

**DEPARTMENT OF PHARMACY**  
**DOCTOR OF PHARMACY**  
**PHASE – I AND PHASE – II**  
**ACADEMIC REGULATIONS 2019**

**This document shall be called as Pharm.D. Academic Regulations - 2019 of Annamalai University. These academic regulations shall come in to force from the academic year 2019 - 2020.**

Rules and Regulations for conducting Phase – I and Phase – II of Pharm. D. programmes by Annamalai University [Framed as per Pharm. D. regulations 2008 of Pharmacy Council of India] and will be called as “Pharm.D. Academic Regulations 2019 of Annamalai University”

They shall come into effect from the Academic Year 2019-20. The regulations framed are subject to modifications from time to time by the authorities of the Annamalai University.

**CHAPTER-I**

1. Short title and commencement. –
  - (1) These regulations may be called the Pharm.D. Regulations 2008.
  - (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 speciality 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 speciality 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. Course of study. – The course of study for Pharm.D. (Six Year Integrated) and Pharm.D. (Post Baccalaureate) programme 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 (3), (4) and (5) below.

**T A B L E S****PHARM.D. (SIX YEAR INTEGRATED)****First Year:**

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	<b>Total hours</b>	<b>16</b>	<b>18</b>	<b>6 = 40</b>

\* For Biology

**Second Year:**

S.No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	-	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	<b>Total Hours</b>	<b>17</b>	<b>9</b>	<b>6 = 32</b>

**Third Year:**

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1

3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	<b>Total hours</b>	<b>16</b>	<b>15</b>	<b>5 = 36</b>

**Fourth Year:**

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	<b>Total hours</b>	<b>15</b>	<b>12</b>	<b>6 = 33</b>

**Fifth Year:**

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	<b>Total hours</b>	<b>8</b>	<b>20</b>	<b>4 = 32</b>

\* Attending ward rounds on daily basis.

**PHARM.D. (POST BACCALAUREATE)****First Year:**

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
4.7	Pharmacotherapeutics-I & II	3	3	1
	<b>Total hours</b>	<b>18</b>	<b>15</b>	<b>7 = 40</b>

**Second Year:**

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	<b>Total hours</b>	<b>8</b>	<b>20</b>	<b>4 = 32</b>

\* Attending ward rounds on daily basis.

**Sixth Year (Pharm. D. Six Years Integrated Programme) / Third Year (Pharm. D. Post Baccalaureate):**

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
8. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix –A to these regulations.
9. 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.
- (2) Any person or pharmacy college for the purpose of obtaining permission under sub-section (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.
- (3) 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.
10. 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 :

**T A B L E S**  
**PHARM. D. (SIX YEARS INTEGRATED) EXAMINATIONS**

**First Year Pharm. D. (Six Years Integrated) Examinations:**

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/Biology	70	30	100	70*	30*	100*
				600			600 = 1200

\* for Biology.

**Second Year Pharm. D. (Six Years Integrated) Examinations:**

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Pathophysiology	70	30	100	-	-	-
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology-I	70	30	100	-	-	-
2.5	Community Pharmacy	70	30	100	-	-	-
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100
				600			300 = 900

**Third Year Pharm. D. (Six Years Integrated) Examinations:**

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology-II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics-II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-
3.5	Medicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 1100

**Fourth Year Pharm. D. (Six Years Integrated) Examinations:**

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

**Fifth Year Pharm. D. (Six Years Integrated) Examinations:**

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

\* Attending ward rounds on daily basis.

\*\* 30 marks – viva-voce (oral)

70 marks – Thesis work

**PHARM. D. (POST BACCALAUREATE) EXAMINATIONS****First Year Pharm. D. (Post Baccalaureate) Examinations:**

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
4.7	Pharmacotherapeutics-I & II	70	30	100	70	30	100
				700			500 = 1200

**Second Year Pharm. D. (Post Baccalaureate) Examinations:**

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

\* Attending ward rounds on daily basis.

\*\* 30 marks – viva-voce (oral)

70 marks – Thesis work

11. 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.

12. Mode of examinations.— (1) Theory examination shall be of three hours and practical examination shall be of four 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.

13. 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.

(2) There shall be at least two periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.

(3) 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).

14. 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.

15. Eligibility for promotion to next year.— (a) 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.

(b) Any one of the two subjects i.e. either Remedial Mathematics or Biology can be carried forward to 2<sup>nd</sup> year Pharm. D. as an additional failed subject along with 2

failed subjects of I year under regulation 15 of the Pharm.D. regulations, 2008, subject to the condition that failure in more than two subjects debar the candidate from promotion to next year class (III year). This is applicable to all Pharm. D. batches admitted from 2008 – 2009 academic session.

16. 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.

17. 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.

18. 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.

18 (a). Miscellaneous

Candidates who have been admitted to 1<sup>st</sup> year integrated six year Pharm. D programme, without biology subject at the plus two level have to undergo a bridge course in Biology called remedial Biology in addition to other 1<sup>st</sup> year integrated six year Pharm. D subjects for which the syllabus is prescribed. The total number of hours in remedial Biology is prescribed as 75 hours each for theory and practical. There shall be a university examination of three hours duration continuous at the end of 1<sup>st</sup> year integrated six year Pharm. D programme. There shall be continuous internal assessment of 30 marks for theory & Practical separately and 70 marks for university examination for theory & practical separately.

Candidates who have been admitted to 1<sup>st</sup> year integrated six year Pharm. D programme, without mathematics subjects at the plus two levels are required to undertake a course on remedial mathematics. A syllabus for remedial Mathematics subjects is prescribed. The total number of contact hours prescribed for this course is 75 hours. There shall be university examination of three hours duration at the end of one year 1<sup>st</sup>

year integrated six year Pharm. D programme. There shall be a continuous internal assessment for 30 marks and university examination for 70 marks.

A separate mark sheet shall be issued for remedial biology or remedial mathematics and this mark shall not be included for classification of division.

18 (b). Student Counsellors (Mentors)

To help the students in planning their course of study and for general advise on the academic programme, the Dean / Head of the Department will attach a certain number of students to a member of the faculty who shall function as student counsellor for those students throughout their period of study. Such student counsellors shall advise the students, give preliminary approval for the courses to be taken by the students during each semester and obtain the final approval of the Dean/ Head of the Department.

### **CHAPTER-III**

#### **Practical training**

19. 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.

20. 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.

21. 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.

22. Methodology.— To complete the project work following methodology shall be adopted, namely:—

- (i) students shall work in groups of not less than *two* and not more than *four* under an authorized teacher;
- (ii) project topic shall be approved by the Head of the Department or Head of the Institution;
- (iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilization reviews, pharmacoepidemiology, pharmacovigilance or pharmacoconomics;
- (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.

23. Reporting .— (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorized teacher, Head of the Department as well as by the Head of the Institution

- (2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, subtitles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorized teacher with font size 14.

- (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

24. 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 thirty 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:	<b>Marks</b>
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)
<b>Total</b>	(30 marks)

(v) Final evaluation of project work shall be done on the following items:	<b>Marks</b>
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
<b>Total</b>	(70 marks)

*Explanation.*— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

## **25. Transitory Regulations**

The University shall have powers to revise or change or amend the regulations, the scheme of examinations, the course of study and syllabus as and when the statutory authorities recommend.

### **Program Outcomes (POs)**

**The post graduate in Pharm.D. and Pharm. D. (PB) Programme Degree Programme shall be able to:**

1. **Caregiver:** Provide patient centred care as the medication expert (collect and interpret evidence, prioritize, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities)
2. **Decision Maker:** Develop problem-based learning approach and analytical thinking in his/her academic and professional life.

3. **Learner** - Develop, integrate, and apply knowledge from the foundational sciences (i.e., pharmaceutical, social/ behavioral/ administrative and clinical sciences) to evaluate the scientific literature, explain drug action, solve therapeutic problems, and advance population health and patient centred care
4. **Teacher:** Population based care - Describe how population based care influences patient centered care and influences the development of practice guidelines and evidence-based best practices
5. **Communicator:** The students are in an ideal position to provide a link between prescriber and patient, and to communicate information on health and medicines to the public. The students must be knowledgeable and confident while interacting with other health professionals and the public.
6. **Leader:** In multidisciplinary areas where other health care providers are in short supply pharmacist should assume a leadership position in the overall welfare of the patient and the community. Leadership involves compassion and empathy as well as vision and the ability to make decisions, communicate, and manage effectively. A student whose leadership role is to be recognized must have vision and the ability to lead.
7. **Manager:** Medication use systems management - Manage patient healthcare needs using human, financial, technological, and physical resources to optimize the safety and efficacy of medication use systems
8. **Knowledge:** Demonstrate knowledge of pharmacy practice and the ability to acquire, manage and use current information for problem solving, patient-specific, population-specific, evidence-based care to promote safe and optimal pharmacotherapy outcomes.
9. **Skills:** Apply critical thinking skills, including investigation, application, analysis, creativity, synthesis and evaluation of information, data and documents related to drug, poison, clinical investigations, pharmaceutical care and practices.
10. **Researcher:** The students are able to use the evidences effectively in order to advise on the rational use of medicines in the healthcare team. By sharing and documenting experiences, the students can also contribute to the evidence base with the goal of optimizing patient care and outcomes. As a researcher, the student is able to increase the accessibility of unbiased health and medicines-related information to the public and other healthcare professionals.

### **Program Specific Outcomes (PSOs)**

**The post graduate in Pharm.D. and Pharm. D. (PB) Programme Degree Programme shall be able to:**

1. Identify and assess drug related problems relative to specific patient cases
2. Appreciate and utilize pharmaceutical and pharmacokinetics mathematics to perform accurate medication calculations.
3. Understand and comply with central and state laws related to pharmacy practice.
4. Apply and assess the literature and other research resources to provide evidence-based drug information that meets the needs of patients and other health care providers.

5. Discuss how patients and care givers can obtain the most cost-efficient medications and related pharmaceuticals per patient-specific health insurance coverage options

Alignment of Programme Specific Outcomes (PSOs) to Programme Educational Objectives (PEOs):\*

	<b>PSO1</b>	<b>PSO2</b>	<b>PSO3</b>	<b>PSO4</b>	<b>PSO5</b>	<b>PSO6</b>	<b>PSO7</b>
<b>PEO1</b>	X						
<b>PEO2</b>							
<b>PEO3</b>		X					
<b>PEO4</b>							
<b>PEO5</b>						X	

\*PSOs deal with domain specific knowledge. All the domain knowledge objectives are stated in PEO1 itself.

**PHARM.D. SYLLABUS****First Year****75Hrs****1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)****Theory: 3 Hrs. /Week**

**1. Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.

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

- a. describe the structure (gross and histology) and functions of various organs of the human body;
- b. describe the various homeostatic mechanisms and their imbalances of various systems;
- c. identify the various tissues and organs of the different systems of the human body;
- d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
- e. appreciate coordinated working pattern of different organs of each system; and
- f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

**3. Course materials:**

**Text books**

- a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology  
Publisher Harpercollins college New York.
- b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology.  
Publisher: Churchill Livingstone, Edinburg.

**Reference books**

- a. Arthur C. Guyton. *Physiology of human body*. Publisher: Holtsaunders.
- b. Chatterjee, C.C. *Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
- c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
- d. *Gray's anatomy*. Publisher: Churchill Livingstone, London.

