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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
(Separate paging is given to this Part in order that it may be filed as a separate compilation)

भाग III—खण्ड 4
[PART III—SECTION 4]
[सांविधिक निकायों द्वारा जारी की गई विविध अधिसूचनाएं जिसमें कि आदेश, विज्ञापन और सूचनाएं सम्मिलित हैं]
[Miscellaneous Notifications including Notifications, Orders, Advertisements and Notices issued by Statutory Bodies]

भारतीय रिज़र्व बैंक

मुंबई-400001, दिनांक 9 अप्रैल 2008

सदर्भ : बैंपविवि. सं. आईबीडी.-14241/23.13.048/2007-08--भारतीय रिज़र्व बैंक अधिनियम, 1934 (1934 का 2) की धारा 42 की उप-धारा (6) के खण्ड (ग) के अनुसरण में भारतीय रिज़र्व बैंक इसके द्वारा निदेश देता है कि उक्त अधिनियम की दूसरी अनुसूची में निम्नलिखित परिवर्तन किये जाएं :--

''अरब बांगलादेश बैंक लिमिटेड'' शब्दों के स्थान पर ''एबी बैंक लिमिटेड'' शब्द होंगे।

आनन्द सिन्हा
कार्यपालक निदेशक

Pharm.D. Regulations – 2008.

No. 14-126/2007-PCI/1756-57.-

Regulations framed under section 10 of the Pharmacy Act, 1948.

(As approved by the Government of India, Ministry of Health vide, letter No. 13013/1/2007-PMS, dated the 13th March 2008 and notified by Pharmacy Council of India).

No. 14-126/2007-PCI – In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations namely:-

CHAPTER-I

(1) Short title and commencement**.** – (1) these regulations may be called the Pharm.D Regulations.

(2) They shall come into force on the date of their publication in the official Gazette.

(3) Pharm.D shall consist of a certificate of having passed the "course of study" and "examination" prescribed in these regulations for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

CHAPTER-II

(4) DURATION OF THE COURSE. –

a) Pharm.D - The duration of the course shall be for 6 academic years (5 years of study and 1 year internship/residency) full time with each academic year spread over a period of not less than two hundred working days.

Period of 6 years duration is divided into two phases –

- Phase I – consisting of Ist, IInd , IIIrd IVth & Vth year.
- Phase II – consisting of Internship/residency training during VIth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice/clinical pharmacy services and acquires skill under supervision so that he/she may become capable of functioning independently.

b) Pharm.D - The duration of the course shall be for 3 academic years (2 years of study and 1 year internship/residency) full time with each academic year spread over a period of not less than two hundred working days.

Period of 3 years duration is divided into two phases –

- Phase I – consisting of Ist (equivalent to IV year of six year Pharm. D programme) & IInd year (equivalent to V year of six year pharm. D programme).
- Phase II – consisting of Internship/residency training during IIIrd year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice/clinical pharmacy services and acquires skill under supervision so that he/she may become capable of functioning independently.

(5) MINIMUM QUALIFICATION FOR ADMISSION TO –

a) Pharm. D (six year programme) Part-I Course -

(1) should be a pass in 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 PCI u/s 12 of the Pharmacy Act, 1948.

(3) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examination.

b) Pharm.D. Course (3 year programme) - B.Pharm from an institution approved by the PCI u/s 12 of the Pharmacy Act.

Provided that –

- candidate shall complete the age of 17 years on or before 31st December of the year admission to the course.

- there shall be reservation of seats for Scheduled Caste and Scheduled Tribes candidates in accordance with the instructions issued by the Central Govt./State Govts./Union Territory Admns. as the case may be from time to time].

(6) number of admissions in above programmes shall be as prescribed by PCI from time to time and presently be restricted as below –

i) Pharm.D. Programme (6 year programme) – 30 students.

ii) Pharm.D. Programme (3 year programme) – 10 students.

(7) Institutions running B.Pharm programme approved u/s 12 of the Pharmacy Act, 1948 will only be permitted to run Pharm.D. programme (6 years). Pharm.D. programme (3 years) will be permitted only in those Institutions which are running Pharm.D. programme.

(8) COURSE OF STUDY. —The course of study for Pharm.D (6 year programme) / Pharm. D (3 years programme) shall include the subjects as given in the Tables below. The number of hour devoted to each subject for its teaching in Theory and Practical, shall not be less than that noted against it in columns below.

