sulphate- Cerimetry
- i. Copper sulpahte- Iodometry
- j. Calcilugluconate- Complexometry
- k. Hydrogen peroxide Permanganometry
- 1. Sodium benzoate Nonaqueous titration
- m. Sodium chloride Modified volhard's method

- n. Assay of KI KIO<sub>3</sub> titration
- o. Gravimetric estimation of barium as barium sulphate
- p. Sodium antimony gluconate or antimony potassium tartarate

## **Estimation of mixture (Any two exercises)**

- q. Sodium hydroxide and sodium carbonate
- r. Boric acid and Borax
- s. Oxalic acid and sodium oxalate

## **Test for identity (Any three exercises)**

- t. Sodium bicorbonate
- u. Barium sulphate
- v. Ferrous sulphate
- w. Potassium chloride

## **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

#### **Preparations (Any two exercises)**

- f. Boric acids
- g. Potash alum
- h. Calcium lactate
- i. Magnesium suphate

## **Suggested Readings:**

- 1. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
- 2. Inorganic Pharmaceutical Chemistry III-Edition P. Gundu Rao

- 1. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
- 2. Analytical Chemistry Principles by John H. Kennedy
- 3. I.P.1985 and 1996, Govt. of India, Ministry of Health

22PD106RMT FIRST YEAR

#### REMEDIAL MATHEMATICS THEORY 4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory: 4 Hrs./Week

## **Course Objectives:**

- This is an introductory course in mathematics.
- This subject deals with the ntroduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.
- Able to Perform calculations using matrices and determinants.
- Able to Solve problems using differential and integral calculus.
- To Calculcate the equation for straight line and coordinates.
- Students can able to apply differential equations and Laplace transformation for solving problems

Course Outcomes (CO's): On successful completion of the course the student will

- 1. Understand the partial fraction, logarithms, function and limits.
- 2. Perform calculations using matrices and determinants.
- 3. Solve problems using differential and integral calculus.
- 4. Calculate the equation for straight line and coordinates.
- 5. Apply differential equations and Laplace transformation for solving problems
- 6. Appreciate the important application of mathematics in Pharmacy

#### **UNIT I**

Algebra: Determinants, Matrices

**UNIT II** 

**Trigonometry:** Sides and angles of a triangle, solution of triangles

**UNIT III** 

Analytical Geometry: Points, Straight line, circle, parabola

#### **UNIT IV**

**Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function.

#### **UNIT V**

**Differential calculus:** Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables

#### **UNIT VI**

**Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.

#### **UNIT VII**

**Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear.

#### **UNIT VIII**

**Differential equations:** Differential equation with constant coefficient, simultaneous linear equation of second order.

#### **UNIT IX**

**Laplace transform:** Definition, Laplace transform of elementary functions

#### **UNIT X**

**Laplace transform:** Properties of linearity and shifting.

## **Suggested Readings:**

- 1. Differential calculus By Shantinarayan
- 2. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

- 1. Integral calculus By Shanthinarayan
- 2. Engineering mathematics By B.S.Grewal
- 3. Trigonometry Part-I By S.L.Loney

22PD106RBT

FIRST YEAR

**4H** 

#### REMEDIAL BIOLOGY

**4C** 

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100 External Semester Exam: 3 Hours

Theory: 4 Hrs. /Week

## **Course Objectives:**

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

- To know the classification and salient features of five kingdoms of life and morphology of flowering plants.
- To understand the circulatory, digestive and respiratory systems.
- To know the Nervous, Excretory and reproductive systems.
- To understand the photosynthesis and plant and mineral nutrition.
- Will be able to know the respiration, growth of plants

## Course Outcomes (CO's): On successful completion of the course the student will

- 1. Explain the classification and salient features of five kingdoms of life and morphology of flowering plants.
- 2. Describe the circulatory, digestive and respiratory systems.
- 3. Discuss the Nervous, Excretory and reproductive systems.
- 4. Understand the photosynthesis and plant and mineral nutrition.
- 5. Discuss the respiration, growth of plants
- 6. Elaborate the cell and tissues of plant and animal.

#### UNIT I

- Introduction
- General organization of plants and its inclusions

#### **UNIT II**

- Plant tissues
- Plant kingdom and its classification
- Morphology of plants

#### **UNIT III**

- Root, Stem, Leaf and its modifications
- Inflorescence and Pollination of flowers
- Morphology of fruits and seeds

#### **UNIT IV**

- Plant physiology
- Taxonomy of Leguminosae, Umbelliferae, Solanaceae, Liliaceae, Zinziberaceae, Rubiaceae

#### **UNIT V**

• Study of Fungi, Yeast, Penicillin and Bacteria

#### **UNIT VI**

- Study of Animal cell
- Study animal tissues

#### **UNIT VII**

• Detailed study of frog

#### **UNIT VIII**

• Study of Pisces, Raptiles, Aves

#### **UNIT IX**

• Genearal organization of mammals

#### **UNIT X**

• Study of poisonous animal

## **Suggested Readings:**

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

- 1. A Text book of Biology by B.V.Sreenivasa aidu
- 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.

22PD112RBP

FIRST YEAR

#### REMEDIAL BIOLOGY PRACTICAL

3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

#### Practical: 3 Hrs./Week

#### **Course Objectives:**

- Students will be able to understand the microscope, cutting sections, mount, stain and slide preparation.
- To know about cell and its organelles
- To understand the parts of plant and their modifications
- Able to know the system using software
- Able to Identify types of bones.
- To determine blood group, blood pressure and tidal volume.

## Course Outcomes (CO's): On successful completion of the course the student will

- 1. Understand the microscope, cutting sections, mount, stain and slide preparation.
- 2. Study cell and its organelles
- 3. Study the parts of plant and their modifications
- 4. Study the system in from using software
- 5. Identify types of bones.
- 6. Determine blood group, blood pressure and tidal volume.

## Title:

- 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

## **Suggested Readings:**

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

- 1. A Text book of Biology by B.V.Sreenivasa aidu
- 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.

22PD201T

SECOND YEAR

#### PATHOPHYSIOLOGY THEORY

4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

## Theory: 3 Hrs./Week

## **Course Objectives:**

• Pathophysiology is the study of causes of diseases and reactions of the body to such 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
- Understanding of basic pathophysiological mechanisms
- Hence it will not only help to study the syllabus of pathology,
- To get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.
- To understand the etiology and pathogenesis of diseases.

## **Course Outcomes (CO's):**

Upon completion of the subject student shall be able to –

- 1. Describe the etiology and pathogenesis of the selected disease states;
- 2. Name the signs and symptoms of the diseases; and
- 3. Mention the complications of the diseases.
- 4. Describe the mechanism of the diseases.
- 5. Understand the etiology and pathogenesis of diseases.
- 6. Discuss about the Sexually transmitted diseases.

## **UNIT I**

#### Basic principles of cell injury and Adaptation

- Causes, Pathogenesis and morphology of cell injury
- Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases

#### UNIT II

#### **Inflammation**

- Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
- Repairs of wounds in the skin, factors influencing healing of wounds

#### UNIT III

#### **Diseases of Immunity**

- Introduction to T and B cells
- MHC proteins or transplantation antigens

#### **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)
- Amylodosis

## **UNIT IV**

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.
- Types of shock, mechanisms, stages and management
- Biological effects of radiation

#### **UNIT V**

#### **Environmental and nutritional diseases**

- Air pollution and smoking- SO2,NO, NO2, and CO
- Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.

#### **UNIT VI**

## Pathophysiology of common diseases

- Parkinsonism
- Schizophrenia
- Depression and mania

#### **UNIT VII**

## Pathophysiology of common diseases

- Hypertension,
- Stroke (ischaemic and hemorrhage)
- Angina, CCF, Atherosclerosis, Myocardial infarction

#### **UNIT VIII**

## Pathophysiology of common diseases

Diabetes Mellitus

Peptic ulcer and inflammatory bowel diseases

#### **UNIT IX**

## Pathophysiology of common diseases

- Cirrhosis and Alcoholic liver diseases
- Acute and chronic renal failure
- Asthma and chronic obstructive airway diseases

#### **UNIT X**

#### **Infectious diseases:**

Sexually transmitted diseases (HIV,Syphilis,Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

#### **Assignments:**

#### **Title of the Experiment**

- 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.

## **Suggested Readings:**

- 1. Pathologic basis of disease by- Cotran, Kumar, Robbins
- 2. Text book of Pathology- Harsh Mohan
- 3. Text book of Pathology- Y.M. Bhinde

## **Reference Books (Latest Editions):**

Clinical Pharmacy and Therapeutics; Second edition; Roger Walker;
 Churchill Livingstone publication

22PD202T SECOND YEAR

#### PHARMACEUTICAL MICROBIOLOGY THEORY

4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

## Theory: 4 Hrs. /Week

#### **Course Objectives:**

- Know the anatomy, identification, growth factors and sterilization of microorganisms;
- Know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- Do estimation of RNA and DNA and there by identifying the source;
- Do cultivation and identification of the microorganisms in the laboratory;
- Do identification of diseases by performing the diagnostic tests; and
- Appreciate the behavior of motility and behavioral characteristics of microorganisms

## **Course Outcomes (CO's):**

Upon completion of the subject student shall be able to –

- 1. Know the origin of microorganisms and the scope of Pharmaceutical microbiology.
- 2. Know the Anatomy identifications and Cultivation, growth culture and patterns, isolation of preservations and enumeration of microorganism.
- 3. Perform sterilization of various pharmaceutical products, culture media etc. perform sterility testing of pharmaceutical products.
- 4. Know the mode of transmission of disease causing microorganism, symptoms of the disease and treatment aspects.
  - 5. Do identification of disease by performing the diagnostic test and immunological tests.
  - 6. Perform microbial assay for Antibiotics and vitamins.