**4. Detailed syllabus:**



**Topics**

- 1 Scope of anatomy and physiology, basic terminologies used in this subject  
(Description of the body as such planes and terminologies)
- 2 Structure of cell – its components and their functions.
- 3 Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
- 4 a) Osseous system – structure, composition and functions of the Skeleton. (done in practical classes – 6hrs)  
b) Classification of joints, Types of movements of joints and disorders of joints  
(Definitions only)
- 5 **Haemopoetic System**
  - a) Composition and functions of blood
  - b) Haemopoiesis and disorders of blood components (definition of disorder)
  - c) Blood groups
  - d) Clotting factors and mechanism
  - e) Platelets and disorders of coagulation
- 6 **Lymph**
  - a) Lymph and lymphatic system, composition, formation and circulation.
  - b) Spleen: structure and functions, Disorders
  - c) Disorders of lymphatic system (definition only)
- 7 **Cardiovascular system**
  - a) Anatomy and functions of heart
  - b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
  - c) Electrocardiogram (ECG)
  - d) Cardiac cycle and heart sounds
  - e) Blood pressure – its maintenance and regulation
  - f) Definition of the following disorders  
Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias
- 8 **Respiratory system**
  - a) Anatomy of respiratory organs and functions
  - b) Mechanism / physiology of respiration and regulation of respiration
  - c) Transport of respiratory gases

- d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

9 **Digestive system**

- a) Anatomy and physiology of GIT
- b) Anatomy and functions of accessory glands of GIT
- c) Digestion and absorption
- d) Disorders of GIT (definitions only)

- 10 **Nervous system**
  - a) Definition and classification of nervous system
  - b) Anatomy, physiology and functional areas of cerebrum
  - c) Anatomy and physiology of cerebellum
  - d) Anatomy and physiology of mid brain
  - e) Thalamus, hypothalamus and Basal Ganglia
  - f) Spinal cord: Structure & reflexes – mono-poly-planter
  - g) Cranial nerves – names and functions
  - h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.
- 11 **Urinary system**
  - a) Anatomy and physiology of urinary system
  - b) Formation of urine
  - c) Renin Angiotensin system – Juxtaglomerular apparatus – acid base Balance
  - d) Clearance tests and micturition
- 12 **Endocrine system**
  - a) Pituitary gland
  - b) Adrenal gland
  - c) Thyroid and Parathyroid glands
  - d) Pancreas and gonads
- 13 **Reproductive system**
  - a) Male and female reproductive system
  - b) Their hormones – Physiology of menstruation
  - c) Spermatogenesis & Oogenesis
  - d) Sex determination (genetic basis)
  - e) Pregnancy and maintenance and parturition
  - f) Contraceptive devices
- 14 **Sense organs**
  - a) Eye
  - b) Ear
  - c) Skin
  - d) Tongue & Nose
- 15 **Skeletal muscles**
  - a) Histology
  - b) Physiology of Muscle contraction
  - c) Physiological properties of skeletal muscle and their disorders (definitions)
- 16 **Sports physiology**
  - a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
  - b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
  - c) Drugs and athletics

**Course outcome:**

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

- Describe the structure (gross and histology) and functions of various organs of the human body.
- Describe the various homeostatic mechanisms and their imbalances of various systems; c. identify the various tissues and organs of the different systems of the human body.
- Perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes.
- Appreciate coordinated working pattern of different organs of each system
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

1.1 Human Anatomy and Physiology Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X	X	X	X	X	X								
CO2				X	X	X	X					X	X		
CO3			X			X			X			X			x
CO4	X	X	X				X	X	X		X	X			
CO5				X	X	X				X	X	X	X		

**1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)**

**Practical: 3 Hrs./Week**

**75Hrs**

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

**Course materials:****Text books**

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

**Reference books**

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune  
Anderson Experimental Physiology, Latest edition, Publisher: NA

**List of Experiments:**

1. Study of tissues of human body
  - (a) Epithelial tissue.
  - (b) Muscular tissue.
2. Study of tissues of human body
  - (a) Connective tissue.
  - (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
  - (a) Erythrocyte Sedimentation Rate.
  - (b) Hemoglobin content of Blood.
  - (c) Bleeding time & Clotting time.
8. Determination of
  - (a) Blood Pressure.
  - (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
  - (a) Skeleton system part I-axial skeleton.
  - (b) Skeleton system part II- appendicular skeleton.
  - (c) Cardiovascular system.
  - (d) Respiratory system.
  - (e) Digestive system.
  - (f) Urinary system.
  - (g) Nervous system.
  - (h) Special senses.
  - (i) Reproductive system.
10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastrocnemius sciatic nerve preparation.
14. To record simple summation curve using gastrocnemius sciatic nerve preparation.
15. To record simple effect of temperature using gastrocnemius sciatic nerve preparation.
16. To record simple effect of preload & after load using gastrocnemius sciatic nerve preparation.

17. To record simple fatigue curve using gastrocnemius sciatic nerve preparation.

**Scheme of Practical Examination:**

	<b>Sessionals</b>	<b>Annual</b>
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

**Course outcome:**

Upon completion of the course the student shall be able to practically demonstrate Practically.

a. The structure (gross and histology) and functions of various organs of the human body.

b. The various homeostatic mechanisms and their imbalances of various systems; c. identify the various tissues and organs of the different systems of the human body.

d. The hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes.

e. Coordinated working pattern of different organs of each system

f. The interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

1.1 Human Anatomy and Physiology Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	X		X			X			X			X			X
CO2		X		X			X			X			X		
CO3			X		X				X			X			X
CO4						X		X			X			X	
CO5	X	X				X		X				X	X		

## 1.2 PHARMACEUTICS (THEORY)

50Hrs

Theory: 2 Hrs. /Week

1. **Scope and objectives:** This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.
2. **Upon the completion of the course the student should be able to:**
  - a. know the formulation aspects of different dosage forms;
  - b. do different pharmaceutical calculation involved in formulation;
  - c. formulate different types of dosage forms; and
  - d. appreciate the importance of good formulation for effectiveness.

### 3. Course materials:

#### Text books

- a. Cooper and Gunns Dispensing for pharmacy students.
- b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

#### Reference books

- a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- b. Remington's Pharmaceutical Sciences.
- c. Register of General Pharmacy by Cooper and Gunn.
- d. General Pharmacy by M.L.Schroff.

### 4. Detailed Syllabus:

#### Topics

- 1
  - a. Introduction to dosage forms – classification and definitions
  - b. Prescription: definition, parts and handling
  - c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
- 2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
- 3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
- 4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
- 5 **Powders and Granules:** Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
- 6 **Monophasic Dosage forms:** Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

- 7 **Biphasic dosage forms:** Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
- 8 **Suppositories and pessaries:** Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
- 9 **Galenicals:** Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
- 10 **Pharmaceutical calculations**
- 11 **Surgical aids:** Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
- 12 **Incompatibilities:** Introduction, classification and methods to overcome the incompatibilities.

### Course Outcomes

- Understand about the formulation aspects of different dosage forms.
- Gain ability to perform various pharmaceutical calculations involved in formulation
- Formulate different types of dosage forms.
- Appreciate the significance and advantage of good formulation towards improved pharmaceutical care and therapeutic effectiveness

1.2 Pharmaceutics Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	X	X					X	X				X	X		
CO2		X	X	X					X	X	X			X	X
CO3			X	X	X	X									
CO4	X				X		X	X	X	X	X		X	X	X
CO5		X	X	X		X						X			

## 1.2 PHARMACEUTICS (PRACTICAL)

75Hrs

Practical: 3 Hrs./Week

### List of Experiments:

1. **Syrups**
  - a. Simple Syrup I.P
  - b. Syrup of Ephedrine HCl NF



- c. Syrup Vasaka IP
  - d. Syrup of ferrous Phosphate IP
  - e. Orange Syrup
- 2. Elixir**
- a. Piperizine citrate elixir BP
  - b. Cascara elixir BPC
  - c. Paracetamol elixir BPC
- 3. Linctus**
- a. Simple Linctus BPC
  - b. Pediatric simple Linctus BPC
- 4. Solutions**
- a. Solution of cresol with soap IP
  - b. Strong solution of ferric chloride BPC
  - c. Aqueous Iodine Solution IP
  - d. Strong solution of Iodine IP
  - e. Strong solution of ammonium acetate IP
- 5. Liniments**
- a. Liniment of turpentine IP\*
  - b. Liniment of camphor IP
- 6. Suspensions\***
- a. Calamine lotion
  - b. Magnesium Hydroxide mixture BP
- 7. Emulsions\***
- a. Cod liver oil emulsion
  - b. Liquid paraffin emulsion
- 8. Powders\***
- a. Eutectic powder
  - b. Explosive powder
  - c. Dusting powder
  - d. Insufflations
- 9. Suppositories\***
- a. Boric acid suppositories
  - b. Chloral suppositories
- 10. Incompatibilities**
- a. Mixtures with Physical
  - b. Chemical & Therapeutic incompatibilities

\* colourless bottles required for dispensing \* Paper envelope (white), butter paper and white paper required for dispensing.

**Scheme of Practical Examination:**

	<b>Sessionals</b>	<b>Annual</b>
Synopsis	05	15

Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

1.2P Pharmaceutics Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1					X				X					X	
CO2		X		X			X			X		X			X
CO3	X					X		X			X		X		
CO4			X					X		X			X		
CO5	X	X		X	X									X	X

### 1.3 MEDICINAL BIOCHEMISTRY (THEORY) 75Hrs

**Theory: 3 Hrs./Week**

- 1. Scope of the Subject:** Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.
- 2. Objectives of the Subject (Know, do, appreciate) :**  
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 –
  - a. understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
  - b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
  - c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
  - d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
  - e. do the qualitative analysis and determination of biomolecules in the body fluids.

**Text books (Theory)**

- a. Harpers review of biochemistry – Martin
- b. Text book of biochemistry – D. Satyanarayana
- c. Text book of clinical chemistry- Alex Kaplan & Laverve L.Szabo

**Reference books (Theory)**

- a. Principles of biochemistry – Lehninger
- b. Text book of biochemistry – Ramarao
- c. Practical Biochemistry-David T.Plummer.
- d. Practical Biochemistry-Pattabhiraman.

**3. Detailed syllabus:****Topics**

- 1 **Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
- 2 **Enzymes:** Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.
- 3 **Carbohydrate metabolism:** Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.
- 4 **Lipid metabolism:** Oxidation of saturated ( $\beta$ -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).
- 5 **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;
- 6 **Protein and amino acid metabolism:** protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.
- 7 **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.
- 8 **Introduction to clinical chemistry: Cell;** composition; malfunction; Roll of the clinical chemistry laboratory.
- 9 **The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-
  - a) Urine analysis (macroscopic and physical examination, quantitative and

- semiquantitative tests.)
- b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
  - c) Urine concentration test
  - d) Urinary tract calculi. (stones)
- 10 **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.
- a) Test for hepatic dysfunction-Bile pigments metabolism.
  - b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
  - c) Dye tests of excretory function.
  - d) Tests based upon abnormalities of serum proteins.
- Selected enzyme tests.
- 11 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
- 12 **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.
- Radio immunoassay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)
- 13 **Electrolytes:** Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium, potassium, chlorides, bicarbonates in the body fluids.

### Course Outcomes

- Understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases.
- Know the metabolic process of biochemical in health and illness (metabolic disorders)
- Understand the genetic organization of mammalian genome, protein synthesis, replication, mutation, and repair mechanism.
- Know the biochemical principles of organ function, test of kidney, liver and endocrine gland.
- Do the qualitative analysis and determination of biomolecules in the body fluids.

1.3-Medicinal Biochemistry Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X	X						X	X			X	X	
CO2	X		X		X		X		X			X		X	
CO3		X		X		X		X			X		X		
CO4	X			X	X		X			X		X			
CO5						X				X	X				

**1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)****75Hrs****Practical: 3 Hrs./Week****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.

**Scheme of Practical Examination:**

	<b>Sessionals</b>	<b>Annual</b>
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15

<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

### Course Outcome

- Do the qualitative analysis of normal constituents of urine.
- Do the qualitative analysis of abnormal constituents of urine.
- Do the quantitative estimation of urine sugar by benedict's method.
- Do the quantitative estimation of urine creatinine.
- Do the test for lipids.
- Do the titrable acidity and ammonia in urine.
- Do the separation of amino acids by paper chromatography and determine the R<sub>f</sub> value.
- Do the determination of amino acids by ninhydrin method.
- Do the determination of chromic period of salivary amylase.
- Understand the qualitative and quantitative estimation.

1.3P-Medicinal Biochemistry Practical Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	X	X	X												
CO2				X	X	X									
CO3							X	X	X						
CO4										X	X	X			
CO5													X	X	X

### 1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

75Hrs

Theory: 3 Hrs./Week

1. **Scope and objectives:** This course is designed to impart a very good knowledge about
  - a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
  - b. Some important physical properties of organic compounds;
  - c. Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;

- d. Some named organic reactions with mechanisms; and
- e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

## 2. Course materials:

### Text books

- a. T.R.Morrison and R. Boyd – Organic chemistry,
- b. Bentley and Driver-Text book of Pharmaceutical chemistry
- c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

### Reference books

- a. Organic chemistry – J.M.Cram and D.J.Cram
- b. Organic chemistry- Brown
- c. Advanced organic chemistry- Jerry March, Wiley
- d. Organic chemistry- Cram and Hammered, Pine Hendrickson

## 3. Detailed syllabus:

### Topics

- 1 **Structures and Physical properties:**
  - a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
  - b. Acids and bases, Lowry bronsted and Lewis theories
  - c. Isomerism
- 2 **Nomenclature of organic compound belonging to the following classes:** Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.
- 3 **Free radicals chain reactions of alkane :** Mechanism, relative reactivity and stability
- 4 **Alicyclic compounds:** Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.
- 5 **Nucleophilic aliphatic substitution mechanism:** Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN<sub>2</sub> reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN<sub>1</sub> reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN<sub>1</sub> reaction, Ion dipole bonds, SN<sub>2</sub> versus SN<sub>1</sub> solvolyses, nucleophilic assistance by the solvents.
- 6 **Dehydro halogenation of alkyl halides:** 1,2 elimination, kinetics, E<sub>2</sub> and E<sub>1</sub> mechanism, elimination via carbocation, evidence for E<sub>2</sub> mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E<sub>2</sub> versus E<sub>1</sub>, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.
- 7 **Electrophilic and free radicals addition:** Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophilic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism,

halohydrin formation, mechanism of free radicals addition, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.