T A B L E S

Pharm D (6 Year curriculum) First Year

Sl. No.	Name of Subject	Theory Hours/ Week	Practical Hours/ Week	Tutorials Hours/ Week
1.1	Human Anatomy and physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medical 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	Nil	
	Total hours	**16**	**15**	**Total = 36**

Pharm D (6 Year curriculum) Second Year

Sl #	Name of Subject	Theory Hours / Week	Practical Hours/ Week	Tutorials Hours/ Week
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
	Total Hours	**17**	**9**	**Total = 32**

Pharm D (6 Year curriculum) Third Year

Sl#	Name of Subject	Theory Hours/ Week	Practical Hours/ Week	Tutorials Hours/ Week
3.1	Pharmacology- II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Therapeutics II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	Nil	
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical formulations	2	3	1
	Total hours	**16**	**15**	**Total = 36**

Pharm D (6 Year curriculum) Fourth Year / Pharm. D (3 years curriculum) 1st year

Sl#	Name of Subject	Theory Hours/ Week	Practical/ Hospital postings Hours/ Week	Tutorials Hours/ Week
4.1	Therapeutics- 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	Nil	1
	Total hours	**15**	**12**	**Total = 33**

Pharm D (6 Year curriculum) Fifth Year / Pharm. D (3 years curriculum) 2nd year

Sl#	Name of Subject	Theory Hours/ Week	Hospital postings*	Seminars
5.1	Clinical Research	3		1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3		1
5.3	Clinical Pharmacokinetics & Therapeutic drug monitoring	2		1
5.4	Clerkship *	*		1
5.5	Project work (6 Months)		20	
	Total hours	**8**	**20**	**Total = 32**

*Attending ward rounds on daily basis

Pharm D (6 Year curriculum) Sixth Year/ Pharm. D (3 years curriculum) 3rd year

Residency Training including postings in specialty units. Student should independently provide the clinical pharmacy services to the allotted wards.

- Six months in General Medicine department
- Two months each in 3 other specialty departments

(9) SYLLABI - The syllabi for each subject of study in the said Tables shall be as specified in Appendix A to these regulations.

(10) APPROVAL OF THE AUTHORITY CONDUCTING THE COURSE OF STUDY —

(1) No person/institution/society/university shall start and conduct Pharm.D (six years) / Pharm.D (3 years) programmes without the prior approval of the PCI.

(2) a) Any person or pharmacy college for the purpose of obtaining permission under section 12(1) shall submit a scheme as prescribed by the PCI.

b) The scheme referred to in clause (a) 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.

(3) Institution should provide 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.

(11) EXAMINATIONS –

(1) There shall be an examination for each year to examine 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).

(12) ELIGIBILITY FOR APPEARING AT THE PHARM.D (6 years programme) & PHARM.D. EXAMINATION (3 years programme) - Only such candidates who produce certificate from the Head of the Academic institution in which he /she has undergone the Pharm.D & Pharm.D course, in proof of his /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.

(13) MODE OF EXAMINATIONS –

(1) Each theory and practical examination in the subjects shall be of three hours duration.

(2) A Candidate 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.

(14) 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. (6 years) /Pharm.D (3 years) 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. 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-vice record maintenance etc.	10 marks

(15) MINIMUM MARKS FOR PASSING THE EXAMINATION. -A student shall not be declared to have passed examination unless he /she secures at least 50% marks in each of the subject separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The candidates securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D./ Pharm.D course (Part –VI) examinations shall be declared to have passed in first class. Candidates 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/she passes in all the subjects in a single attempt.

(16) ELIGIBILITY FOR PROMOTION TO NEXT YEAR OF PHARM.D (6 years)/ PHARM.D (3 years) - All candidates who have appeared for all the subjects and passed the Part–I examination are eligible for promotion to the Part –II class & so on. However, failure in more than two subject shall debar him/her from promotion to the next Part.

(17) INTERNSHIP –

(1) Internship is a phase of training wherein a graduate is expected to conduct actual practice of pharmacy and health care and acquire skills under supervision so that he/she may become capable of functioning independently.

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

(18) APPROVAL OF EXAMINATIONS. -The examinations mentioned in regulations 11 to 13 and 15 shall be held by an authority herein after 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.

(19) CERTIFICATE OF PASSING EXAMINATION FOR PHARM.D (6 years) & PHARM.D (3 years) - Certificate to having passed the examination for the Pharm.D. (Doctor of Pharmacy) shall 6 years / Pharm. D (Doctor of Pharmacy), 3 years be granted by the Examining Authority to a successful student.

CHAPTER-III

Practical training during Course of Study of Pharm. D

HOSPITAL POSTING:

Every candidate should be posted in constituent Hospital for a period of not less than one hundred and fifty hours to be covered in not less than 12 months after completing II year and III year course. Candidate should submit two copies of the report duly certified by preceptor duly attested and certified by the Head of the Department/ Institution.