#### **UNIT I**

Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.

## **UNIT II**

Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.

#### **UNIT III**

• 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.
- 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.

#### **UNIT IV**

- 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.

#### **UNIT V**

**Disinfectants**- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteriostatic, virucidal activities, evaluation of preservatives in pharmaceutical preparations.

#### **UNIT VI**

Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity( active and passive ).

#### **UNIT VII**

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.

#### **UNIT VIII**

Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite.

## **UNIT IX**

Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of

- Penicillin, Streptomycin and vitamin B2 and B12.
- Standardisation of vaccines and sera.

#### **UNIT X**

Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

#### **Reference Books (Latest Editions):**

- 1. Vanitha Kale and Kishor Bhusari Applied Microbiology | Himalaya Publishing house Mumbai.
- 2. Mary Louis Turgeon Immunology and Serology in Laboratory Medicines 2<sup>nd</sup> edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
- 3. Harsh Mohan, Text book of Pathology 3<sup>rd</sup> edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

## Reference books (Theory)

- Prescot L.M., Jarley G.P Klein D.A —Microbiology 2<sup>nd</sup>- edition Mc Graw Hill Company Inc
- 2. Rawlins E.A. Bentley's Text Book of Pharmaceutics B ailliere Tindals 24-28 London 1988
- 3. Forbisher Fundamentals of Microbiology Philidelphia W.B. Saunders.
- 4. Prescott L.M. Jarley G.P., Klein.D.A. Microbiology. 12<sup>nd</sup> edition WMC Brown Publishers, Oxford. 1993
- 5. War Roitt, Jonathan Brostoff, David male, Immunology||3<sup>rd</sup> edition 1996, Mosby-year book Europe Ltd, London.
- 6. Pharmacopoeia of India, Govt of India, 1996.

22PD207P

SECOND YEAR

#### PHARMACEUTICAL MICROBIOLOGY PRACTICAL 3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical: 3 Hrs./Week

## **Course Objectives:**

- To discuss about the instruments used in experimental microbiology
- To understand the sterilization methods followed in laboratory.
- To know the staining techniques used in microbiology.
- To carry out assay of different antibiotics
- To understand the mechanism of action opf antibiotics.
- To perform different sterility tests and bacteriological analysis of water

#### Course Outcomes (CO's): On successful completion of the course the student will

- 1. Discuss about the instruments used in experimental microbiology
- 2. Understand the sterilization methods followed in laboratory.
- 3. Discover the staining techniques used in microbiology.
- 4. Carry out assay of different antibiotics
- 5. Understand the mechanism of action opf antibiotics.
- 6. Execute different sterility tests and bacteriological analysis of water

#### **Title of the Experiment:**

- 1 Study of apparatus used in experimental microbiology\*.
- 2 Sterilisation 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 (Pasturization) and microbial laboratories (other sterization 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.
  - 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.

#### **Reference Books (Latest Editions):**

- 1. Vanitha Kale and Kishor Bhusari Applied Microbiology | Himalaya Publishing house Mumbai.
- 2. Harsh Mohan, Text book of Pathology 3<sup>rd</sup> edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

## **Reference books (Theory)**

- 1. Prescott L.M. Jarley G.P., Klein.D.A. Microbiology. ||2<sup>nd</sup> edition WMC Brown Publishers, Oxford. 1993
- 2. War Roitt, Jonathan Brostoff, David male, Immunology||3<sup>rd</sup> edition 1996, Mosby-year book Europe Ltd, London.
- 3. Pharmacopoeia of India, Govt of India, 1996.

22PD203T SECOND YEAR

#### PHARMACOGNOSY & PHYTOPHARMACEUTICALS THEORY

H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

## Theory: 4 Hrs. /Week

## **Course 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, and distribution
- To know its method of cultivation,
- To know active constituents, medicinal uses
- To understand its preservation methods, identification tests, substitutes and adulterants.
- To understand the traditional system of medicine.
- To explain the Plant Products Primary metabolites Proteins, Enzymes, Lipids, Marine drugs.

#### **Course Outcomes (CO's):**

- 1. Understand the basic principles of cultivation, collection and storage of crude drugs;
- 2. Explain the source, active constituents and uses of individual crude drugs
- **3.** Understand the applications of primary and secondary metabolites of the plant.
- **4.** Demonstrate the plant tissue culture.
- **5.** Understand the traditional system of medicine.
- **6.** Explain the drug metabolites from natural products.

#### **UNIT I**

- Introduction.
- Definition, history and scope of Pharmacognosy.

#### **UNIT II**

- Classification of crude drugs.
- Cultivation, collection, processing and storage of crude drugs.
- Detailed method of cultivation of crude drugs.

## **UNIT III**

- Study of cell wall constituents and cell inclusions.
- Microscopical and powder Microscopical study of crude drugs.

#### **UNIT IV**

Study of natural pesticides.

#### UNIT V

Detailed study of various cell constituents.

#### **UNIT VI**

- Carbohydrates and related products.
- Detailed study carbohydrates containing drugs.(11 drugs)

#### **UNIT VII**

- Definition sources, method extraction, chemistry and method of analysis of lipids.
- Detailed study of oils.

#### **UNIT VIII**

Definition, classification, chemistry and method of analysis of protein.

## **UNIT IX**

Study of plants fibers used in surgical dressings and related products.

#### **UNIT X**

Different methods of adulteration of crude drugs.

## **Suggested Readings:**

- 1. Pharmacognosy by G.E. Trease & W.C.Evans.
- 2. Pharmacognosy by C.K.Kokate, Gokhale & A.C.Purohit.

- 1. Pharmacognosy by Brady &Tyler.E.
- 2. Pharmacognosy by T.E.Wallis.
- 3. Pharmacognosy by C.S. Shah & Qadery.
- 4. Pharmacognosy by M.A. Iyengar.

22PD208P SECOND YEAR

## PHARMACOGNOSY & PHYTOPHARMACEUTICALS PRACTICAL

3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

## Practical: 3 Hrs./Week

## **Course Objectives:**

- Analyze the crude drugs by chemical tests.
- Determine the stomatal number and index and vein islet number, vein islet termination and palisade ratio.
- Determine the starch grains, calcium oxalate crystals by eye piece micrometer.
- Perform the Fiber length and width starch grains by Lycopodium spore method.
- Analyze the purity of crude drugs by ash value and extractive value.
- Determine the moisture content, swelling index and foaming index.

## Course Outcomes (CO's): On successful completion of the course the student will

- 1. Analyze the crude drugs by chemical tests.
- 2. Determine the leaf constant.
- 3. Determine the starch grains, calcium oxalate crystals by eye piece micrometer.
- 4. Perform the Fiber length and width starch grains by Lycopodium spore method.
- 5. Analyze the purity of crude drugs by ash value and extractive value.
- 6. Determine the moisture content, swelling index and foaming index.

**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.

#### **Suggested Readings:**

- 1. Pharmacognosy by G.E. Trease & W.C.Evans.
- 2. Pharmacognosy by C.K.Kokate, Gokhale & A.C.Purohit.

- 1. Pharmacognosy by Brady &Tyler.E.
- 2. Pharmacognosy by T.E. Wallis.
- 3. Pharmacognosy by C.S. Shah & Qadery.
- 4. Pharmacognosy by M.A. Iyengar.

22PD204T SECOND YEAR

#### PHARMACOLOGY - I THEORY

4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory: 4 Hrs. /Week

## **Course Objectives:**

• This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects

- To know adverse effects, uses, dose
- To understand the 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
- To know the 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.

## **Course Outcome (CO's):**

Upon completion of the subject student shall be able to (Know, do, appreciate) –

- 1. Understand the pharmacological aspects of drugs.
- 2. Handle and carry out the animal experiments.
- 3. Appreciate the importance of pharmacology subject as a basis of therapeutics.
- 4. Correlate and apply the knowledge therapeutically.
- 5. Demonstrate the Pharmacology of drugs acting on various cardio vascular disease.
- 6. Illustrate the Pharmacology of Autocoids, Non-steroidal anti-inflammatory agents, Anti-gout drugs and Antirheumatic drugs.

#### **UNIT I**

#### **General Pharmacology**

- Introduction, definitions and scope of pharmacology
- Routes of administration of drugs
- Pharmacokinetics (absorption, distribution, metabolism and excretion)

#### **UNIT II**

- Pharmacodynamics
- Factors modifying drug effects
- Drug toxicity Acute, sub- acute and chronic toxicity.
- Pre-clinical evaluations
- 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.