- 8 **Carbon-carbon double bond as substituents:** Free radical halogenations of alkenes, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.
- 9 **Theory of resonance:** Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophilic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilization of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substitution in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.
- 10 **Electrophilic aromatic substitution:** Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical.
- 11 **Nucleophilic addition reaction:** Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of carboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.
- 12 Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.
- 13 **Hoffman rearrangement:** Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.
- 14 **Nucleophilic aromatic substitution:** Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.
- 15 **Oxidation reduction reaction.**
- 16 **Study of the following official compounds:** preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.



**Course Outcomes**

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

- 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/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, freeradical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
- Some named organic reactions with mechanisms;
- Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

<b>1.4-Pharmaceutical Organic Chemistry Theory Mapping Pos &amp; PSOs X Course Outcomes:</b>															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X	X								X	X			
CO2				X	X								X	X	
CO3						X	X				X				X
CO4								X	X	X		X	X		
CO5	X	X												X	X

**1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)****75Hrs****Practical: 3 Hrs./Week****List of Experiments**

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

1. Acetanilide / 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-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime



**1.5. PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)****50Hrs****Theory: 2 Hrs. /Week**

**1. Scope and objectives:** This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.

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

- a. understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
- b. know the analysis of the inorganic pharmaceuticals their applications; and
- c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

**3. Course materials:**

**Text books**

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

**Reference books**

- a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
- b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
- c. Analytical chemistry principles by John H. Kennedy
- d. I.P.1985 and 1996, Govt. of India, Ministry of health

**4. Detailed syllabus:**

**Topics****1. Errors**

Errors in quantitative analysis, classification of errors, concept of accuracy and precision, treatment of analytical results.

**2. Volumetric analysis**

Principle of volumetric analysis, different methods of analysis, different methods for expressing concentrations of solutions, primary and secondary standards.

**3. Acid-base titrations**

Acid- base concepts, relative strength of acids and bases, law of mass action, common ion effect, ionic product of water, Henderson-Hasselbalch equation, buffer solutions, theory of indicators, neutralization curves, choice of indicators, mixed and universal indicators.

**4. Redox titrations**

Concepts of oxidation-reduction reactions, redox reactions, theory of redox titrations, redox indicators, iodometry and iodimetry, titrations involving ceric sulphate, potassium iodate, potassium bromate, potassium permanganate, titanous chloride.

### **5. Non-aqueous titrations**

Theoretical basis, types of solvents, preparations and standardisation of titrant solutions, titration of weak acid, weak bases and indicators. standardisation of perchloric acid, lithium and sodium methoxide, tetra butyl ammonium hydroxide.

### **6. Precipitation titrations**

Introduction, types of precipitation titrations, end point detection.

### **7. Complexometric titrations**

Introduction, principle, types of titrations, end point detection.

### **8. Theory of Indicators**

### **9. Gravimetry**

Basic concepts, Precipitation techniques, co-precipitation, post-precipitation, various steps involved in gravimetric analysis, pharmaceutical applications.

### **10. Limit test**

Definition, importance, general procedure for limit test for chlorides, sulphates, iron, arsenic, lead and heavy metals.

### **11. Medicinal Gases**

Preparation and uses of the following: Oxygen, Carbon dioxide, Helium, Nitrogen and Nitrous Oxide.

*Method of preparation, assay, storage conditions and uses of inorganic compounds listed in LP belonging to the following categories.*

### **12. Acidifiers**

Dilute hydrochloric acid, Sodium phosphate, Ammonium chloride.

### **13. Antacids**

Classification, Qualities of an ideal antacid, side effects, advantages, combination therapy, acid neutralizing capacity, Sodium bicarbonate, Potassium citrate, Aluminium hydroxide gel, Dried aluminium hydroxide gel, Magnesium hydroxide, Light and heavy magnesium trisilicate, light and heavy magnesium carbonate, Calcium carbonate, Magaldrate and Bismuth carbonate.

### **14. Cathartics**

Magnesium hydroxide, Magnesium sulphate, Magnesium carbonate and Sodium phosphate.

**15. Electrolyte replenisher**

*Electrolytes used for replacement therapy:* Sodium chloride, Potassium chloride, Calcium chloride, Calcium gluconate,

*Electrolytes used in the acid-base therapy:* Sodium acetate, Potassium acetate, Sodium bicarbonate, Potassium bicarbonate, Sodium citrate, Sodium lactate, Ammonium chloride. Electrolyte combination therapy, Compound sodium chloride solution, Sodium chloride injection and Oral rehydration salts.

**16. Essential Trace elements**

Definition, physiologic role of Iron, Copper, Zinc, Chromium, Manganese, Molybdenum, Selenium, Sulphur, and Idoine.

**17. Antimicrobials**

Hydrogen Peroxide, Potassium Permanganate, Chlorinated Lime, Iodine, Boric Acid, Silver Nitrate, Selenium Sulphide.

**18. Pharmaceutical Aids:** Sodium bisulphite, sodium metabisulphite, bentonite, magnesium stearate, zinc stearate, aluminium sulphate, sodium carboxy methyl cellulose, purified water, water for injection and sterile water for injection.

**19. Dental products**

*Anti-caries agents:* Role of fluorides as anti-caries agents, sodium fluoride.

*Dentifrices:* Calcium carbonate, dibasic calcium phosphate, Zinc chloride.

**20. Miscellaneous compounds.**

Sclerosing agents: Hypertension saline, sodium tetra decyl sulphate

Expectorants: Potassium citrate and potassium iodide.

Sedative: Potassium bromide

Antidotes: Sodium nitrite, sodium thiosulphate and charcoal

Respiratory stimulant: Ammonium carbonate

**21. Radiopharmaceuticals**

Introduction, measurement of radioactivity, clinical applications and dosage, hazards and precautions.

**Course Outcomes**

- Student will be able to understand of analysis of inorganic pharmaceuticals and their application.
- Student will be able to understand the importance of inorganic pharmaceuticals in preventing and curing diseases.
- Student will be able to understand the importance of Radiopharmaceutical and their application

1.5-Pharmaceutical Inorganic Chemistry Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1				X	X	X	X			X	X	X	X		
CO2	X	X	X	X				X	X	X	X			X	X
CO3			X	X	X	X				X	X	X	X		
CO4		X	X	X	X			X	X	X	X			X	X
CO5	X	X	X				X	X	X				X	X	X

## 1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

75Hrs

Practical: 3 Hrs./Week

List of Experiments:

### 1. Limit test (6 exercises)

- Limit test for chlorides
- Limit test for sulphates
- Limit test for iron
- Limit test for heavy metals
- Limit test for arsenic
- Modified limit tests for chlorides and sulphates

### 2. Assays (10 exercises)

- Ammonium chloride- Acid-base titration
- Ferrous sulphate- Cerimetry
- Copper sulphate- Iodometry
- Calcilugluconate- Complexometry
- Hydrogen peroxide – Permanganometry
- Sodium benzoate – Nonaqueous titration
- Sodium chloride – Modified volhard's method
- Assay of KI – KIO<sub>3</sub> titration
- Gravimetric estimation of barium as barium sulphate
- Sodium antimony gluconate or antimony potassium tartarate

### 3. Estimation of mixture (Any two exercises)

- Sodium hydroxide and sodium carbonate
- Boric acid and Borax
- Oxalic acid and sodium oxalate

### 4. Test for identity (Any three exercises)

- Sodium bicarbonate
- Barium sulphate



**1.6 REMEDIAL MATHEMATICS/ REMEDIAL BIOLOGY (THEORY)**

75Hrs

Theory: 3 Hrs. /Week

**REMEDIAL MATHEMATICS:**

**1. Scope and objectives:** This is an introductory course in mathematics. This subject deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.

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

- a. Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
- b. solve the problems of different types by applying theory; and
- c. appreciate the important applications of mathematics in pharmacy.

**3. Course materials:**

**Text books**

- a. Differential calculus By Shantinakaran
- b. Text book of Mathematics for second year pre-university by Prof. B.M. Sreenivas

**Reference books**

- a. Integral calculus By Shanthinarayan
- b. Engineering mathematics By B.S.Grewal
- c. Trigonometry Part-I By S.L.Loney

**4. Detailed syllabus:**

**Topics**

- 1 **Algebra** : Determinants, Matrices
- 2 **Trigonometry** : Sides and angles of a triangle, solution of triangles
- 3 **Analytical Geometry** :Points, Straight line, circle, parabola
- 4 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
- 5 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.
- 6 **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
- 7 **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

**REMEDIAL BIOLOGY:**



**1. Scope and objectives:** This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduced to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

**2. Course materials:**

**Text books**

- a. Text book of Biology by S.B. Gokhale
- b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

**Reference books**

- a. A Text book of Biology by B.V. Sreenivasa Naidu
- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C. Dutta.
- d. Outlines of Zoology by M. Ekambaranatha ayyer and T.N. Ananthakrishnan.
- e. A manual for pharmaceutical biology practical by S.B. Gokhale and C.K. Kokate.

**3. Detailed syllabus:**

**Topic**

**PART – A**

- 01 Introduction
- 02 General organization of plants and its inclusions
- 03 Plant tissues
- 04 Plant kingdom and its classification
- 05 Morphology of plants
- 06 Root, Stem, Leaf and Its modifications
- 07 Inflorescence and Pollination of flowers
- 08 Morphology of fruits and seeds
- 09 Plant physiology
- 10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
- 11 Study of Fungi, Yeast, Penicillin and Bacteria

**PART-B**

- 01 Study of Animal cell
- 02 Study animal tissues
- 03 Detailed study of frog
- 04 Study of Pisces, Raptiles, Aves
- 05 General organization of mammals
- 06 Study of poisonous animals

**1.6 REMEDIAL BIOLOGY (PRACTICAL)****75Hrs****Practical: 3 Hrs./Week****List of Experiments:**

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

**Scheme of Practical Examination:**

	<b>Sessionals</b>	<b>Annual</b>
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

## Second year

### 2.1 PATHOPHYSIOLOGY (THEORY)

75Hrs

**Theory: 3 Hrs. /Week**

1. **Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to –
  - a. describe the etiology and pathogenesis of the selected disease states;
  - b. name the signs and symptoms of the diseases; and
  - c. mention the complications of the diseases

#### 3. Course material

##### Text books (Theory)

- a. Pathologic basis of disease by- Cotran, Kumar, Robbins
- b. Text book of Pathology- Harsh Mohan
- c. Text book of Pathology- Y.M. Bhide

##### Reference books (Theory)

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

#### 4. Detailed syllabus:

##### Topics

- 1 **Basic principles of cell injury and Adaptation**
  - a) Causes, Pathogenesis and morphology of cell injury
  - b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases
- 2 **Inflammation**
  - a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
  - b) Repairs of wounds in the skin, factors influencing healing of wounds
- 3 **Diseases of Immunity**
  - a) Introduction to T and B cells
  - b) MHC proteins or transplantation antigens
  - c) Immune tolerance
    - Hypersensitivity  
Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
    - Autoimmunity  
Criteria for autoimmunity, Classifications of autoimmune diseases in

man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.