#### **UNIT III**

## Pharmacology of drugs acting on ANS

- Adrenergic and antiadrenergic drugs
- Cholinergic and anticholinergic drugs
- Neuromuscular blockers
- Mydriactics and miotics

#### **UNIT IV**

- Drugs used in myasthenia gravis
- Drugs used in Parkinsonism

#### **UNIT V**

## Pharmacology of drugs acting on cardiovascular system

- Antihypertensives
- Anti-anginal drugs
- Anti-arrhythmic drugs
- Drugs used for therapy of Congestive Heart Failure
- Drugs used for hyperlipidaemias

#### **UNIT VI**

## Pharmacology of drugs acting on Central Nervous System

- General anesthetics
- Sedatives and hypnotics
- Anticonvulsants
- Analgesic and anti-inflammatory agents

## **UNIT VII**

- Psychotropic drugs
- Alcohol and methyl alcohol
- CNS stimulants and cognition enhancers
- Pharmacology of local anaesthetics

#### **UNIT VIII**

## Pharmacology of Drugs acting on Respiratory tract

- Bronchodilators
- Mucolytics
- Expectorants
- Antitussives
- Nasal Decongestants

#### **UNIT IX**

#### Pharmacology of Hormones and Hormone antagonists

- Thyroid and Antithyroid drugs
- Insulin, Insulin analogues and oral hypoglycemic agents
- Sex hormones and oral contraceptives
- Oxytocin and other stimulants and relaxants

## **UNIT X**

#### Pharmacology of autocoids and their antagonists

- Histamines and Antihistaminics
- 5-Hydroxytryptamine and its antagonists
- Lipid derived autocoids and platelet activating factor
- The following details shall be submitted for any 25 selected drugs in the form of assignment/PPT.
  - \*\*Name of the Drug, Brand name, Category, Therapeutic uses, Dose, Pharmacological action, Route of administration, Side effects, Contraindications, Drug Interactions with drug/food, Pharmacokinetics

#### Suggested Readings(Theory):

(Author, Title, Edition, Publication Place, Publisher, Year of Publication)

- 1. Tripathi, K. D. Essentials of medical pharmacology. 4<sup>th</sup> Ed, 1999. Publisher: Jaypee, Delhi.
- 2. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16<sup>th</sup> edition (single volume), 1999. Publisher: Popular, Dubai.
- 3. Rang, H.P. & Dale, M.M. Pharmacology. 4<sup>th</sup> edition, 1999. Publisher: Churchill Living stone.

## **Reference Books (Theory-Latest Editions):**

(Author, Title, Edition, Publication Place, Publisher, Publication Year)

1. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and

Gilman's The pharmacological Basis of therapeutics. 9<sup>th</sup> Ed, 1996. Publisher Mc Graw Hill, Pergamon press.

- 2. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
- 3. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
- 4. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

22PD205T

SECOND YEAR

#### **COMMUNITY PHARMACY THEORY**

3H 3C

Instruction hours/ week: L:2 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory: 3 Hrs. /Week

# **Course Objectives:**

• 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
- To know responding to minor ailments by providing suitable safe medication
- To understand patient counseling
- To know health screening services for improved patient care in the community set up.
- To study the concept of Rational drug therapy

# **Course Outcome (CO's):**

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

- 1. To understand the rules and responsibilities of community pharmacy
- 2. Explain about community pharmacy management
- 3. Understand the concept of pharmaceutical care
- 4. Understand the importance of patient counselling and health screening services.
- 5. Discuss about health education.
- 6. Explain about management of minor ailments

#### **Special requirements:**

- 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 equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

## UNIT I

# Definition, scope, of community pharmacy

Roles and responsibilities of Community pharmacist

## **UNIT II**

## **Community Pharmacy Management**

- a) Selection of site, Space layout, and design
- b) Staff, Materials- coding, stocking
- c) Legal requirements

- d) Maintenance of various registers
- e) Use of Computers: Business and health care soft wares

#### **UNIT III**

**Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.

## Inventory control in community pharmacy Definition,

various methods of Inventory Control

## ABC, VED, EOQ, Lead time, safety stock

#### **UNIT IV**

#### Pharmaceutical care

Definition and Principles of Pharmaceutical care.

## **Patient counselling**

Definition, outcomes, various stages, barriers, Strategies to overcome barriers Patient information leaflets- content, design, & layouts, advisory labels

#### **UNIT V**

#### Patient medication adherence

Definition, Factors affecting medication adherence, role of Pharmacist in improving the adherence.

## **Health screening services**

Definition, importance, methods for screening Blood pressure/ blood sugar/ lung function and Cholesterol testing

#### **UNIT VI**

## OTC Medication- Definition, OTC medication list & Counselling

#### **Health Education**

WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.

#### **UNIT VII**

Introduction to Social and Preventive Pharmacy:

Commonly occurring Communicable Diseases, causative agents, Clinical presentations and prevention of Communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea And AIDS, HIV & AIDS control programme, National leprosy control programme.

#### **UNIT VIII**

Balance diet, and treatment & prevention of deficiency disorders

Family planning – role of pharmacist

## **UNIT IX**

**Responding to symptoms of minor ailments** Relevant pathophysiology, common drug therapy to, Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms, worms infestations.

## **UNIT X**

Essential Drugs concept and Rational Drug Therapy Role of community pharmacist Code of ethics for community pharmacists

## **Suggested Readings:**

- 1. Health Education and Community Pharmacy by N.S.Parmar.
- 2. WHO consultative group report.
- 3. Drug store & Business management by Mohammed Ali & Jyoti.

- 1. Handbook of pharmacy health care.Edt. Robin J Harman. The Pharmaceutical press.
- 2. Comprehensive Pharmacy Review Edt. Leon Shargel. Lippincott Williams & Wilkins.

22PD206T SECOND YEAR

## PHARMACOTHERAPEUTICS - I THEORY 4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

# Theory: 4 Hrs./Week

#### **Course Objectives:**

- 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.
- To know the importance of preparation of individualized therapeutic plans based on diagnosis;
- To understand patient-specific parameters relevant in initiating drug therapy
- To know the pathophysiology of selected disease states and explain the rationale for drug therapy

# **Course Outcome (CO's):**

At completion of this subject it is expected that students will be able to understand –

- 1. Understand the etiologic factors, signs and symptoms of selected diseases
- 2. Explain pathophysiology of selected diseases.
- 3. Explain drug drug interactions for selected drugs
- 4. Explain drug- food interactions for selected drugs
- 5. Illustrate the therapeutic approach of management of selected disease
- 6. Understand the basic concepts of different guidelines for prescribing.

7. 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).

## Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/diseases

**UNIT I** 

Cardiovascular system: Hypertension, Congestive cardiac failure, Angina Pectoris

**UNIT II** 

Myocardial infarction, Hyperlipidaemias

**UNIT III** 

Electrophysiology of heart and Arrhythmias

**UNIT IV** 

**Respiratory system:** Introduction to Pulmonary function test, Asthma,

**UNIT V** 

Chronic obstructive airways disease, Drug induced pulmonary diseases

**UNIT VI** 

Endocrine system: Diabetes, Thyroid diseases, Oral contraceptives

**UNIT VII** 

Hormone replacement therapy, Osteoporosis

**UNIT VIII** 

# General prescribing guidelines for

- a. Paediatric patients
- b. Geriatric patients
- c. Pregnancy and breast feeding

**UNIT IX** 

Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial

**UNIT X** 

Introduction to rational drug use

Definition, Role of pharmacist Essential drug concept Rational drug formulations

# **Suggested Readings:**

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.

 Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

- 1. Pathologic basis of disease Robins SL, W.B.Saunders publication.
- 2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice Green and Harris, Chapman and Hall publication.
- 3. Clinical Pharmacy and Therapeutics Eric T. Herfindal, Williams and Wilkins Publication.
- 4. Applied Therapeutics:The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- 5. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- 6. Relevant review articles from recent medical and pharmaceutical literature

22PD209P

SECOND YEAR

## PHARMACOTHERAPEUTICS - I PRACTICAL

3H 2C

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100 External Semester Exam: 3 Hours

Practical: 3 Hrs./Week

# **Course Objectives:**

- 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.
- To know the importance of preparation of individualized therapeutic plans based on diagnosis;
- To understand patient-specific parameters relevant in initiating drug therapy
- To know the pathophysiology of selected disease states and explain the rationale for drug therapy

## **Course Outcome (CO's):**

At completion of this subject it is expected that students will be able to understand –

- 1. Understand the etiologic factors, signs and symptoms of selected diseases
- 2. Explain pathophysiology of selected diseases.
- 3. Explain drug drug interactions for selected drugs
- 4. Explain drug- food interactions for selected drugs
- 5. Illustrate the therapeutic approach of management of selected disease
- 6. Understand the basic concepts of different guidelines for prescribing.

#### **Practicals:**

- Hospital postings in various departments 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:**

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.

## **Suggested Readings:**

- 1. Clinical Pharmacy and Therapeutics Roger and Walker, Churchill Livingstone publication.
- 2. Pharmacotherapy: A Pathophysiologic approach Joseph T. Dipiro et al. Appleton & Lange.