- Acquired immune deficiency syndrome (AIDS)
  - Amyloidosis
- 4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.
  - 5 Types of shock, mechanisms, stages and management
  - 6 Biological effects of radiation
  - 7 Environmental and nutritional diseases
    - i) Air pollution and smoking- SO<sub>2</sub>,NO, NO<sub>2</sub>, and CO
    - ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.
  - 8 Pathophysiology of common diseases
    - a. Parkinsonism
    - b. Schizophrenia
    - c. Depression and mania
    - d. Hypertension,
    - e. Stroke (ischaemic and hemorrhage)
    - f. Angina, CCF, Atherosclerosis, Myocardial infarction
    - g. Diabetes Mellitus
    - h. Peptic ulcer and inflammatory bowel diseases
    - i. Cirrhosis and Alcoholic liver diseases
    - j. Acute and chronic renal failure
    - k. Asthma and chronic obstructive airway diseases
  - 9 Infectious diseases :  
Sexually transmitted diseases (HIV, Syphilis, Gonorrhoea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

#### 4. Assignments:

##### List 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.

**Course Outcomes**

- Understand to identify the sign and symptoms of various diseases
- Know the abnormal laboratory findings related to causes of illness
- Understand the pathology and management of various diseases
- Understand the complication of diseases
- Acquiring the skills of patient counselling and non pharmacological management

<b>2.1-Pathophysiology Theory</b>															
<b>Mapping Pos &amp; PSOs X Course Outcomes:</b>															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X			X	X					X	X		
CO2		X		X					X				X	X	
CO3					X			X			X				X
CO4	X									X					X
CO5			X			X			X				X		X

**2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)****75Hrs****Theory: 3 Hrs. /Week**

1. **Scope of the Subject:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. Its also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. **Objectives of the Subject:**

Upon completion of the subject student shall be able to –

- a. know the anatomy, identification, growth factors and sterilization of microorganisms;
- b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- c. do estimation of RNA and DNA and there by identifying the source;
- d. do cultivation and identification of the microorganisms in the laboratory;
- e. do identification of diseases by performing the diagnostic tests; and
- f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

### 3. Course materials

#### Text books (Theory)

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

#### Reference books (Theory)

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

### 4. Detailed syllabus:

#### Topics

- 1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.
- 2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.
- 3 Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.
- 4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria –Total and Viable counting techniques.
- 5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations. Brief information on Validation.

- 6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, virucidal activities, evaluation of preservatives in pharmaceutical preparations.
- 7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity (active and passive). Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.
- 8 Diagnostic tests: Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantoux Peripheral smear. Study of malarial parasite.
- 9 Microbial culture sensitivity Testing: Interpretation of results, Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B<sub>2</sub> and B<sub>12</sub>. Standardisation of vaccines and sera.
- 10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhoea and HIV.

## 2.2. PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

75Hrs

**Practical: 3 Hrs./Week**

### List of 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 sterilisation methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
  - a. Report of recent microbial techniques developed in diagnosing some common diseases.
  - b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

**Format of the assignment:**

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

**Scheme of Practical Examination:**

	<b>Sessionals</b>	<b>Annual</b>
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

**Course Outcomes**

- Better understanding of theory concepts by the student.
- The student will be familiar about various apparatuses and equipments used in Pharmaceutical Microbiology Lab.
- The student will be skilled to perform experiments using microorganisms, to operate various equipments and to handle apparatuses in Pharmaceutical Microbiology Lab.

2.2 P-Pharmaceutical Microbiology Practical Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X	X	X	X										
CO2								X	X	X	X				
CO3												X	X	X	X



CO4	X					X					X			X	X
CO5		X					X					X			X

## 2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

75Hrs

Theory: 3 Hrs. /Week

- 1. Scope and objectives:** This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs and its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.
- 2. Upon completion of the course student shall be able to:**
  - a. under stand the basic principles of cultivation, collection and storage of crude drugs;
  - b. know the source, active constituents and uses of crude drugs; and
  - c. appreciate the applications of primary and secondary metabolites of the plant.

### 3. Course materials:

#### Text books

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

#### Reference books

- a. Pharmacognosy by Brady & Tyler. E.
- b. Pharmacognosy by T.E. Wallis.
- c. Pharmacognosy by C.S. Shah & Qadery.
- d. Pharmacognosy by M.A. Iyengar.

### 4. Detailed syllabus: [Revised]

Topics	Hrs
1 <b>Introduction.</b>	01
2 Definition, history and scope of Pharmacognosy.	02
3 <b>Classification of crude drugs:</b>	04
▪ Study of Alphabetical, Morphological, Taxonomical, Chemical, Pharmacological, Chemotaxonomical and Serotaxonomical methods of Classification of crude drugs including their merits and demerits.	
4 <b>Cultivation, collection, processing and storage of crude drugs:</b>	04
▪ General methods applicable to each group of drugs such as – Barks, Leaves, Flowers, Fruits, Roots, Rhizomes etc.	
5 <b>Detailed method of cultivation of crude drugs:</b>	04
▪ Various Propagation methods illustrated with an example for each method	

- 6 **Study of cell wall constituents and cell inclusions:** 03
- Detailed study of cell, cellulose walls, lignified walls, suberized and cutinized cells and mucilaginous cell walls and various crystals exhibited by plant cells and their chemical composition and identification.
- 7 **Microscopical and powder Microscopical study of crude drugs:** 13
- Microscopical and powder Microscopical study of crude drugs mentioned in Practical Section of the Syllabus (2.3 Practical) which include –
- Datura, Senna, Cassia, Cinnamon, Cinchona, Ephedra, Quassia, Clove, Fennel, Coriander, Isapgol, Nux vomica, Rauwolfia, Liquorice, Ginger and Podophyllum and including the study of their source, morphological characters, active constituents and uses.
- 8 **Study of natural pesticides:** 04
- Study of Plant Derived Compounds with Pesticidal potential – Herbicides, Insecticides, Fungicides, Nematicides and Molluscicides and Rodenticides. Study of monograph on natural pesticides: Pyrethrum, Tobacco and Neem
- 9 **Detailed study of various cell constituents:** 04
- Study of cell constituents – secondary metabolites – Occurrence, Distribution, Isolation, Identification Tests and Therapeutic uses of various secondary metabolites with suitable examples.
- 10 **Carbohydrates and related products:** 11
- Related products means drugs containing carbohydrates and hence can be combined with serial number
- 11 **Detailed study of carbohydrates containing drugs (11 drugs):** 13
- Introduction to carbohydrates. Study of 11 carbohydrate containing drugs: 1. Gum acacia, 2. Gum Tragacanth, 3. Guar Gum, 4. Honey, 5. Agar, 6. Starch, 7. Ispaghula, 8. Sodium Alginate, 9. Gum Ghatti, 10. Pectin and 11. Chitin
- 12 **Definition sources, method of extraction, chemistry and method of analysis of lipids:** 05
- Self explanatory: One example for detailed study from each group – fixed oil, fat and wax.
- 13 **Detailed study of oils:** 04
- Study of Volatile oils: Introduction, classification, occurrence, distribution, methods of extraction, analytical techniques and uses of volatile oils.
- 14 **Definition, classification, chemistry and method of analysis protein:** 04
- Study of Gelatin may be included as an example for protein.
- 15 **Study of plants fibers used in surgical dressings and related products:** 05
- Source, preparation, characters, active constituents, identification

tests and Uses of plant fibres such as Absorbent cotton, Jute, and Hemp.

16 **Different methods of adulteration of crude drugs.**

05

**Course Outcomes**

- Explain meaning of the term pharmacognosy, its history, development, linkages to other branches of pharmaceutical sciences. Significance of study of natural products
- Explain need, approaches of classification of crude drug along with their merits & demerits.
- Explain significance of internationally accepted standards of nomenclature.
- Illustrate the different methods of propagation with merits and demerits including production, collection, processing and storage of crude drugs as per prescribed standards.
- Explain basic components of cell, their functions & fundamental processes of cell division.
- Clarify on basic tissues & tissue systems & apply that knowledge in understanding of anatomy of different parts of plant.
- Understand the botanical source, family, chemical structures, pharmaceutical importance and qualitative analysis of plant sources.
- Identify and analyse the unorganized crude drugs using morphological, physical and chemical characteristics including qualitative analysis.
- Describe the different methods of adulteration of crude drugs and herbal formulation with suitable example.

2.3-Pharmacognosy and Phytopharmaceuticals Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X	X	X									X	X	X
CO2					X	X	X			X	X	X			
CO3								X	X					X	X
CO4	X	X					X	X				X	X		
CO5			X	X						X	X				

**2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)**

75Hrs

**Practical: 3 Hrs./Week**

**General Requirements:** Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

**List of experiments:**

- 1 Introduction of Pharmacognosy laboratory and experiments.

- 2 Study of cell wall constituents and cell inclusions.
- 3 Macro, powder and microscopic study of Datura.
- 4 Macro, powder and microscopic study of Senna.
- 5 Macro, powder and microscopic study of Cassia.cinnamon.
- 6 Macro, powder and microscopic study of Cinchona.
- 7 Macro, powder and microscopic study of Ephedra.
- 8 Macro, powder and microscopic study of Quassia.
- 9 Macro, powder and microscopic study of Clove
- 10 Macro, powder and microscopic study of Fennel.
- 11 Macro, powder and microscopic study of Coriander.
- 12 Macro, powder and microscopic study of Isapgol.
- 13 Macro, powder and microscopic study of Nux vomica.
- 14 Macro, powder and microscopic study of Rauwolfia.
- 15 Macro, powder and microscopic study of Liquorice.
- 16 Macro, powder and microscopic study of Ginger.
- 17 Macro, powder and microscopic study of Podophyllum.
- 18 Determination of Iodine value.
- 19 Determination of Saponification value and unsaponifiable matter.
- 20 Determination of ester value.
- 21 Determination of Acid value.
- 22 Chemical tests for Acacia.
- 23 Chemical tests for Tragacanth.
- 24 Chemical tests for Agar.
- 25 Chemical tests for Starch.
- 26 Chemical tests for Lipids. (Castor oil, sesame oil, shark liver oil, bees wax)
- 27 Chemical tests for Gelatin.

#### Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

#### Course Outcomes

- Explain correct use of glassware and various equipment/instruments in Pharmacognosy laboratory. Learn the importance and identify the different part of microscope for histological study. Handle simple and compound microscope technically in a correct way.
- Demonstrate skill of plant material sectioning, staining, mounting & focusing. Decide on staining and chemical reagents required for specific part of plant.

- Identify the anatomy of plants from its morphological & microscopical features by applying experimental & theoretical knowledge of morphology & anatomy obtained in theory classes.
- Draw morphological & microscopical diagrams of different plant part & able to label different component/parts.
- Detect and identify the unorganized crude drugs by various qualitative as well as quantitative tests.
- Analyse and identify the adulterant in fixed oil by various qualitative test

2.3 P-Pharmacognosy and Phytopharmaceuticals Practical Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	X				X				X			X			X
CO2			X	X		X				X			X		
CO3	X						X					X			X
CO4			X	X				X			X			X	
CO5	X				X				X				X		

## 2.4 PHARMACOLOGY – I (THEORY)

75Hrs

Theory: 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
  - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
  - b. handle and carry out the animal experiments;
  - c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
  - d. correlate and apply the knowledge therapeutically.

3. **Course materials:**

**Text books (Theory)**

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

**Reference books (Theory)**

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9<sup>th</sup> Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
- b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
- d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

**4. Detailed syllabus:****Topics**

1. **General Pharmacology**
  - a) Introduction, definitions and scope of pharmacology
  - b) Routes of administration of drugs
  - c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
  - d) Pharmacodynamics
  - e) Factors modifying drug effects
  - f) Drug toxicity – Acute, sub- acute and chronic toxicity.
  - g) Pre-clinical evaluations
  - h) Drug interactions

*Note:* The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2. **Pharmacology of drugs acting on ANS**
  - a) Adrenergic and antiadrenergic drugs
  - b) Cholinergic and anticholinergic drugs
  - c) Neuromuscular blockers
  - d) Mydriatics and miotics
  - e) Drugs used in myasthenia gravis
  - f) Drugs used in Parkinsonism
3. **Pharmacology of drugs acting on cardiovascular system**
  - a) Antihypertensives
  - b) Anti-anginal drugs
  - c) Anti-arrhythmic drugs
  - d) Drugs used for therapy of Congestive Heart Failure
  - e) Drugs used for hyperlipidaemias

4. **Pharmacology of drugs acting on Central Nervous System**
  - a) General anesthetics
  - b) Sedatives and hypnotics
  - c) Anticonvulsants
  - d) Analgesic and anti-inflammatory agents
  - e) *Psychotropic drugs*
  - f) Alcohol and methyl alcohol
  - g) CNS stimulants and cognition enhancers
  - h) Pharmacology of local anaesthetics
  
5. **Pharmacology of Drugs acting on Respiratory tract**
  - a) Bronchodilators
  - b) Mucolytics
  - c) Expectorants
  - d) Antitussives
  - e) Nasal Decongestants
  
6. **Pharmacology of Hormones and Hormone antagonists**
  - a) Thyroid and Antithyroid drugs
  - b) Insulin, Insulin analogues and oral hypoglycemic agents
  - c) Sex hormones and oral contraceptives
  - d) Oxytocin and other stimulants and relaxants
  
7. **Pharmacology of autocoids and their antagonists**
  - a) Histamines and Antihistaminics
  - b) 5-Hydroxytryptamine and its antagonists
  - c) Lipid derived autocoids and platelet activating factor

### Course Outcomes

- This subject will provide a basic opportunity for the student to learn about the drug with regard to classification, pharmacodynamics and pharmacokinetic aspects, adverse effects, uses, dose, and route of administration, precautions, contraindications and interaction with other drugs.
- In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be clearly understood by the students
- In addition to theoretical knowledge, the students will understand about the mechanism of drugs how it acts on the body system
- The students was able to know the dosage of each and every drugs

<b>2.4 Pharmacology I</b>															
<b>Mapping Pos &amp; PSOs X Course Outcomes:</b>															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	X			X			X			X			X	X	X

CO2			X	X	X	X	X	X					X	X	X
CO3	X	X	X			X	X	X	X			X	X	X	X
CO4				X	X	X				X	X	X			
CO5	X			X		X			X		X			X	

## 2.5 COMMUNITY PHARMACY (THEORY)

50Hrs

Theory: 2 Hrs. /Week

**1. Scope:** In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counseling, health screening services for improved patient care in the community set up.

**2. Objectives:** Upon completion of the course, the student shall be able to –

- know pharmaceutical care services;
- know the business and professional practice management skills in community pharmacies;
- do patient counseling & provide health screening services to public in community pharmacy;
- respond to minor ailments and provide appropriate medication;
- show empathy and sympathy to patients; and
- appreciate the concept of Rational drug therapy.

**3. Course materials:**

**Text Books:**

- Health Education and Community Pharmacy by N.S. Parmar.
- WHO consultative group report.
- Drug store & Business management by Mohammed Ali & Jyoti.
- Good Pharmacy Practice (GPP) guidelines for community pharmacy practice, Indian Pharmaceutical Association, 2002.

**Reference Books:**

- Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.
- Good Pharmacy Practice (GPP) in Community and Hospital Pharmacy Settings, World Health Organization, 1996.



- d. Good Pharmacy Practice (GPP) in Developing Countries – Recommendation for Stepwise Implementation – International Pharmaceutical Federation, 1997.
- e. Primary health care – Report of the international conference on primary health care, Alma – Ata; USSR 1978.
- f. Role of Pharmacist in Self Care and Self Medication. World Health Organization, 1998.

### **3[a] Special requirements:**

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counseling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

## **4. Detailed syllabus:**

### **Topics**

- 1 Definition, scope, of community pharmacy:** Roles and responsibilities of Community pharmacist
- 2 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
- 3 Prescriptions:** parts of prescription, legality & identification of medication related problems like drug interactions.
- 4 Inventory control in community pharmacy:** Definition, various methods of Inventory Control, ABC, VED, EOQ, Lead time, safety stock
- 5 Pharmaceutical care:** Definition and Principles of Pharmaceutical care.
- 6 Patient counseling:** Definition, outcomes, various stages, barriers, Strategies to overcome barriers, Patient information leaflets- content, design, & layouts, advisory labels
- 7 Patient medication adherence:** Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.
- 8 Health screening services:** Definition, importance, methods for screening Blood pressure, blood sugar, lung function and Cholesterol testing.
- 9 OTC Medication- Definition, OTC medication list & Counselling**
- 10 Health Education:**

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

Commonly occurring Communicable Diseases, causative agents.

Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhoea and AIDS.

Balance diet, and treatment & prevention of deficiency disorders.

Family planning – role of pharmacist

### 11 Responding to symptoms of minor ailments:

Relevant pathophysiology, common drug therapy to, Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms, worms infestations.

### 12 Essential Drugs concept and Rational Drug Therapy: Role of community pharmacist

### 13 Code of ethics for community pharmacists

### 14 Good Pharmacy Practice in community pharmacy setting

Structure Guidelines – Facilities, Premises, Furniture and Fixtures, Equipment; Personnel, Systems – Quality Policy, Service Policy, Staff Training Policy, Complaint Policy, Drugs Recall Policy, Audit Policy, Documentation System; Process Guidelines – Procurement and Inventory Management, Storage, Prescription Handling, Dispensing, Information for Patients, Patient Counselling, Health Promotion and Ill Health Prevention, Pharmacovigilance, Enhancement of Professional Role, Professional Interactions.

### Course Outcomes

- Know the Pharmaceutical care services.
- Understand the business and professional practice management skills in community pharmacies.
- Know the Patient counselling and provide health screening services to public community pharmacy.
- Understand about respond to minor ailments and provide appropriate medication.
- Know empathy and sympathy to patients.
- Understand the concept of Rational drug therapy.

2.5-Community Pharmacy Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	X	X	X	X									X	X	
CO2						X	X								
CO3									X	X					
CO4				X	X			X	X			X	X		
CO5		X	X			X	X				X	X		X	X

## 2.6 PHARMACOTHERAPEUTICS – I (THEORY)

75Hrs

### Theory: 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
  - a. the pathophysiology of selected disease states and the rationale for drug therapy;
  - b. the therapeutic approach to management of these diseases;
  - c. the controversies in drug therapy;
  - d. the importance of preparation of individualized therapeutic plans based on diagnosis;
  - e. 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);

### 3. Course Materials

#### Text Books

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

#### Reference Books

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

### 4. Detailed syllabus:

#### Topics

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

- 1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias
- 2 **Respiratory system:** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases  
**Endocrine system:** Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis

**3 General prescribing guidelines for:**

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

**4 Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial**5 Introduction to Rational Drug Use (RDU)**

Definition, Concept of RDU, Role of pharmacist in promoting RDU  
 Concept of EDL and Formularies.

**Course Outcomes**

By the end of this subject students will be able to understand:

- The pathophysiology of selected disease states and the rationale for drug therapy
- The therapeutic approach to management of these diseases
- The controversies in drug therapy
- The importance of preparation of individualised therapeutic plans based on diagnosis
- 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)
- Describe the pathophysiology of selected disease states and explain the rationale for drug therapy
- Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence
- Discuss the controversies in drug therapy
- Discuss the preparation of individualised therapeutic plans based on diagnosis
- Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects)

2.6-Pharmacotherapeutics I Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X			X	X					X	X		
CO2		X		X					X				X	X	
CO3					X			X			X				X
CO4	X									X					X
CO5			X			X			X				X		X

## 2.6 PHARMACOTHERAPEUTICS – I (PRACTICAL)

75Hrs

**Practical: 3 Hrs./Week**

### 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:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

### Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

### Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

### Course Outcomes

By the end of this subject students will be able to understand:

- Describe the pathophysiology of selected disease states and explain the rationale for drug therapy
- Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence
- Discuss the controversies in drug therapy
- Discuss the preparation of individualised therapeutic plans based on diagnosis
- Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects)

2.6 P-Pharmacotherapeutics I Practical Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X			X	X					X	X		
CO2		X		X					X				X	X	
CO3					X			X			X				X
CO4	X									X					X
CO5			X			X			X				X		X

## **Third Year**

### **3.1 PHARMACOLOGY – II (THEORY)**

75Hrs

#### **Theory: 3 Hrs. /Week**

- 1. Scope of the Subject:** 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.
- 2. Objectives of the Subject Upon completion of the subject student shall be able to:**
  - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
  - b. carry out the animal experiments confidently,
  - c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
  - d. correlate and apply the knowledge therapeutically.

#### **3. Course Materials**

##### **Text books (Theory)**

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

##### **Reference books (Theory)**

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9<sup>th</sup> edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
- b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.

- d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

#### **4. Detailed syllabus:**

##### **Topics**

1. **Pharmacology of Drugs acting on Blood and blood forming agents**
  - a) Anticoagulants
  - b) Thrombolytics and antiplatelet agents
  - c) Haemopoietics and plasma expanders
2. **Pharmacology of drugs acting on Renal System**
  - a) Diuretics
  - b) Antidiuretics
3. **Chemotherapy**
  - a) Introduction
  - b) Sulfonamides and co-trimoxazole
  - c) Penicillins and Cephalosporins
  - d) Tetracyclins and Chloramphenicol
  - e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
  - f) Quinolines and Fluroquinolines
  - g) Antifungal antibiotics
  - h) Antiviral agents
  - i) Chemotherapy of tuberculosis and leprosy
  - j) Chemotherapy of Malaria
  - k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
  - l) Pharmacology of Anthelmintic drugs
  - m) Chemotherapy of cancer (Neoplasms)
4. **Immunopharmacology**

Pharmacology of immunosuppressants and stimulants
5. **Principles of Animal toxicology**

Acute, sub acute and chronic toxicity
6. **The dynamic cell: The structures and functions of the components of the cell**
  - a) Cell and macromolecules: Cellular classification, subcellular



- organelles, macromolecules, large macromolecular assemblies
- b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
  - c) DNA replication: General, bacterial and eukaryotic DNA replication.
  - d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
  - e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors).

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

- a) Gene structure: Organization and elucidation of genetic code.
- b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
- c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events

Altered gene functions: Mutations, deletions, amplifications, LOH, 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

### **Course Outcomes**

- The students will understand the pharmacological aspect of drugs acting on Blood and Blood forming organs, renal system, Chemotherapy, immune pharmacology.
- The students will understand the evaluation of toxicity on animals
- The students will understand the molecular biology and rDNA technology and gene therapy.

3.1-Pharmacology II Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	X			X	X	X				X		X	X	X	
CO2	X		X	X		X			X		X				
CO3		X	X		X			X			X			X	X
CO4		X		X		X			X		X			X	X
CO5	X			X			X			X		X	X		

### 3.1 PHARMACOLOGY – II (PRACTICAL)

75 Hrs

**Practical: 3 Hrs./Week**

**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:
- Analgesic property of drug using analgesiometer.
  - Antiinflammatory effect of drugs using rat-paw edema method.
  - Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
  - Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
  - Locomotor activity evaluation of drugs using actophotometer and rotorod.
  - Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

**Scheme of Practical Examination:**

	<b>Sessionals</b>	<b>Annual</b>
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	20	70
Duration	3hrs	4hrs

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

**Text books (Practical)**

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

**Reference books (Practical)**

- Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.

- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

### Course Outcomes

The students will understand the pharmacological aspect of drugs by doing simulated animal experiments in computers.

3.1P-Pharmacology II Practical Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	X		X				X				X		X		X
CO2		X		X		X		X		X		X		X	
CO3	X		X		X		X		X						X
CO4			X		X			X		X		X		X	
CO5	X	X			X		X		X			X			X

### 3.2 PHARMACEUTICAL ANALYSIS (THEORY)

75Hrs

**Theory: 3 Hrs. /Week**

#### Text Books

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
4. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.

#### Reference Books:

1. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
2. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
3. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.

4. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
5. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
6. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
7. How to practice GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
8. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
9. TLC by Stahl, Spring Verlay.
10. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
11. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
12. I.P.-1996, The Controller of Publications, New Delhi.
13. BPC- Dept. of Health, U.K. for HMSO.
14. USP – Mack Publishing Co., Easton, PA.
15. The Extra Pharmacopoeia – The Pharm. Press, London.

## **Detailed Syllabus**

### **Topics**

#### **1. Quality Assurance:**

- a. Introduction, sources of quality variation, control of quality variation.
- b. Concept of statistical quality control.
- c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
- d. GLP, ISO 9000.
- e. Total quality management, quality review and documentation.
- f. ICH- international conference for harmonization-guidelines.
- g. Regulatory control.

#### **2. Chromatography:**

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

- a. **Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
  - b. **TLC:** Introduction, principle, techniques,  $R_f$  value and applications.
  - c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
  - d. **Ion-exchange chromatography:** Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
  - e. **HPLC:** Introduction, theory, instrumentation, and applications.
  - f. **HPTLC:** Introduction, theory, instrumentation, and applications.
  - g. **Gas Chromatography:** Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors-Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
  - h. **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
  - i. **Gel filtration and affinity chromatography:** Introduction, technique, applications.
3. **Electrometric Methods:**
- Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.
- a. **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
  - b. **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.
  - c. **Polarography:** Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
  - d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.
4. **Spectroscopy:**

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

a. **Absorption Spectroscopy:**

- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

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

- **Infrared Spectroscopy:** Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectrometer – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors– Thermocouple, Golyay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.
- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

- b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.
- c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.
- d. **Atomic Emission Spectroscopy:** Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.
- e. **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications.
- f. **Mass Spectroscopy: (Introduction only)** – Fragmentation, types of ions produced mass spectrum and applications.

- g. **Polarimetry: (Introduction only)** – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.
- h. **X-RAY Diffraction: (Introduction only)** – Theory, reciprocal lattice concept, diffraction patterns and applications.
- i. **Thermal Analysis:** Introduction, instrumentation, applications, and DSC and DTA.