- 1. Pathologic basis of disease Robins SL, W.B.Saunders publication.
- 2. Relevant review articles from recent medical and pharmaceutical literature

22PD301T

THIRD YEAR

## PHARMACOLOGY - II THEORY

4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory: 4 Hrs. /Week

## **Course Objectives:**

- 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 autacoids 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.
- To understand drugs acting on Blood and blood forming agents
- To study structures and functions of the components of the cell

# **Course Outcomes (CO's):**

- 1. Understand the pharmacological aspects of drugs falling under the above mentioned chapters,
- 2. Carry out the animal experiments confidently,
- 3. Appreciate the importance of pharmacology subject as a basis of therapeutics, and
- 4. Correlate and apply the knowledge therapeutically.
- 5. Drugs acting on Blood and blood forming agents
- 6. structures and functions of the components of the cell

#### **UNIT I**

# Pharmacology of Drugs acting on Blood and blood forming agents

- Anticoagulants
- Thrombolytics and antiplatelet agents
- Haemopoietics and plasma expanders

#### UNIT II

# Pharmacology of drugs acting on Renal System

- Diuretics
- Antidiuretics

#### **UNIT III**

## Chemotherapy

- Introduction
- Sulfonamides and co-trimoxazole
- Penicillins and Cephalosporins
- Tetracyclines and Chloramphenicol
- Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
- Quinolines and Fluroquinolines

#### **UNIT IV**

## Chemotherapy

- Antifungal antibiotics
- Antiviral agents
- Chemotherapy of tuberculosis and leprosy
- Chemotherapy of Malaria
- Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
- Pharmacology of Anthelmintic drugs

#### **UNIT V**

**Chemotherapy**: Chemotherapy of cancer (Neoplasms)

## **UNIT VI**

# **Immunopharmacology**

Pharmacology of immune suppressants and stimulants

#### **UNIT VII**

Principles of Animal toxicology Acute, sub acute and chronic toxicity

#### **UNIT VIII**

# 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.

#### **UNIT IX**

#### The Gene: Genome structure and function:

Gene structure: Organization and elucidation of genetic code.

**Gene expression:** Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.

**Transcription and Transcription factors**: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

## **UNIT X**

**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, traslocations, 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

The following details shall be submitted for any 25 selected drugs in the form of assignment/PPT.

\*\*Name of the Drug, Brand name, Category, Therapeutic uses, Dose, Pharmacological action, Route of administration, Side effects, Contraindications, Drug Interactions with drug/food, Pharmacokinetics

#### **Suggested Readings(Theory):**

- Tripathi, K. D. Essentials of medical pharmacology. 4<sup>th</sup> edition, 1999. Publisher: Jaypee, Delhi.
- 2. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16<sup>th</sup> edition (single volume), 1999. Publisher: Popular, Dubai.
- 3. Rang, H.P. and Dale, M.M. Pharmacology. 4<sup>th</sup> edition, 1999. Publisher: Churchill Living stone.

 Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9<sup>th</sup> edition, 1996. Publisher: Mc Graw Hill, Pergamon press.

- 2. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- 3. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- 4. 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.

22PD307P

THIRD YEAR

## PHARMACOLOGY – II PRACTICAL 3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical: 3 Hrs./Week

## **Course Objectives:**

- To Calculate the dose in pharmacological experiments.
- To Perform various pharmacological screening studies.
- To Demonstrate the toxicity studies in animal models.
- To know the student's t test, ANOVA, Chi square test, Wilcoxon Signed Rank test.
- To determine the pharmacokinetic parameters by using the data.
- To evaluate the acute skin irritation, acute eye irritation and corrosion of a test substance.

## Course Outcomes (CO's): On successful completion of the course the student will

- 1. Calculate the dose in pharmacological experiments.
- 2. Perform various pharmacological screening studies.
- 3. Demonstrate the toxicity studies in animal models.
- 4. Describe the student's t test, ANOVA, Chi square test, Wilcoxon Signed Rank test.
- 5. Determine the pharmacokinetic parameters by using the data.
- 6. Evaluate the acute skin irritation, acute eye irritation and corrosion of a test substance.

# **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) Antiinflammatory 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 rotarod.
  - f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

## **Suggested Readings(Theory):**

- Tripathi, K. D. Essentials of medical pharmacology. 4<sup>th</sup> edition, 1999. Publisher: Jaypee, Delhi.
- 2. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16<sup>th</sup> edition (single volume), 1999. Publisher: Popular, Dubai.
- 3. Rang, H.P. and Dale, M.M. Pharmacology. 4<sup>th</sup> edition, 1999. Publisher: Churchill Living stone.

#### **Reference Books (Latest Editions):**

1. 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.

22PD302T

THIRD YEAR

#### PHARMACEUTICAL ANALYSIS THEORY

4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

# Theory: 4 Hrs. /Week

#### **Course Objectives:**

- This subject deals 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.
- To discuss the applications of analytical techniques.
- To perform quantitative analysis of drugs using various analytical instruments.
- To perform qualitative analysis of drugs using various analytical instruments

#### Course Outcomes (CO's): On successful completion of the course the student will

- 1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis.
- 2. Describe the instrumentation of spectroscopy techniques.
- 3. Understand the chromatographic separation and analysis of drugs.
- 4. Discuss the applications of analytical techniques.
- 5. Perform quantitative analysis of drugs using various analytical instruments.
- 6. Perform qualitative analysis of drugs using various analytical instruments

#### UNIT I

## **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.

#### **UNIT II**

# **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.

- h. **Column Chromatography**: Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
- i. TLC: Introduction, principle, techniques, R<sub>f</sub> value and applications.
- j. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
- k. Ion-exchange chromatography: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
- l. **HPLC**: Introduction, theory, instrumentation, and applications.
- m. HPTLC: Introduction, theory, instrumentation, and applications.
- n. **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.

## **UNIT III**

#### **Electrometric Methods:**

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

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.

• **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications.

- **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.
- Amperometric Titrations: Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

#### **UNIT IV**

#### **Spectroscopy:**

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on.

## **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, batho-chromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

#### **UNIT V**

**Instrumentation** – Photometer, UV Visible spectrometer – sources of UV – Visible radiations, collimating systems, monochromators, sample cells and following detectors – photocell Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

#### **UNIT VI**

**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.

#### **UNIT VII**

**Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

**Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.

**Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.

#### **UNIT VIII**

**Atomic Emission Spectroscopy**: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.

NMR & ESR (introduction only): Introduction, theoretical aspects and applications.

#### **UNITIX**

**Mass Spectroscopy**: (**Introduction only**) – Fragmentation, types of ions produced mass spectrum and applications.

**Polarimetry:** (**Introduction only**) – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.

#### **UNIT X**

**X-RAY Diffraction:** (Introduction only) – Theory, reciprocal lattice concept, diffraction patterns and applications.

**Thermal Analysis:** Introduction, instrumentation, applications, and DSC and DTA.

#### **Suggested Readings:**

- A.H.Beckett& J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I&II, Stahlone Press of University of London.
- 2. A.I. Vogel, TextBook of Quantitative Inorganic analysis.
- 3. P.Gundu Rao, Inorganic Pharmaceutical Chemistry.
- 4. Bentley and Driver's Textbook of Pharmaceutical Chemistry.

- 1. John H. Kennedy, Analytical chemistry principles.
- 2. Indian Pharmacopoeia.

22PD308P

THIRD YEAR

#### PHARMACEUTICAL ANALYSIS PRACTICAL

3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical: 3 Hrs./Week

# **Course Objectives:**

- To estimate the samples using analytical instruments.
- To perform assay of drug samples using analytical intruments
- To determine the effect of solvents on absorption maxima.
- To separate the mixtures of sample using chromatographic techniques.
- To demonstrate HPLC.
- To demonstrate gas chromatography.

## Course Outcomes (CO's): On successful completion of the course the student will

- 1. Estimate the samples using analytical instruments.
- 2. Perform assay of drug samples using analytical intruments
- 3. Determine the effect of solvents on absorption maxima.
- 4. Separate the mixtures of sample using chromatographic techniques.
- 5. Demonstrate HPLC.
- 6. Demonstrate gas chromatography.

# **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 a 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 Nepheloturbidimetric 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.

# **Suggested Readings:**

- A.H.Beckett& J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I&II, Stahlone Press of University of London.
- 2. A.I.Vogel, TextBook of Quantitative Inorganic analysis.
- 3. P.Gundu Rao, Inorganic Pharmaceutical Chemistry.
- 4. Bentley and Driver's Textbook of Pharmaceutical Chemistry.

- 1. John H. Kennedy, Analytical chemistry principles.
- 2. Indian Pharmacopoeia.

22PD303T

THIRD YEAR

## PHARMACOTHERAPEUTICS – II THEORY

4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory: 4 Hrs./Week

## **Course Objectives:**

- 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.
- To know the importance of preparation of individualised therapeutic plans based on diagnosis
- To appreciate 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).
- To develop patient case based assessment skills

#### **Course Outcomes (CO's):**

- 1. Know the pathophysiology of selected disease states and the rationale for drug therapy
- 2. Know the therapeutic approach to management of these diseases;
- 3. Know the controversies in drug therapy;
- 4. Know the importance of preparation of individualised therapeutic plans based on diagnosis; and
- 5. Appreciate 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).
- 6. Students will be developing patient case based assessment skills

Detailed syllabus and lecture wise schedule : Etiopathogenesis and pharmacotherapy of diseases associated with following systems  $\!\!\!/$  diseases -

## UNIT I

**Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections

#### **UNIT II**

Infectious disease: Gastroenteritis, Endocarditis, Septicemia

**UNIT III** 

Infectious disease: Urinary tract infections, Protozoal infection- Malaria, HIV &

Opportunistic infections

**UNIT IV** 

Infectious disease: Fungal infections, Viral infections, Gonarrhoea and Syphillis

**UNIT V** 

Musculoskeletal disorders

Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.

**UNIT VI** 

**Renal system** 

Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

**UNIT VII** 

**Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents

**UNIT VIII** 

Chemotherapy of breast cancer, leukemia.

**UNIT IX** 

**Infectious disease:** Management of chemotherapy nausea and emesis

**UNIT X** 

Dermatology: Psoriasis, Scabies, Eczema, Impetigo

**Suggested Readings:** 

 Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

- Pharmacotherapy: A Pathophysiologic approach Joseph T. Dipiro et al. Appleton & Lange
- 2. Clinical Pharmacy and Therapeutics Eric T. Herfindal, Williams and Wilkins Publication
- 3. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

22PD309P

THIRD YEAR

## PHARMACOTHERAPEUTICS – II PRACTICAL 3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

# Practical: 3 Hrs./Week Course Objectives:

- 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.
- To know the importance of preparation of individualised therapeutic plans based on diagnosis
- To appreciate 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).
- To develop patient case based assessment skills

## **Course Outcomes (CO's):**

- 1. Know the pathophysiology of selected disease states and the rationale for drug therapy
- 2. Know the therapeutic approach to management of these diseases;
- 3. Know the controversies in drug therapy;
- 4. Know the importance of preparation of individualised therapeutic plans based on diagnosis; and
- 5. Appreciate 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).
- 6. Students will be developing patient case based assessment skills

#### **Practicals:**

• Hospital postings in various departments 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.

# **Suggested Readings:**

 Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

## **Reference Books (Latest Editions):**

 Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

22PD304T

THIRD YEAR

#### PHARMACEUTICAL JURISPRUDENCE THEORY

2H 2C

Instruction hours/ week: L: 2 T:0 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

# Theory: 2 Hrs./Week

# **Course Objectives:**

- 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 is 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.
- To acquire clear idea on drug price control order and its implication in India.
- To acquire information regarding the licenses to be achieved for a new drug discovery process.

#### **Course Outcomes (CO's):**

Upon completion of the subject student shall be able to (Know, do, and appreciate) –

- 1. Practice the Professional ethics;
- 2. Understand the various concepts of the pharmaceutical legislation in India;
- 3. Know the various parameters in the Drug and Cosmetic Act and rules;
- 4. Know the Drug policy, DPCO, Patent and design act;
- 5. Understand the labeling requirements and packaging guidelines for drugs and cosmetics;
- 6. Be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act.

## Detailed syllabus and lecture wise schedule:

## **UNIT I**

- **Pharmaceutical Legislations** A brief review.
- Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.

#### **UNIT II**

## 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.

#### **UNIT III**

## Pharmacy Act -1948.

Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.

#### **UNIT IV**

## Medicinal and Toilet Preparation Act –1955.

Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory,

Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations.

#### **UNIT V**

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.

#### **UNIT VI**

Study of Salient Features of Drugs and magic remedies Act and its rules.

## **UNIT VII**

Study of essential Commodities Act Relevant to drugs price control Order.

#### **UNIT VIII**

Drug Price control Order & National Drug Policy (Current).

#### **UNIT IX**

Prevention of Cruelty to animals Act-1960.

Patents & design Act-1970.

#### **UNIT X**

Brief study of prescription and Non-prescription Products.

## **Assignments:**

## Format of the assignment

- Minimum & Maximum number of pages
- It shall be a computer draft copy
- Reference(s) shall be included at the end.

- Name and signature of the student
- Assignment can be a combined presentation at the end of the academic year.
- Time allocated for presentation may be 8+2 Min

# Case studies relating to

- 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.
- Various prescription and non-prescription products.
- Medical and surgical accessories.
- Diagnostic aids and appliances available in the market.

## **Suggested Readings:**

1. Mithal, B.M. Textbook of Forensic Pharmacy. Calcutta: National; 1988.

- Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- 2. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan; 1995.
- 3. Reports of the Pharmaceutical enquiry Committee
- 4. I.D.M.A., Mumbai. DPCO 1995
- 5. Various reports of Amendments.
- 6. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- 7. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

22PD305T

THIRD YEAR

#### MEDICINAL CHEMISTRY THEORY

4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

# Theory: 4 Hrs. /Week

## **Course Objectives:**

- 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)
- To understand the prodrug concept, combinatorial chemistry and Computer aided drug design (CADD).
- The subject also emphasizes on the chemistry, mechanism of action, metabolism,
- To know adverse effects, Structure Activity Relationships (SAR) and therapeutic uses
- To synthesis of important drugs.

Course Outcomes (CO's): On successful completion of the course the student will

- 1. Illustrate the classification of drugs.
- 2. Explain the mechanism of action of drugs.
- 3. Understand the chemistry of drugs with respect to their biological activity.
- 4. Know the metabolism, adverse effects and therapeutic value of drugs.
- 5. Discuss the importance of SAR of drugs.
- 6. Understand the importance of drug design and different techniques of drug design.

#### UNIT I

Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationaship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

#### **UNIT II**

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.

## **UNIT III**

## **Anti-infective agents**

- Local anti-infective agents
- Preservatives
- Antifungal agents

• Urinary tract anti-infectives

#### **UNIT IV**

# **Anti-infective agents**

- Antitubercular agents
- Antiviral agents and Anti AIDS agents
- Antiprotozoal agents
- Anthelmentics
- Antiscabies and Antipedicular agents

## **UNIT V**

- Sulphonamides and sulphones
- Antimalarials

## **UNIT VI**

- Antibiotics
- Antineoplastic agents

## **UNIT VII**

# Cardiovascular agents

- Antihypertensive agents
- Antianginal agents and vasodilators

# **UNIT VIII**

# Cardiovascular agents

- Antiarrhythmic agents
- Antihyperlipidemic agents
- Coagulants and Anticoagulants
- Endocrine

#### **UNIT IX**

- Hypoglycemic agents
- Thyroid and Antithyroid agents

# **UNIT X**

- Diureties
- Diagnostic agents
- Steroidal Hormones and Adrenocorticoids

## **Suggested Readings:**

- 1. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical
- 2. Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- 3. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
- 4. Burgers, Medicinal Chemistry, M.E., Welly Med. Chemistry M.E. Walffed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
- 5. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- 6. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi 54.

- Current Index of Medical Specialities (CIMS) and MIMS India, MIMS,
   A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- 2. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- 3. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- 4. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

22PD310P

THIRD YEAR

## MEDICINAL CHEMISTRY PRACTICAL 3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical: 3 Hrs./Week

#### **Course Objectives:**

- To prepare drugs and medicinally important compounds by traditional and microwave method.
- To prepare drug intermediates by traditional and microwave method.
- To perform assay of drug substances.
- To draw structures of chemicals using soft ware's.
- To determine physicochemical properties for drugs using software.
- To screen drug likeliness.

## Course Outcomes (CO's): On successful completion of the course the student will

- 1. Prepare drugs and medicinally important compounds by traditional and microwave method.
- 2. Prepare drug intermediates by traditional and microwave method.
- 3. Perform assay of drug substances.
- 4. Draw structures of chemicals using softwares.
- 5. Determine physicochemical properties for drugs using software.
- 6. Screen drug likeliness.

#### **CONTENT**

- 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.

#### **Suggested Readings:**

- 1. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical
- 2. Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- 3. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi 54.

## **Reference Books (Latest Editions):**

Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E.
 Morgan Publications (I) Pvt. Ltd, New Delhi-19.

- 2. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- 3. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.

4. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

22PD306T

THIRD YEAR

#### PHARMACEUTICAL FORMULATIONS THEORY

3H 3C

Instruction hours/ week: L: 2 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

# Theory: 3 Hrs./Week

## **Course Objectives:**

- 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.
- To discover various formulation considerations in development of pharmaceutical dosage forms like tablets, capsules, etc.
- To Understand the quality control tests for the dosage forms.
- To know parenterals and novel drug delivery system.
- To understand clearly about packaging and cosmetic preparations.
- To interpret the various pharmaceutical additives to be included in all dosage forms.

# Course Outcomes (CO's): On successful completion of the course the student will

- 1. Aquire knowledge about the various pharmaceutical dosage forms and their manufacturing techniques.
- 2. Discover various formulation considerations in development of pharmaceutical dosage forms like tablets, capsules, etc.
- 3. Understand the quality control tests for the dosage forms.
- 4. Detail on parenterals and Novel Drug Delivery System.
- 5. Understand clearly about packaging and cosmetic preparations.
- 6. Interpret the various pharmaceutical additives to be included in all dosage forms.

#### **Detailed syllabus and lecture wise schedule:**

## **UNIT I**

Pharmaceutical dosage form- concept and classification

## **UNIT II**

**Tablets**: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets.

## **UNIT III**

Tablet coating, Type of coating, quality control tests for coated tablet.

#### **UNIT IV**

**Capsules**; Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules.

# UNIT V

Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.

## **UNIT VI**

**Liquid orals**: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations

## **UNIT VII**

**Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization

#### **UNIT VIII**

**Ophthalmic preparations** (**Semi – Solids**): Introduction and classification Factors affecting absorption and anatomy of eye Packaging storage and labeling

## **UNIT IX**

Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging

## **UNIT X**

Definition and concept of Controlled and novel Drug delivery systems with available examples, viz. parentral, trans dermal, buccal, rectal, nasal, implants, ocular

## **Suggested Readings:**

- 1. Pharmaceutical dosage forms, Vol, I,II and III by lachman
- 2. Rowlings Text book of Pharmaceutics
- 3. Tutorial Pharmacy Cooper & Gunn

- 1. Remington's Pharmaceutical Sciences
- 2. USP/BP/IP

# 22PD311P THIRD YEAR

## PHARMACEUTICAL FORMULATIONS PRACTICAL 3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

#### Practical: 3 Hrs./Week

## **Course Objectives:**

- To manufacture tablets.
- To understand the strict formulation considerations in parenteral and ophthalmic manufacturing.
- To demonstrate the evaluations of different packaging materials in pharmaceutical industry.
- To achieve skills in making a pharmaceutical product.
- To demonstrate the manufacturing of capsules.
- To exploit the formulation of various cosmetics.