### Course Outcomes

- Understand the design and working principles of various analytical instruments
- Students comes out with the knowledge of regulatory control and validation protocol
- Able to design the bio analytical method for therapeutic drug monitoring
- Students can able to maintain the analytical laboratory as per the Good Laboratory Practice guidelines

3.2-Pharmaceutical Analysis Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X					X	X						X
CO2			X					X	X						X
CO3			X					X	X						X
CO4			X					X	X						X
CO5			X					X	X						X

## 3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

75 Hrs

Practical: 3 Hrs./Week

### List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.



6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of an acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by 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.

### Reference Book

Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.

### Scheme of Practical Examination:

	<b>Sessionals</b>	<b>Annual</b>
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

### Course Outcomes

- Students are able to identify the separated compounds based on the Paper chromatography and Thin layer chromatography
- Manage to analyse the Pharmaceutical compounds in bulk and in the formulations
- Able to estimate the drug using UV Visible spectrophotometry, flame photometry, fluorimetry and nephelometry
- Gains knowledge to find out the presence of functional groups in the pharmaceutical compounds using interpretation of IR spectra

3.2 P-Pharmaceutical Analysis Practical Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X					X	X						X
CO2			X					X	X						X
CO3			X					X	X						X
CO4			X					X	X						X
CO5			X					X	X						X

### 3.3 PHARMACOTHERAPEUTICS – II (THEORY)

75 Hrs

**Theory: 3 Hrs. /Week**

1. **Scope:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:**
  - a. know the pathophysiology of selected disease states and the rationale for drug therapy
  - b. know the therapeutic approach to management of these diseases;
  - c. know the controversies in drug therapy;
  - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
  - e. 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).

#### 3. Course Materials:

**Text books (Theory)**

Clinical Pharmacy and Therapeutics – Roger and Walker, Churchill Livingstone publication.

**Reference books (Theory)**

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

**4. Detailed syllabus:****Topic**

**Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –**

- 1. Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
- 2 Musculoskeletal disorders**  
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
- 3 Renal system**  
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders
- 4 Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

**Course Outcome**

- Understand the pathophysiology of selected disease states and the rationale for drug therapy and the therapeutic approach to management of these diseases.
- Know the controversies in drug therapy and the importance of preparation of individualised therapeutic plans based on diagnosis.

- Understand 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)

3.3-Pharmacotherapeutics II Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X			X	X					X	X		
CO2		X		X					X				X	X	
CO3					X			X			X				X
CO4	X									X					X
CO5			X			X			X				X		X

### 3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

75 Hrs

**Practical: 3 Hrs./Week**

#### 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.

**Scheme of Practical Examination:**

	<b>Sessionals</b>	<b>Annual</b>
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

**Course Outcomes**

- Understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy by P hospital postings for a period of at least one month.
- Understanding the practical- clinical discussion by attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients with case presentation upon discharge.

<b>3.3 P-Pharmacotherapeutics II Practical Mapping Pos &amp; PSOs X Course Outcomes:</b>															
	<b>PO1</b>	<b>PO2</b>	<b>PO3</b>	<b>PO4</b>	<b>PO5</b>	<b>PO6</b>	<b>PO7</b>	<b>PO8</b>	<b>PO9</b>	<b>PO10</b>	<b>PSO1</b>	<b>PSO2</b>	<b>PSO3</b>	<b>PSO4</b>	<b>PSO5</b>
<b>CO1</b>			X			X	X					X	X		
<b>CO2</b>		X		X					X				X	X	
<b>CO3</b>					X			X			X				X
<b>CO4</b>	X									X					X
<b>CO5</b>			X			X			X				X		X

### 3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

50 Hrs

**Theory: 2 Hrs. /Week**

1. **Scope:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
2. **Objectives:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
  - a. practice the Professional ethics;
  - b. understand the various concepts of the pharmaceutical legislation in India;
  - c. know the various parameters in the Drugs and Cosmetics Act and rules;
  - d. know the Drug policy, DPCO, Patent and design act;
  - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
  - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
  - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

#### 3. Course Materials

##### Text books

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

##### Reference books

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

#### 4. Detailed syllabus:

##### Topics

1. **Pharmaceutical Legislations** – A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cosmetics Act, 1940, and its rules 1945.**  
Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.  
Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems.  
Constitution and Functions of DTAB, DCC, CDL.  
Qualification and duties –Govt. analyst and Drugs Inspector.
4. **Pharmacy Act –1948.**  
Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**  
Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Current).**
10. **Prevention Of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

#### 4. [a] Assignments:

##### Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy

3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

**[b] Case studies relating to**

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

**Course Outcomes**

- Practice the Professional ethics
- Understands the various concepts of the pharmaceutical legislation in India
- Know the various parameters in the Drug and Cosmetic Act and rules
- Knows the Drug policy, DPCO, Patent and design act
- Understand the labeling requirements and packaging guidelines for drugs and cosmetics
- Be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act
- Other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

<b>3.4-Pharmaceutical Jurisprudence Theory Mapping Pos &amp; PSOs X Course Outcomes:</b>															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
<b>CO1</b>	X			X			X				X			X	
<b>CO2</b>	X		X		X		X	X			X	X	X		X
<b>CO3</b>	X			X		X			X			X		X	
<b>CO4</b>		X	X			X				X		X			X
<b>CO5</b>		X			X				X		X		X		X



**3.5. MEDICINAL CHEMISTRY (THEORY)**

75 Hrs

**Theory: 3 Hrs. /Week****Detailed Syllabus:****Topics**

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

A study of the development of the following classes of drugs including SAR, mechanism of action, stereochemical aspects, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti-infective agents
  - a. Local anti-infective agents
  - b. Preservatives
  - c. Antifungal agents
  - d. Urinary tract anti-infectives
  - e. Antitubercular agents
  - f. Antiviral agents and Anti AIDS agents
  - g. Antiprotozoal agents
  - h. Anthelmintics
  - i. Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
  - a. Antihypertensive agents
  - b. Antianginal agents and vasodilators
  - c. Antiarrhythmic agents
  - d. Antihyperlipidemic agents
  - e. Coagulants and Anticoagulants
  - f. Endocrine

8. Hypoglycemic agents
9. Thyroid and Antithyroid agents
10. Diuretics
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids

### Course Outcomes

- To understand the chemistry of drugs with respect to their biological activity
- To understand the different modern techniques and concepts of drug design
- To know the mechanism of action, adverse effect and therapeutic activity of drugs
- To know the appropriate use of some important drug classes.
- To acquire knowledge in the chemotherapy for cancer and microbial diseases and different antiviral agents
- To give knowledge about drugs used in the treatment of diabetes and hypertension
- To have been introduced to a variety of drug classes and some pharmacological problems

3.5-Medicinal Chemistry Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X				X	X							X
CO2			X				X	X							X
CO3			X				X	X							X
CO4			X				X	X							X
CO5			X				X	X							X

### 3.5 MEDICINAL CHEMISTRY (PRACTICAL)

**Practical: 3 Hrs./Week**

**75 Hrs**

#### Practicals

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.

**Reference Books:**

- a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
- c. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walffed Johnwiley and Sons, Wiley-interscience Publication, New York, Toronto.
- d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi – 54.
- f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

**Course Outcomes**

3.5 Medicinal Chemistry Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X				X	X							X
CO2			X				X	X							X
CO3			X				X	X							X
CO4			X				X	X							X
CO5			X				X	X							X

### 3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

50 Hrs

**Theory: 2 Hrs. /Week**

1. **Scope:** Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.
2. **Objectives:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
  - a. understand the principle involved in formulation of various pharmaceutical dosage forms;
  - b. prepare various pharmaceutical formulation;
  - c. perform evaluation of pharmaceutical dosage forms; and
  - d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

#### 3. Course Materials

##### Text books (Theory)

- a. Pharmaceutical dosage forms, Vol, I,II and III by Lachman
- b. Rowlings Text book of Pharmaceutics
- c. Tutorial Pharmacy – Cooper & Gun

##### Reference books (Theory)

- a. Remington's Pharmaceutical Sciences
- b. USP/BP/IP

#### 4. Detailed syllabus:

##### Topics:

1. Pharmaceutical dosage form- concept and classification
2. **Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
3. **Capsules;** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
4. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization

6. **Ophthalmic preparations (Semi – Solids):** Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular

### Course Outcomes

3.6 Pharmaceutical Formulations Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1	X	X					X	X				X	X		
CO2		X	X	X					X	X	X			X	X
CO3			X	X	X	X									
CO4	X				X		X	X	X	X	X		X	X	X
CO5		X	X	X		X						X			

### 3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

75 Hrs

**Practical: 3 Hrs./Week**

#### 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. Salicylic acid and benzoic acid ointment
  - b. Gel formulation Diclofenac gel
7. Cosmetic preparations
  - a. Lipsticks
  - b. Cold cream and vanishing cream
  - c. Clear liquid shampoo
  - d. Tooth paste and tooth powders.
8. Tablet coating (demonstration)

**Scheme of Practical Examination:**

	<b>Sessionals</b>	<b>Annual</b>
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

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

**Course Outcomes**

- Students can learn about basics on drug formulations and various approaches of dosage form design.

**3.6 Pharmaceutical Formulations Practical  
Mapping Pos & PSOs X Course Outcomes:**



**FOURTH YEAR / FIRST YEAR (POST  
BACCALAUREATE)**

**4.1 PHARMACOTHERAPEUTICS – III (THEORY)**

75Hrs

**Theory: 3 Hrs. /Week**

- 1. Scope:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
  
- 2. Objectives:** At completion of this subject it is expected that students will be able to understand –
  - a. the pathophysiology of selected disease states and the rationale for drug therapy;
  - b. the therapeutic approach to management of these diseases;
  - c. the controversies in drug therapy;
  - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
  - e. 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);

**3. Course Materials**

**Text Books**

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

**Reference Books**

- a. Pathologic basis of disease – Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice – Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics – Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA



- e. Avery's Drug Treatment, 4<sup>th</sup> Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

#### 4. Detailed Syllabus

##### Topics:

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

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders – Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, headaches.
- 6 Evidence Based Medicine

##### 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.

#### Course Outcomes

By the end of this subject students will be able to understand:

1. The pathophysiology of selected disease states and the rationale for drug therapy
2. The therapeutic approach to management of these diseases
3. The controversies in drug therapy
4. The importance of preparation of individualised therapeutic plans based on diagnosis
5. 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. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy
7. Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence
8. Discuss the controversies in drug therapy
9. Discuss the preparation of individualised therapeutic plans based on diagnosis
10. 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)

4.1 Pharmacotherapeutics – III Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X			X	X					X	X		
CO2		X		X					X				X	X	
CO3					X			X			X				X
CO4	X									X					X
CO5			X			X			X				X		X

#### 4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

**Practical : 3 Hrs./Week**

**75 Hrs**

##### **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.

**Scheme of Practical Examination :**

	<b>Sessionals</b>	<b>Annual</b>
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

4.1 Pharmacotherapeutics – III Practical Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X			X	X					X	X		
CO2		X		X					X				X	X	
CO3					X			X			X				X
CO4	X									X					X
CO5			X			X			X				X		X

## 4.2 HOSPITAL PHARMACY (THEORY)

**50 Hrs**

**Theory: 2 Hrs. /Week**

- Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counseling, and therapeutic drug monitoring for improved patient care.
- Objectives:** Upon completion of the course, the student shall be able to –
  - know various drug distribution methods;

- b. know the professional practice management skills in hospital pharmacies;
- c. provide unbiased drug information to the doctors;
- d. know the manufacturing practices of various formulations in hospital set up;
- e. appreciate the practice based research methods; and
- f. appreciate the stores management and inventory control.

### 3. Course Materials

#### Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh.
- c. Good Pharmacy Practice (GPP) in Community and Hospital Pharmacy Settings, World Health Organization, 1996.

#### References:

- a) WHO consultative group report.
- b) R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c) Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- d) Good Pharmacy Practice (GPP) in Developing Countries – Recommendation for Stepwise Implementation – International Pharmaceutical Federation, 1997.
- e) Primary health care – Report of the international conference on primary health care, Alma – Ata; USSR 1978.
- f) The Role of Pharmacist in Health Care System – Report of a WHO Consultation Group, New Delhi, India, 1994.
- g) Role of Pharmacist in Support of the WHO Revised Drug Strategy, 47<sup>th</sup> World Health Assembly, 1994.
- h) Role of Pharmacist in Health Care System – Preparing the Future Pharmacist: Curriculum Development. World Health Organization 1997.