# Course Outcomes (CO's): On successful completion of the course the student will

- 1. Manufacture tablets.
- 2. Understand the strict formulation considerations in parenteral and ophthalmic manufacturing.
- 3. Demonstrate the evaluations of different packaging materials in pharmaceutical industry.
- 4. Achieve skills in making a pharmaceutical product.
- 5. Demonstrate the manufacturing of capsules.
- 6. Exploit the formulation of various cosmetics.

## **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)

# **Suggested Readings:**

- 1. Pharmaceutical dosage forms, Vol, I,II and III by lachman
- 2. Rowlings Text book of Pharmaceutics
- 3. Tutorial Pharmacy Cooper & Gunn

- 1. Remington's Pharmaceutical Sciences
- 2. USP/BP/IP

22PD401T

FOURTH YEAR

#### PHARMACOTHERAPEUTICS – III THEORY

4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory: 4 Hrs./Week

# **Course Objectives:**

- 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.
- To summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
- To diagnose a disease using biochemical & pathological Parameters.
- To discuss the preparation of individualized therapeutic plans based on diagnosis

Course Outcome (CO's): On successful completion of the course the student will

- 1. Explain Pathophysiology of selected disease states and the rationale for drug therapy;
- 2. Understand the therapeutic approach to manage of these diseases;
- 3. Diagnose a dynamic based on biochemical & Pathological Parameters;
- 4. Evaluate the importance of individualized therapeutic plans based on diagnosis;
- 5. Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring drug therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
- 6. Demonstrate patient counselling points for various diseases;

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

**UNIT I** 

Gastrointestinal system: Peptic ulcer disease, Gastro Esophageal Reflux Disease

**UNIT II** 

Inflammatory bowel disease

#### **UNIT III**

Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice

#### **UNIT IV**

Drug induced liver disorders.

#### **UNIT V**

Haematological system: Anaemias, Venous thromboembolism

#### **UNIT VI**

Drug induced blood disorders.

#### **UNIT VII**

Nervous system: Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,

#### **UNIT VIII**

Psychiatry disorders: Schizophrenia, Affective disorders, Anxiety disorders, Sleep

disorders, Obsessive Compulsive disorders

#### **UNIT IX**

Pain management including Pain pathways, neuralgias, headaches.

#### **UNIT X**

Evidence Based Medicine

The following details shall be submitted for any 25 selected drugs in the form of assignment/PPT.

\*\*Name of the Drug, Brand name, Category, Therapeutic uses, Dose, Pharmacological action, Route of administration, Side effects, Contraindications, Drug Interactions with drug/food, Pharmacokinetics

#### **Suggested Readings:**

- 1. Clinical Pharmacy and Therapeutics Roger and Walker, Churchill Livingstone publication
- 2. Pharmacotherapy: A Pathophysiologic approach Joseph T. Dipiro et al. Appleton & Lange

- 1. Pathologic basis of disease Robins SL, W.B.Saunders publication
- 2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice Green and Harris, Chapman and Hall publication
- Clinical Pharmacy and Therapeutics Eric T. Herfindal, Williams and Wilkins Publication
- Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda -Kimble MA
- 5. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

#### 22PD407P

#### FOURTH YEAR

#### PHARMACOTHERAPEUTICS – III PRACTICAL 3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

#### Practical: 3 Hrs./Week

#### **Course Objectives:**

- 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.
- To summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
- To discuss the controversies in drug therapy;
- To discuss the preparation of individualized therapeutic plans based on diagnosis

#### Course Outcome (CO's): On successful completion of the course the student will

- 1. Analyze individual cases for various diseases;
- 2. Present case reports for various diseases;
- 3. Demo Patient counselling points;
- 4. Identify advance drug reactions;
- 5. Analyze various drug interactions;
- 6. Manage selection of drug therapy during ward rounds participations;

#### **Practicals:**

Hospital postings for a period of at least 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.

### **Suggested Readings:**

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

- 1. Pathologic basis of disease Robins SL, W.B.Saunders publication
- 2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice Green and Harris, Chapman and Hall publication

22PD402T

FOURTH YEAR

#### HOSPITAL PHARMACY THEORY

3H 3C

Instruction hours/ week: L: 2 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100 External Semester Exam: 3 Hours

Theory: 3 Hrs. /Week

# **Course Objectives:**

- 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,
- to know drug dispensing, manufacturing of parenteral preparations,
- to understand drug information, patient counselling,
- to learn therapeutic drug monitoring for improved patient care.
- To know The Stores Management and Inventory Control.

#### **Course Outcome (CO's):**

Upon completion of the course, the student will –

- 1. Outline on hospital pharmacy Organize & understand the management of materials & finance;
- 2. Understand budget prepare and implementation in Hospital Pharmacy;
- 3. Illustrate the Stores Management and Inventory Control.
- 4. Discuss various drug distribution methods in hospital & for scheduled drugs;
- 5. Describe the manufacturing practices of various formulations in hospital set up & radio Pharmaceuticals;
- 6. Understand the professional practice management skills in hospital pharmacies;

# **UNIT I**

#### **Hospital - its Organization and functions**

#### **UNIT II**

#### 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

#### **UNIT III**

#### The Budget – Preparation and implementation

# **Hospital drug policy**

a) Pharmacy and Therapeutic committee (PTC)

#### b) Hospital formulary

#### **UNIT IV**

Hospital committees

- Infection committee
- Research and ethical committee
- c) developing therapeutic guidelines
- d) Hospital pharmacy communication Newsletter

#### **UNIT V**

# Hospital pharmacy services

- Procurement & warehousing of drugs and Pharmaceuticals
- Inventory control
- Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock

#### **UNIT VI**

Drug distribution in the hospital

- Individual prescription method
- Floor stock method
- Unit dose drug distribution method

#### **UNIT VII**

Distribution of Narcotic and other controlled substances

Central sterile supply services – Role of pharmacist

#### **UNIT VIII**

# **Manufacture of Pharmaceutical preparations**

Sterile formulations – large and small volume parenterals manufacture

Of Ointments, Liquids, and cream, Pharmaceutical compounding

**Sterile preparations:** Sterile compounding, Good Compounding Practices, Responsibility of Compounding personnel.

#### **UNIT IX**

Manufacturing of Tablets, granules, capsules, and powders

Total parenteral nutrition

#### Continuing professional development programs

Education and training

### Radio Pharmaceuticals - Handling and packaging

# UNIT X

# Professional Relations and practices of hospital pharmacist

# **Suggested Readings:**

- 1. Hospital pharmacy by William E. Hassan
- 2. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

- 1. WHO consultative group report.
- 2. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- 3. Handbook of pharmacy health care. Edt. Robin J Harman. The Pharmaceutical press.

22PD408P

FOURTH YEAR

#### HOSPITAL PHARMACY PRACTICAL

3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

# Practical: 3 Hrs./Week Course Objectives:

• 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,
- to know drug dispensing, manufacturing of parenteral preparations,
- to understand drug information, patient counselling,
- to learn therapeutic drug monitoring for improved patient care.
- To know The Stores Management And Inventory Control.

# **Course Outcome (CO's):**

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

- 1. Evaluate drug interactions in outpatient prescriptions;
- 2. Evaluate drug interactions in ward prescription;
- 3. Defending drug information queries;
- 4. Identify adverse drug reactions;
- 5. Assessing drug inventory control in Hospital Pharmacy
- 6. Assessing drug inventory control in Nursing Station.

### **COURSE CONTENT**

- 1. Assessment of drug interactions in the given prescriptions
- 2. Drug information queries.
- 3. 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
- 8. Sterile compounding

# **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.

# **Suggested Readings:**

1. Hospital pharmacy by William E. Hassan

- 1. WHO consultative group report.
- 2. R.P.S. Vol.2. Part –B; Pharmacy Practice section.

22PD403T

FOURTH YEAR

#### CLINICAL PHARMACY THEORY

4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

# Theory: 4 Hrs./Week

#### **Course objective:**

 To Monitor drug therapy of patient through medication chart review and clinical review;

- To Obtain medication history interview and counsel the patients;
- To Identify and resolve drug related problems;
- To detect, assess and monitor adverse drug reaction;
- To Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- To Retrieve, analyse, interpret and formulate drug or medicine information.

# Course Outcomes (CO's): Upon completion of the course the students shall be able to-

- 1. Describe the daily activities of clinical Pharmacist in improving the patient case.
- 2. Understand the basis for evaluating the biomedical literatures;
- 3. Identify and resolve drug related problems;
- 4. Detect, assess and monitor adverse drug reaction;
- 5. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states;
- 6. Retrieve, analyse, interpret and formulate drug or medicine information.

# Detailed syllabus and lecture wise schedule:

#### **UNIT I**

# Definitions, development and scope of clinical pharmacy

#### 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

#### **UNIT II**

Medication history

Patient counseling

#### **UNIT III**

Drug utilisation evaluation (DUE) and review (DUR)

# **UNIT IV**

Quality assurance of clinical pharmacy services

#### **UNIT V**

# 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.

# Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results

- a. Haematological, 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

#### **UNIT VI**

#### **Drug & Poison information**

- Introduction to drug information resources available
- Systematic approach in answering DI queries
- Critical evaluation of drug information and literature
- Preparation of written and verbal reports
- Establishing a Drug Information Centre
- Poisons information- organization & information resources

# **UNIT VII**

#### **Pharmacovigilance**

- Scope, definition and aims of pharmacovigilance
  - Adverse drug reactions Classification, mechanism, predisposing factors, causality assessment [different scales used]
  - Reporting, evaluation, monitoring, preventing & management of ADRs
  - Role of pharmacist in management of ADR.

#### **UNIT VIII**

Communication skills, including patient counselling techniques, medication history interview, presentation of cases.

#### **UNIT IX**

- Pharmaceutical care concepts
- Critical evaluation of biomedical literature

#### **UNIT X**

Medication errors

# **Suggested Readings:**

- 1. Practice Standards and Definitions The Society of Hospital Pharmacists of Australia.
- 2. Basic skills in interpreting laboratory data Scott LT, American Society of Health System Pharmacists Inc.
- 3. Biopharmaceutics and Applied Pharmacokinetics Leon Shargel, Prentice Hall publication.
- A text book of Clinical Pharmacy Practice; Essential concepts and skills,
   Dr.G.Parthasarathi etal, Orient Orient Langram Pvt. Ltd. ISSBN8125026

- 1 Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- 2 Clinical Pharmacokinetics Rowland and Tozer, Williams and Wilkins Publication.
- 3 Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

22PD409P

FOURTH YEAR

#### CLINICAL PHARMACY PRACTICAL

3H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical: 3 Hrs./Week

# **Course objective:**

- To Monitor drug therapy of patient through medication chart review and clinical review;
- To Obtain medication history interview and counsel the patients;
- To Identify and resolve drug related problems;
- To detect, assess and monitor adverse drug reaction;
- To Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- To Retrieve, analyse, interpret and formulate drug or medicine information.

#### **Course Outcomes (CO's):**

- 1. Demonstrate patient meditation history;
- 2. Illustrate patient counselling interview;
- 3. Defending drug information queries;
- 4. Detect, assess and monitor adverse drug reaction;
- 5. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states;
- 6. Analyze & interpret drug or medicine information.

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- 1 Answering drug information questions (4 Nos)
- 2 Patient medication counseling (4 Nos)
- 3 Case studies related to laboratory investigations (4 Nos)
- 4 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.

# **Suggested Readings:**

- 1. Practice Standards and Definitions The Society of Hospital Pharmacists of Australia.
- A text book of Clinical Pharmacy Practice; Essential concepts and skills,
   Dr.G.Parthasarathi etal, Orient Orient Langram Pvt. Ltd. ISSBN8125026

- 1 Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- 2 Clinical Pharmacokinetics Rowland and Tozer, Williams and Wilkins Publication.

22PD404T FOURTH YEAR

#### BIOSTATISTICS AND RESEARCH METHODOLOGY THEORY 3H 3C

Instruction hours/ week: L: 2 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

# Theory: 3 Hrs. /Week Course Objectives:

- To understand some basic concepts of research and its methodologies
- To identify appropriate research topics
- To select and define appropriate research problem and parameters
- To prepare a project proposal
- To organize and conduct research in a more appropriate manner
- To write a research report and thesis

# **Course Outcomes (CO's):**

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

- 1. Understand some basic concepts of research and its methodologies;
- 2. Execute computer applications in Hospital Pharmacy;
- 3. Select and define appropriate research problem and parameters;
- 4. Construct various data graphics in research;
- 5. Organize and conduct research in a more appropriate manner;
- 6. Implement statistical parameter in research;

#### **UNIT I**

### **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

#### **UNIT II**

#### **Biostatistics**

- Introduction
- Types of data distribution
- Measures describing the central tendency distributions- average, median, mode

 Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

#### **UNIT III**

#### **Data graphics**

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarthimic plots

#### **UNIT IV**

#### **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, Pearsonn's and Spearmann's correlation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

#### **UNIT V**

#### Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

#### **UNIT VI**

#### **Computer applications in pharmacy**

#### **UNIT VII**

<u>Computer System in Hospital Pharmacy</u>: 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.

#### **UNIT VIII**

#### **Computer In Community Pharmacy**

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

#### **UNIT IX**

Accounting and General ledger system

#### **UNIT X**

# **Drug Information Retrieval & Storage:**

Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval

# **Suggested Readings:**

 Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3<sup>rd</sup> edition, publisher Marcel Dekker Inc. NewYork.

# **Reference Books (Latest Editions):**

 Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3<sup>rd</sup> edition, McGraw Hill Publications 2006

#### 22PD405T FOURTH YEAR

BIOPHARMACEUTICS AND PHARMACOKINETICS THEORY 4H

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100 External Semester Exam: 3 Hours

# Theory: 4 Hrs. /Week

# **Course Objectives:**

- 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 raised therein.
- To explain the use of plasma drug concentration-time data to calculate the pharmacokinetic parameters.
- To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- To understand various pharmacokinetic parameters, their significance & applications.
- To demonstrate a clear information on compartmental models and methods to assess the models.
- To describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

# Course Outcomes (CO's): On successful completion of the course the student will

- 1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- 2. Explain the use of plasma drug concentration-time data to calculate the pharmacokinetic parameters.
- 3. Understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- 4. Understand various pharmacokinetic parameters, their significance & applications.
- 5. Demonstrate a clear information on compartmental models and methods to assess the models.
- 6. Describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

#### **UNIT I**

#### **Biopharmaceutics**

Introduction to Biopharmaceutics

- Absorption of drugs from gastrointestinal tract.
- Drug Distribution.
- Drug Elimination.

#### **UNIT II**

# **Pharmacokinetics**

**4C** 

#### Introduction to Pharmacokinetics.

- Mathematical model
- Drug levels in blood.
- Pharmacokinetic model
- Compartment models
- Pharmacokinetic study.

#### **UNIT III**

# One compartment open model.

- Intravenous Injection (Bolus)
- Intravenous infusion.

#### **UNIT IV**

#### Multicompartment models.

- Two compartment open model.
- IV bolus, IV infusion and oral administration

#### **UNIT V**

# Multiple - Dosage Regimens.

Repititive Intravenous injections - One Compartment Open Model

Repititive Extravascular dosing – One Compartment Open model c.

Multiple Dose Regimen - Two Compartment Open Model

#### **UNIT VI**

#### **Nonlinear Pharmacokinetics.**

- Introduction
- Factors causing Non-linearity.
- Michaelis-menton method of estimating parameters.

#### **UNIT VII**

#### Non-compartmental Pharmacokinetics.

- Statistical Moment Theory.
- MRT for various compartment models.

# **UNIT VIII**

Physiological Pharmacokinetic model.

# **UNIT IX**

## Bioavailability and Bioequivalence.

- Introduction.
- Bioavailability study protocol.

#### **UNIT X**

Methods of Assessment of Bioavailability

# **Suggested Readings:**

- 1 Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- 2 Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
- 3 Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
- 4 Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- 5 Biopharmaceutics and Pharmacokinetics; By Robert F Notari

- 1. Biopharmaceutics; By Swarbrick
- 2. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- 3. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.

22PD410P FOURTH YEAR

### BIOPHARMACEUTICS AND PHARMACOKINETICS PRACTICAL

H 2C

Instruction hours/ week: L: 0 T:0 P:3 Marks: Internal: 30 External: 70 Total: 100 External Semester Exam: 3 Hours

# Practical: 3 Hrs./Week Course Objectives:

- 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 raised therein.
- To explain the use of plasma drug concentration-time data to calculate the pharmacokinetic parameters.
- To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- To understand various pharmacokinetic parameters, their significance & applications.
- To demonstrate a clear information on compartmental models and methods to assess the models.
- To describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

# Course Outcomes (CO's): On successful completion of the course the student will

- 1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- 2. Explain the use of plasma drug concentration-time data to calculate the pharmacokinetic parameters.
- 3. Understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- 4. Understand various pharmacokinetic parameters, their significance & applications.
- 5. Demonstrate a clear information on compartmental models and methods to assess the models.
- 6. Describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- 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, Sulphamethoxzole, 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.

# **Suggested Readings:**

- 1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- 2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari

- 1. Biopharmaceutics; By Swarbrick
- 2. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi.

22PD406T FOURTH YEAR

# CLINICAL TOXICOLOGY THEORY

3H 3C

Instruction hours/ week: L: 2 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100 External Semester Exam: 3 Hours

# Theory: 3 Hrs./Week

# **Course Objectives:**

- To understand the general working knowledge of the principles and practice of clinical toxicology
- To know the health implications of toxic exposures and commonly involved chemicals for toxicity
- To understand principles of general toxicology and clinical management practice.
- To demonstrate and apply history, assessment and therapy considerations associated with the management of a toxic exposure.
- To understand treatment guidelines for specific toxic substances.
- To get knowledge about preventive approaches to reduce unintentional poisoning.

# Course Outcomes (CO's): On successful completion of the course the student will

- 1. Understand the general working principles and practice of clinicaltoxicology
- 2. The health implications of toxic exposures and commonly involved chemicals for toxicity
- 3. Understand principles of general toxicology and clinical management practice.
- 4. Demonstrate the assessment and therapy considerations associated with the management of a toxic exposure.
- 5. Understand treatment guidelines for specific toxic substances.
- 6. Knowledge about preventive approaches to reduce unintentional poisoning.

# UNIT I

- General principles involved in the management poisoning
- Antidotes and the clinical applications.
- Supportive care in clinical Toxicology.

#### **UNIT II**

- Gut Decontamination.
- Elimination Enhancement.
- Toxicokinetics.

#### **UNIT III**

Clinical symptoms and management of acute poisoning with the following agents –

• Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.

- Opiates overdose.
- Antidepressants
- Barbiturates and benzodiazepines.