### 4. Detailed Syllabus:

#### Topics

#### 1 Hospital – its Organisation and functions

#### 2 Hospital pharmacy-Organisation and management

- a) Organizational structure-Staff, Infrastructure & work load statistics
- b) Management of materials and finance
- c) Roles & responsibilities of hospital pharmacist

**3 The Budget – Preparation and implementation****4 Hospital drug policy**

- a) Pharmacy and Therapeutic committee (PTC)
- b) Hospital formulary
- c) Hospital committees
  - Infection committee
  - Research and ethical committee
- d) developing therapeutic guidelines
- e) Hospital pharmacy communication – Newsletter

**5 Hospital pharmacy services**

- a) Procurement & warehousing of drugs and Pharmaceuticals
- b) Inventory control
  - Definition, various methods of Inventory Control
  - ABC, VED, EOQ, Lead time, safety stock
- c) Drug distribution in the hospital
  - i) Individual prescription method
  - ii) Floor stock method
  - iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services – Role of pharmacist

**6 Manufacture of Pharmaceutical preparations**

- a) Sterile formulations – large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition

**7 Continuing professional development programs**

Education and training

**8 Radio Pharmaceuticals – Handling and packaging****9 Professional Relations and practices of hospital pharmacist****10 Good Pharmacy Practice in hospital pharmacy setting**

Procurement and Storage; Distribution; Administration of medicines, vaccines and injectable medications; Dispensing; Disposal of Medicines; Effective therapy management; Patient Medication Therapy Management; Monitoring Progress and Out

Comes; Providing Information; Maintaining and Improving Professional Performance; Contribution for Improving Effectiveness of Health Care System and Public Health.

### Course Outcomes

- Understand about the storage condition of various medicine in the Hospital
- Provide population based care
- To promote health and wellness
- Provide care through the Drug and Poison Information services
- Understand about budgeting and inventory control
- Understand about handling, safe usage and storage of Drugs.

4.2-Hospital Pharmacy Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1				X	X		X	X							
CO2		X	X			X	X				X	X	X	X	
CO3			X	X	X	X	X		X				X	X	X
CO4	X	X		X				X	X				X	X	X
CO5			X		X						X	X	X	X	

## 4.2 HOSPITAL PHARMACY (PRACTICAL)

75 Hrs

### Practical: 3 Hrs./Week

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

### List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.

6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

**Special requirements:**

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

**Scheme of Practical Examination:**

	<b>Sessionals</b>	<b>Annual</b>
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

**Course Outcomes**

- Understand about the storage condition of various medicine in the Hospital
- Provide population based care
- To promote health and wellness
- Provide care through the Drug and Poison Information services
- Understand about budgeting and inventory control
- Understand about handling, safe usage and storage of Drugs.

4.2-Hospital Pharmacy Practical Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X	X		X	X	X					X	X	X	
CO2		X	X		X	X	X				X	X	X		
CO3			X	X		X	X		X	X		X			

CO4		X	X	X	X	X	X	X	X	X	X			X	
CO5				X	X			X		X	X	X		X	

### 4.3 CLINICAL PHARMACY (THEORY)

75 Hrs

**Theory: 3 Hrs. /Week**

#### 1. Objectives:

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

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

#### 2. Course Materials:

##### Text books (Theory)

- Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- 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. ISSN8125026

##### References

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

#### 3. Detailed syllabus:

##### Topics:



1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
  - a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
  - b. Ward round participation
  - c. Adverse drug reaction management
  - d. Drug information and poisons information
  - e. Medication history
  - f. Patient counseling
  - g. Drug utilization evaluation (DUE) and review (DUR)
  - h. Quality assurance of clinical pharmacy services.
3. **Patient data analysis**

The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
  - a. 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
5. **Drug & Poison information**
  - a. Introduction to drug information resources available
  - b. Systematic approach in answering DI queries
  - c. Critical evaluation of drug information and literature
  - d. Preparation of written and verbal reports
  - e. Establishing a Drug Information Centre
  - f. Poisons information- organization & information resources
6. **Pharmacovigilance**
  - a. Scope, definition and aims of pharmacovigilance
  - b. Adverse drug reactions – Classification, mechanism, predisposing factors, causality assessment [different scales used]

- c. Reporting, evaluation, monitoring, preventing & management of ADRs
  - d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counseling techniques, medication history interview, presentation of cases.
  8. Pharmaceutical care concepts
  9. Critical evaluation of biomedical literature
  10. Medication errors

### Course Outcomes

- Know the monitoring the drug therapy of patient through medication chart review and clinical review; the medication history interview and counsel the patients.
- Understanding to identify and resolve drug related problems.
- Understanding the activities include detection, assessment and monitor of adverse drug reaction.
- Know to interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and retrieve, analyse, interpret and formulate drug or medicine information.

4.3-Clinical Pharmacy Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X	X		X	X	X					X	X	X	
CO2		X	X		X	X	X				X	X	X		
CO3			X	X		X	X		X	X		X			
CO4		X	X	X	X	X	X	X	X	X	X			X	
CO5				X	X			X		X	X	X		X	

### 4.3 CLINICAL PHARMACY (PRACTICAL)

75 Hrs

#### Practical: 3 Hrs./Week

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

- a. Answering drug information questions (4 Nos)
- b. Patient medication counseling (4 Nos)

- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

**Assignment:**

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counseling, 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.

**Course Outcomes**

- Know the monitoring the drug therapy of patient through medication chart review and clinical review; the medication history interview and counsel the patients.
- Understanding to identify and resolve drug related problems.
- Understanding the activities include detection, assessment and monitor of adverse drug reaction.
- Know to interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and retrieve, analyse, interpret and formulate drug or medicine information.

4.3 P-Clinical Pharmacy Practical Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X	X		X	X	X					X	X	X	
CO2		X	X		X	X	X				X	X	X		
CO3			X	X		X	X		X	X		X			

CO4		X	X	X	X	X	X	X	X	X	X			X	
CO5				X	X			X		X	X	X		X	

#### 4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

50 Hrs

Theory: 2 Hrs. /Week

##### 1. Detailed syllabus

Topics:

##### 1 Research Methodology

- a) Types of clinical study designs:  
Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study  
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
- d) Report writing and presentation of data

##### 2 Biostatistics

##### 2.1 a) Introduction

- b) Types of data distribution
- c) Measures describing the central tendency distributions- average, median, mode
- d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

##### 2.2 Data graphics

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

##### 2.3 Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.

- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

#### 2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

### 3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

#### Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

#### Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

#### Reference books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3<sup>rd</sup> edition, publisher Marcel Dekker Inc. New York.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3<sup>rd</sup> edition, McGraw Hill Publications 2006

#### Course Outcomes

- Students should be able to write a proposal, engage in independent studies and work collaboratively and in biostatistics.
- Students should be able to identify correct sampling technique and fix optimal power of the study.

- Students should be able to solve basic statistics, including probability, descriptive statistics and inferential statistics for means and proportions, and regression methods are presented.
- Students should be able to demonstrate skills in the analysis of epidemiological data.
- Students should be able to utilize the computers effectively in the process of drug information system, dispensing of prescriptions and inventory controlling

4.4-Biostatistics and Research Methodology Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			x												X
CO2					X							X			
CO3	X										X				
CO4								X						X	
CO5				X							X				

## 4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

75 Hrs

Theory : 3 Hrs. /Week

### Topics

#### 1. Biopharmaceutics

1. Introduction to Biopharmaceutics
  - a. Absorption of drugs from gastrointestinal tract.
  - b. Drug Distribution.
  - c. Drug Elimination.

#### 2. Pharmacokinetics

1. Introduction to Pharmacokinetics.
  - a. Mathematical model
  - b. Drug levels in blood.
  - c. Pharmacokinetic model
  - d. Compartment models
  - e. Pharmacokinetic study.

2. One compartment open model.
  - a. Intravenous Injection (Bolus)
  - b. Intravenous infusion.
3. Multicompartment models.
  - a. Two compartment open model.
  - b. IV bolus, IV infusion and oral administration
4. Multiple – Dosage Regimens.
  - a. Repetitive Intravenous injections – One Compartment Open Model
  - b. Repetitive Extravascular dosing – One Compartment Open model
  - c. Multiple Dose Regimen – Two Compartment Open Model
5. Nonlinear Pharmacokinetics.
  - a. Introduction
  - b. Factors causing Non-linearity.
  - c. Michaelis-menton method of estimating parameters.
6. Noncompartmental Pharmacokinetics.
  - a. Statistical Moment Theory.
  - b. MRT for various compartment models.
  - c. Physiological Pharmacokinetic model.
7. Bioavailability and Bioequivalence.
  - a. Introduction.
  - b. Bioavailability study protocol.
  - c. Methods of Assessment of Bioavailability

### Course Outcomes

The students will have e the knowledge on basic concepts in biopharmaceutics, pharmacokinetics such as ADME, application of pharmacokinetics.

4.5 Biopharmaceutics and Pharmacokinetics Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X	X		X	X	X					X	X	X	

CO2		X	X		X	X	X				X	X	X		
CO3			X	X		X	X		X	X		X			
CO4		X	X	X	X	X	X	X	X	X	X			X	
CO5				X	X			X		X	X	X		X	

#### 4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

75 Hrs

**Practical: 3 Hrs./Week**

##### List of Experiments

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  $K_a$ ,  $K_e$ ,  $t_{1/2}$ ,  $C_{max}$ , 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, Sulphamethoxazole, 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.

##### References:

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.



- c. Pharmacokinetics: By Milo Gibaldi Donald, R. Merceel Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil  
B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Cilinal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4<sup>th</sup> edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

### Course Outcomes

- The students will have e the knowledge on basic concepts in biopharmaceutics, pharmacokinetics such as ADME, application of pharmacokinetics.

4.5 Biopharmaceutics and Pharmacokinetics Practical Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X	X		X	X	X					X	X	X	
CO2		X	X		X	X	X				X	X	X		
CO3			X	X		X	X		X	X		X			
CO4		X	X	X	X	X	X	X	X	X	X			X	
CO5				X	X			X		X	X	X		X	

### 4.6 CLINICAL TOXICOLOGY (THEORY)

50 Hrs

Theory: 2 Hrs. /Week

Topics:

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
  - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
  - b) Opiates overdose.
  - c) Antidepressants
  - d) Barbiturates and benzodiazepines.
  - e) Alcohol: ethanol, methanol.
  - f) Paracetamol and salicylates.
  - g) Non-steroidal anti-inflammatory drugs.
  - h) Hydrocarbons: Petroleum products and PEG.
  - i) Caustics: inorganic acids and alkali.
  - j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents –  
Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

**Substance abuse:**

Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants: amphetamine
- b) Opioids
- c) CNS depressants

- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

### References:

- a. Matthew J Ellenhorn. Ellenhorns Medical toxicology – diagnosis and treatment of poisoning. Second Edition. Williams and Willkins publication, London
- b. V V Pillay. Handbook of forensic medicine and toxicology. Thirteenth edition 2003 Paras Publication, Hyderabad

### Course Outcomes

- Know the general principles involved in the management of poisoning, antidotes and its clinical applications, gut decontamination, elimination enhancement, toxicokinetics and supportive care in clinical toxicology. Understand the clinical symptoms and management of poisoning including: Heavy metals, Pesticide, hydrocarbons, alcohols, opiates overdose, caustics and Radiation poisoning.
- Know the various drugs induced poisoning like NASID's, antidepressants, barbiturates, benzodiazepines, paracetamol and salicylates including clinical symptoms, prevention, pre & post-hospital management of drug induced poisoning.
- Understand the venomous snake bites, arthropod bites and stings, mycotoxins, mushroom and food poisoning (including toxic dose, mechanism of action, general management, early manifestations and hospital management). Know the signs and symptoms of substance abuse and treatment of dependence including: CNS stimulants and depressants, opioids, hallucinogens, cannabis group and tobacco

4.6 Clinical Toxicology Theory															
Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X	X		X	X	X					X	X	X	
CO2		X	X		X	X	X				X	X	X		
CO3			X	X		X	X		X	X		X			
CO4		X	X	X	X	X	X	X	X	X	X			X	
CO5				X	X			X		X	X	X		X	

### 4.7 PHARMACOTHERAPEUTICS I & II (THEORY)

[For I Pharm.D. (Post Baccalaureate) only]

Theory: 3Hrs/week

75 Hrs

1. **Scope:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives**
  - a. know the pathophysiology of selected disease states and the rationale for drug therapy
  - b. know the therapeutic approach to management of these diseases;
  - c. know the controversies in drug therapy;
  - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
  - e. 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).