#### **UNIT IV**

Clinical symptoms and management of acute poisoning with the following agents – Alcohol: ethanol, methanol.

- Paracetamol and salicylates.
- Non-steroidal anti-inflammatory drugs.

# **UNIT V**

Clinical symptoms and management of acute poisoning with the following agents –

Hydrocarbons: Petroleum products and PEG.

Caustics: inorganic acids and alkali.

Radiation poisoning

# **UNIT VI**

Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper

#### **UNIT VII**

Clinical symptoms and management of acute poisoning with the following agents –

Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.

#### **UNIT VIII**

Plants poisoning. Mushrooms, Mycotoxins.

Food poisonings

Envenomations – Arthropod bites and stings.

#### **UNIT IX**

#### **Substance abuse:**

Signs and symptoms of substance abuse and treatment of dependence

• CNS stimulants :amphetamine

- Opioids
- CNS depressants

#### **UNIT X**

Hallucinogens: LSD

- Cannabis group
- Tobacco

The following details shall be submitted for any 25 selected drugs in the form of assignment/PPT.

\*\*Name of the Drug, Brand name, Category, Therapeutic uses, Dose, Pharmacological action, Route of administration, Side effects, Contraindications, Drug Interactions with drug/food, Pharmacokinetics.

# **Suggested Readings:**

- 1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- 2. Matthew J Ellenhorn. Ellenhorns Medical Toxicology Diagnosis and Treatment of Poisoning. Second edition. Williams and Willkins publication, London

### **Reference Books (Latest Editions):**

V V Pillay. Handbook of Forensic Medicine and Toxicology. Thirteenth edition 2003
 Paras Publication, Hyderabad

22PD501T

FIFTH YEAR

#### CLINICAL RESEARCH THEORY

4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100 External Semester Exam: 3 Hours

# Theory: 4 Hrs. /Week Course Objectives:

- Understand various approaches to drug discovery
- Understand the regulatory and ethical process
- Describe the new drug development process
- Estimate and Discuss the clinical trials activities
- Estimate safety monitoring and reporting in clinical trials
- Identify preventive approaches to reduce unintentional poisoning.
- Related the roles & responsibilities of Clinical trial Personnels.

# Course Outcomes (CO's): On successful completion of the course the student will

- 1. Understand various approaches to drug discovery
- 2. Understand the regulatory and ethical process
- 3. Describe the new drug development process
- 4. Estimate and Discuss the clinical trials activities
- 5. Estimate safety monitoring and reporting in clinical trials
- 6. Identify preventive approaches to reduce unintentional poisoning.
- 7. Related the roles & responsibilities of Clinical trial Personnels.

# **UNIT I**

#### **Drug development process:** Introduction

Various Approaches to drug discovery

Pharmacological

**Toxicological** 

#### **UNIT II**

**IND Application** 

Drug characterization

Dosage form

#### **UNIT III**

#### Clinical development of drug:

- o Introduction to Clinical trials
- o Various phases of clinical trial.
- o Methods of post marketing surveillance

#### **UNIT IV**

Abbreviated New Drug Application submission.

 Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines

- o Challenges in the implementation of guidelines
- o Ethical guidelines in Clinical Research

#### **UNIT V**

- o Composition, responsibilities, procedures of IRB / IEC
- o Overview of regulatory environment in USA, Europe and India.

#### **UNIT VI**

Role and responsibilities of clinical trial personnel as per ICH GCP

- Sponsor
- Investigators
- Clinical research associate
- Auditors
- Contract research coordinators
- Regulatory authority

#### **UNIT VII**

Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)

### **UNIT VIII**

**Informed consent Process** 

#### **UNIT IX**

Data management and its components

# **UNIT X**

Safety monitoring in clinical trials.

# **Suggested Readings:**

- 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 Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised 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.

- 1. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- 2. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

22PD502T FIFTH YEAR

# PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS THEORY 4H 4C

Instruction hours/ week: L: 3 T: 1 P: 0

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory: 4 Hrs. /Week Course Objectives:

- Identify the application pharmacoepidemiology and pharmacoeconomics in clinical settings
- Discuss the various pharmacoepidemiology outcome measures.
- Understand the concept of risk in pharmacoepidemiology and different methods of measuring risk
- Examine various pharmacoepidemiological methods
- Interpret various types case studies
- Asses about current pharmacoenomic evaluation methods

# Course Outcomes (CO's): On successful completion of the course the student will

- 1. Identify the application pharmacoepidemiology and pharmacoeconomics in clinical settings
- 2. Discuss the various pharmacoepidemiology outcome measures.
- 3. Understand the concept of risk in pharmacoepidemiology and different methods of measuring risk
- 4. Examine various pharmacoepidemiological methods
- 5. Interpret various types case studies
- 6. Asses about current pharmacoenomic evaluation methods

# **UNIT I**

# Pharmacoepidemiology:

# **Definition and scope:**

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

#### **UNIT II**

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

#### UNIT III

# Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

#### **UNIT IV**

# Pharmacoepidemiological methods

 Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

#### **UNIT V**

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.

#### **UNIT VI**

**Sources of data for pharmacoepidemiological studies** Ad Hoc data sources and automated data systems

#### **UNIT VII**

# Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

#### **UNIT VIII**

#### **Pharmacoeconomics:**

# Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

# **UNIT IX**

#### 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

# **UNIT X**

### Applications of Pharmacoeconomics Software and case studies

#### **Suggested Readings:**

- Rascati K L. Essentials of Pharmacoeconomics, 2<sup>nd</sup> ed. Philadelphia: Woulters Kluwer Lippincott Williams & Wilkins, 2013.
- 2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. 1997, 2003. John Wiley & Sons, second edition.

3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health EconomicEvaluation, PublishedbytheOxfordUniversityPress2006.

- Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brienand Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press (Third Edition) – 2005.
- 2. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics, 2013.

22PD503T

FIFTH YEAR

# CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING THEORY 3H 3C

Instruction hours/ week: L: 2 T:1 P:0 Marks: Internal: 30 External: 70 Total: 100 External Semester Exam: 3 Hours

Theory: 3 Hrs. /Week

# **Course Objectives:**

- 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.
- To explain the use of plasma drug concentration-time data to calculate the pharmacokinetic parameters.
- To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- To understand various pharmacokinetic parameters, their significance & applications.
- To demonstrate a clear information on compartmental models and methods to assess the models.
- To describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

# Course Outcomes (CO's): On successful completion of the course the student will

- 1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- 2. Describe Therapeutics drug monitoring of drugs in various disease conditions
- 3. Compare the concepts of bioavailability and bioequivalence of drug products and their significance.
- 4. Discuss various pharmacokinetic parameters, their significance & applications.
- 5. Demonstrate compartmental models its methods.
- 6. Evaluate dosage adjustment in renal and hepatic impairment.

# **UNIT I**

Introduction to Clinical pharmacokinetics.

#### **UNIT II**

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.

#### **UNIT III**

# **Pharmacokinetics of Drug Interaction:**

- a. Pharmacokinetic drug interactions
- b. Inhibition and Induction of Drug metabolism
- c. Inhibition of Biliary Excretion.

#### **UNIT IV**

# **Therapeutic Drug monitoring:**

- d. Introduction
- e. Individualization of drug dosage regimen (Variability Genetic, Age and Weight, disease, Interacting drugs).
- f. Indications for TDM. Protocol for TDM.

#### **UNIT IV**

Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.

TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

#### **UNIT V**

#### Dosage adjustment in Renal and hepatic Disease.

- Renal impairment
- Pharmacokinetic considerations

#### **UNIT VI**

General approach for dosage adjustment in Renal disease.

- Measurement of Glomerular Filtration rate and creatinine clearance.
- Dosage adjustment for uremic patients.

#### **UNIT VII**

- Extracorporeal removal of drugs.
- Effect of Hepatic disease on pharmacokinetics.

#### **UNIT VIII**

# **Population Pharmacokinetics.**

- Introduction to Bayesian Theory.
- Adaptive method or Dosing with feed back.

• Analysis of Population pharmacokinetic Data.

#### **UNIT IX**

# **Pharmacogenetics**

- Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
- Genetic Polymorphism in Drug Transport and Drug Targets.

#### **UNIT X**

Pharmacogenetics and Pharmacokinetics / Pharmacodynamic considerations

The following details shall be submitted for any 25 selected drugs in the form of assignment/PPT.

\*\*Name of the Drug, Brand name, Category, Therapeutic uses, Dose, Pharmacological action, Route of administration, Side effects, Contraindications, Drug Interactions with drug/food, Pharmacokinetics

# **Suggested Readings:**

- 1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. 6th edition. New York: Mc Graw Hill; 2012.
- 2. Peter L. Bonate. Pharmacokinetic Pharmacodynamic Modeling and Simulation. 2nd edition. USA: Springer; 2011.
- 3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring.4th edition. US: Lippincott Williams & Wilkins; 2005.

- 1. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. 1st edition. USA: CRC Press; 1996.
- 2. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press;2006.

22PD504S FIFTH YEAR CLERKSHIP 1H 1C

Instruction hours/ week: L:0 T:0 P:1 Marks: Internal: 30 External: 70 Total: 100 External Semester Exam: 3 Hours

Seminar: 1 Hrs. /Week

22PD505P FIFTH YEAR PROJECT WORK 20H 10C

Instruction hours/ week: L:0 T:0 P:20 Marks: External: 100 Total: 100 External Semester Exam: 3 Hours

Practicals: 20 Hrs./Week