### 3. Course Materials

#### Text books (Theory)

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

#### Reference books (Theory)

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

### 4. Detailed Syllabus

#### Topics:

**Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases.**

1. **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias, Electrophysiology of heart and Arrhythmias.
2. **Respiratory system:** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases.
3. **Endocrine system:** Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis.
4. **General prescribing guidelines for**

- a. Paediatric patients
- b. Geriatric patients.
- c. Pregnancy and breast feeding.
5. **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial.
6. **Introduction to rational drug use:** Definition, Role of pharmacist Essential drug concept Rational drug formulations.
7. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis.
8. **Musculoskeletal disorders:** Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
9. **Renal system:** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders.
10. **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis.
11. **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

### Course Outcomes

- Know the pathophysiology of selected disease states and the rationale for drug therapy and the therapeutic approach to management of these diseases and the controversies in drug therapy
- Understanding the importance of preparation of individualised therapeutic plans based on diagnosis and identifying 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)
- Understand the management of the diseases including reference to the latest available evidence
- Discuss the preparation of individualised therapeutic plans based on diagnosis.

4.7 P Pharmacotherapeutics – I & II Theory															
Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X			X	X					X	X		
CO2		X		X					X				X	X	
CO3					X			X			X				X

CO4	X								X					X
CO5			X		X			X				X		X

#### 4.7 P PHARMACOTHERAPEUTICS – I & II (PRACTICAL)

[For I Pharm.D. (Post Baccalaureate) only]

75 Hrs

**Practical: 3 Hrs./Week**

##### 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:

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.

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

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

### Course Outcomes

By the end of this subject students will be able to understand:

- Describe the pathophysiology of selected disease states and explain the rationale for drug therapy
- Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence
- Discuss the controversies in drug therapy
- Discuss the preparation of individualised therapeutic plans based on diagnosis
- Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects)

4.7 P Pharmacotherapeutics – I & II Practical Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X			X	X					X	X		
CO2		X		X					X				X	X	
CO3					X			X			X				X
CO4	X									X					X
CO5			X			X			X				X		X

**FIFTH YEAR / SECOND YEAR (POST BACCALAUREATE)****5.1 CLINICAL RESEARCH (THEORY)**

75 Hrs

**Theory: 3 Hrs. /Week****1. Course Materials****Text Books:**

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- c. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

**Reference Books:**

- a. 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.
- b. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- c. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- d. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

**2. Detailed Syllabus****1. Drug development process:**

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization



5. Dosage form

**2. Clinical development of drug:**

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
  - a. Sponsor
  - b. Investigators
  - c. Clinical research associate
  - d. Auditors
  - e. Contract research coordinators
  - f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

**Course Outcomes**

5.2-Clinical Research Theory Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1					x				x						x
CO2											x				

CO3														
CO4				x										x
CO5	x				x				x		x			

## 5.2 PHARMACOEPIDEMOLOGY AND PHARMACOECONOMICS (THEORY)

75 Hrs

**Theory: 3 Hrs. /Week**

### 1. Course Materials

#### Text Books:

- a. Textbook of Pharmacoepidemiology. Editors Brian L. Strom and Stephen E. Kimmel. West Sussex (England). John Wiley & Sons Ltd.; 2006
- b. Martin Dunitz. Pharmaco-economic in Psychiatry. Edited by David Taylor, Martin Knapp, Robert Kerwin. Taylor & Francis, Martin Dunitz Ltd, (UK); 2002.

#### Reference Books:

- a. Neil Pearce. A Short Introduction to Epidemiology. 2<sup>nd</sup> Ed. Wellington (NZ). Centre for Public Health Research; 2005.
- b. Pharmacoepidemiology, 3<sup>rd</sup> Ed. Edited by Brian L. Strom. West Sussex (England). John Wiley & Sons Ltd.; 2000.
- c. Remington's Pharmaceutical Sciences.

### 2. Detailed Syllabus

#### Topics

#### 1. Pharmacoepidemiology:

##### Definition and scope:

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

##### Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

##### Concept of risk in pharmacoepidemiology

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

##### Pharmacoepidemiological methods

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

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

### **Sources of data for pharmacoepidemiological studies**

Ad Hoc data sources and automated data systems.

### **Selected special applications of pharmacoepidemiology**

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

## **2. Pharmacoeconomics:**

### **Definition, history, needs of pharmacoeconomic evaluations**

Role in formulary management decisions

### **Pharmacoeconomic evaluation**

Outcome assessment and types of evaluation

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

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

## **3. Applications of Pharmacoeconomics**

Software and case studies

## **Course Outcomes**

The students will understand the concepts and develop competency:

- To explain the terminology used in Pharmacoepidemiological studies;
- To describe the advantages, disadvantages and application of various Pharmacoepidemiological methods;
- To calculate the various parameters in risk assessment: risk, attributable risk, relative risk, time –risk relationship and odds ratio;
- To explain the safety issues associated with vaccines, drugs causing birth defects;
- To describe the pharmaceutical pricing policy, regulatory mechanism of price control and access to medicines;
- To describe pharmacoeconomic methods and perform pharmacoeconomic evaluations: cost minimization, cost effective, cost benefit and cost utility analysis; and
- To apply pharmacoeconomic principles in practice

5.2-Pharmacoepidemiology and Pharmacoeconomics Theory															
Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X			X			X				X	X		
CO2	X			X					X				x		
CO3			X			X	X			X	X			X	
CO4	X	X			X	X						X	X	X	
CO5			X	X				X	X					X	X

## **5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)**

**50 Hrs**

**Theory : 2 Hrs. /Week**

### **1. Course Materials**

#### **Text Books:**

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- c. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4<sup>th</sup> edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York and Basel, 1987.

#### **Reference Books:**

- a. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- b. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercei Dekker Inc.
- c. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- d. Biopharmaceutics; By Swarbrick
- e. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- f. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and A. Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
- g. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- h. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Royle, Marcel Dekker Inc, New York 1996.

### **2. Detailed Syllabus**

#### **Topics:**

#### **1. Introduction to Clinical pharmacokinetics.**

#### **2. Design of dosage regimens:**

Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

**3. Pharmacokinetics of Drug Interaction:**

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

**4. Therapeutic Drug monitoring:**

- a. Introduction
- b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs).
- c. Indications for TDM. Protocol for TDM.
- d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
- e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

**5. Dosage adjustment in Renal and hepatic Disease.**

- a. Renal impairment
- b. Pharmacokinetic considerations
- c. General approach for dosage adjustment in Renal disease.
- d. Measurement of Glomerular Filtration rate and creatinine clearance.
- e. Dosage adjustment for uremic patients.
- f. Extracorporeal removal of drugs.
- g. Effect of Hepatic disease on pharmacokinetics.

**6. Population Pharmacokinetics.**

- a. Introduction to Bayesian Theory.
- b. Adaptive method or Dosing with feed back.
- c. Analysis of Population pharmacokinetic Data.

**7. Pharmacogenetics**

- a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
- b. Genetic Polymorphism in Drug Transport and Drug Targets.
- c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

**Course Outcomes**

Students will be exposed to regulations, drug-drug interactions, and positive therapeutic outcomes by conduction therapeutic drug monitoring for various drugs.

5.3 Clinical Pharmacokinetics and Pharmacotherapeutic Drug Monitoring Theory															
Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1		X			X			X	X				X		X
CO2	X		X			X	X			X	X				
CO3				X				X				X		X	
CO4					X								X		X
CO5	X		X			X		X		X			X		

#### 5.4 CLERKSHIP (12 Months)

##### Guidelines for Clerkship

1. The students of V year Pharm.D. (Integrated) or II year Pharm.D. (Post Baccalaureate) have to undergo clerkship as per the time table.
2. The clerkship involves ward round on daily basis as per time table.
3. The students have to maintain a record of this clerkship and the record is to be written with the following formats (Case Studies) covering wide variety of patients and disease conditions:
  - a. Subjective.
  - b. Objective.
  - c. Assessment.
  - d. Planning.

Therapeutic management provided to the patient is to be critically evaluated/ assessed for:

- Appropriateness of therapeutic agents.
- Medication Errors - Dose, Frequency, Dosage Form, Drug - Drug Interaction etc.
- Suggestive clinical pharmacist's intervention with references.

##### Examination Norms:

##### University Examination (70 marks)

- The final practical examination shall be conducted after completion of clerkship.
- The student has to present the allotted case and would be followed by discussion.
- Assessment parameters:
  - ability to deliver clinical pharmacy services.
  - planning of pharmaceutical care, and
  - knowledge of therapeutics.

##### Sessional Examination (30 marks)

- There would be two periodic sessional examinations and the total would be the basis of calculating sessional marks.
- Awarding of marks :
  - Actual performance in sessional examination:
  - Day to day assessment of clerkship:



- Examination pattern :
  - The student has to present the allotted case and would be followed by discussion.
  - Assessment parameters :
    - ❖ ability to deliver clinical pharmacy services,
    - ❖ planning of pharmaceutical care, and
    - ❖ knowledge of therapeutics.

### Course Outcomes

The students would have competency:

- To work in a healthcare team;
- To identify drug related issues and plan for intervention;
- To provide drug information service;
- To identify and document the ADRs; and
- To provide patient counselling in promoting medication adherence and appropriate use.

5.4 Clerkship Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1				X	X				X		X		X	X	
CO2	X	X				X		X							X
CO3			X	X						X			X	X	X
CO4					X	X		X	X			X	X		
CO5	X	X					X	X			X				

### 5.5 Project Work (6 Months)

#### Guidelines for Project Work

1. The students of V year Pharm.D. (Integrated) or II year Pharm.D. (Post Baccalaureate) have to do project work as per the time table.
2. The aim of the project work:
  - To get an exposure to published work (literature survey) and art of recording the finding in an impartial manner;
  - The develop skill on study design, data collection, analysis and interpretation of data, deriving conclusion and writing report.

3. The project work to be done in anyone of the areas: Community Pharmacy, Hospital Pharmacy, Clinical Pharmacy. It shall be patient and treatment oriented like Drug Utilization Reviews, Pharmacoepidemiology, Pharmacovigilance or Pharmacoeconomics.
4. The project work would be done in groups of students of not less than two and not more than four students ad decided by the department.
5. The project work topic should be identified by the group in consultation with their guide(s). The project topic is to be approved by the head of the Department of Pharmacy within one month of the commencement of V year class.
6. Two pages write up the identified project indicating title, objective, methodology, anticipated benefits and references should be submitted through guide (s) to the Head of the Department for approval of the topic.
7. The project work must be approved by the Institutional Human Ethical Committee. The students are required to submit the proposal for approval in the prescribed format by the end of July 2009.
8. The students have to present at least three seminars: one in the beginning (after one month of starting with study design and pilot test result), one at the middle and the third one at the end of the project work.

### **Project Report Writing:**

1. The project report is to be written jointly by group of students working together for project work.
2. The report should have 40-50 pages with certificate from guide and Head of the Department.
3. The project report should be in typed form in double spacing using Times Roman font on A4 Papers. The title should be in bold with font size 18, sub titles in bold with the 14 and text font size 12. The cover page of the project report should have the details about the name of the students and the name of the guides with font size 14. (please refer the syllabus and regulation for more details).
4. The project report is to be submitted at least one month prior to the commencement of annual examination (to be submitted before the last date of submission fixed by the Head of the Department).
5. The other details of writing the report including references are enclosed separately.

**Scheme of Evaluation:****Sessional:**

- ✓ Three seminars each for 30 marks. The average of best two would be the sessional marks.
- ✓ Scheme of evaluation:
  - Write up of the seminar : 7.5
  - Presentation of work : 7.5
  - Communication Skill : 7.5
  - Question and answer Skill : 7.5

**University Examination:**

- ✓ One seminar for 70 marks.
- ✓ Scheme of evaluation:
  - Write up of the seminar : 17.5
  - Presentation of work : 17.5
  - Communication Skill : 17.5
  - Question and answer Skill : 17.5

5.5 Project Mapping Pos & PSOs X Course Outcomes:															
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PSO1	PSO2	PSO3	PSO4	PSO5
CO1			X	X		X	X		X		X				
CO2					X	X	X			X	X	X	X	X	X
CO3	X	X			X										
CO4				X	X		X			X	X	X	X		
CO5				X	X	X	X	X	X	X			X	X	

## **INTERNSHIP**

### **1) SPECIFIC OBJECTIVES:**

- i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.
- ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.
- iii) to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.
- iv) to demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.
- v) to develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.
- vi) to communicate effectively with patients and the community.

### **2) OTHER DETAILS:**

- i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.
- ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

iii) Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

### 3. ASSESSMENT OF INTERNSHIP:

- i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practitioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.
- ii) Satisfactory completion of internship shall be determined on the basis of the following:-
  - (1) Proficiency of knowledge required for each case management SCORE 0-5
  - (2) The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5
  - (3) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5
  - (4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5
  - (5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