PROJECT WORK:

Goal of this project is to allow the student to develop data collection and reporting skills in the area of Community, hospital and clinical Pharmacy. Project work shall be carried out under the supervision 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 fifth year classes. Project work to be presented as a written report and as a seminar at the end of the year. External and the internal examiners do the assessment of the project work.

Project work shall comprise of objectives of the work, methodology, results & discussions and conclusions.

OBJECTIVES OF THE PROJECT WORK:

1. To show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner.
2. To develop the students data collection analysis and reporting & interpretation skills.

METHODOLOGY

1. Students shall work in groups of not less than **TWO** and not more than **FOUR** under a recognized teacher
2. Project topic shall be approved by the head of the department and head of the institution
3. Project work chosen shall be related to Pharmacy Practice in community, hospital and Clinical setup. It shall be patient and treatment (Medicine) oriented, like Drug utilization reviews, pharmacoepidemiology, pharmacovigilance, pharmacoeconomics.
4. Project be shall be approved by institutional ethical committee
5. Candidate shall present at least three seminars in the beginning, middle and at the end of the project work.
6. Two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the HOD/Head of the institution.

REPORTING

1. Candidate working on the project shall submit jointly, to HOD/Head of the institution, a project report of about 40-50 pages. Project report should include a certificate by the teacher, HOD and Head of the institution
2. Project report shall be prepared using MS-word. Type in double space using Times Roman font in A4 pages. Title shall be in the font size 18(title case, bold face), names of the candidates and guide in 16, subtitles in 14 (bold face capitals) and the text in font size12.

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

EVALUATION:

1. Project work will be evaluated by internal and external examiners.
2. Students shall be evaluated in a batch 20 for 4 hours (i.e. about half an hour for a group of **four** students).
3. Three seminars presented by candidates shall be evaluated for 20 marks each. Average of best two shall be forwarded to the university with other subjects.

4. Evaluation can be done on the following items

		Marks
a) Write up of the seminar		(7.5)
b) Presentation of work		(7.5)
c) Communication skills		(7.5)
d) Question and answer skills		(7.5)
	Total	(30 marks)

FINAL EVALUATION

Final evaluation of project work can be done on the following items

a)	Write up of the seminar	(17.5)
b)	Presentation of work	(17.5)
c)	Communication skills	(17.5)
d)	Question and answer skills	(17.5)
	Total	(70 marks)

Although the topic being the same for the group of students, students shall be differentiated based on item numbers b, c and d mentioned above.

Appendix-A

Pharm.D. Syllabus

First Year

1.1 Human Anatomy & Physiology (Theory)

1. Scope and Objectives: This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations from normal 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.

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

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

2. 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. Guyton arthur, C. 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. Gray's anatomy. Publisher: Churchill Livingstone, London.

Lecture wise program

	Topics	Hrs
1	Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)	1
2	Structure of cell – its components and their functions.	1
3	Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics	2

4.	a) Osseous system - structure, composition and functions of the Skeleton. (done in practical classes - 6hrs)	1
	(b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)	1
5	Haemopoetic System.	
	a) Composition and functions of blood	1
	b) Haemopoesis and disorders of blood components (definition of disorder)	1
	c) Blood groups	1
	d) Clotting factors and mechanism	1
	e) Platelets and disorders of coagulation	
6	Lymph	
	a) Lymph and lymphatic system, composition, formation, and circulation.	
	b) Spleen: structure and functions, Disorders	2
	c) Disorders of lymphatic system (definition only)	1
		1
7	Cardiovascular system	
	a) Anatomy and functions of heart	1
	b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)	2
		1
	d) Electrocardiogram (ECG)	1
	e) Cardiac cycle and heart sounds	2
	f) Blood pressure – its maintenance and regulation	1
	g) 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	2
	b) Mechanism / physiology of respiration and regulation of respiration	2
	c) Transport of respiratory gases	1
	d) Respiratory volumes and capacities, and **Definition of:** Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.	1
9	Digestive system	
	a) Anatomy and physiology of GIT	3
	b) Anatomy and functions of accessory glands of GIT	1
	c) Digestion and absorption	1
	d) Disorders of GIT (definitions only)	1
10	Nervous system	
	a) Definition and classification of nervous system	1
	b) Anatomy, physiology and functional areas of cerebrum	2
	c) Anatomy and physiology of cerebellum	1
	d) Anatomy and physiology of mid brain	1
	e) Thalamus, hypothalamus and Basal Ganglia	1
	f) Spinal card: Structure & reflexes – mono-poly-planter	2
	h) Cranial nerves – names and functions	1
	i) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.	2

11	Urinary system	
	a) Anatomy and physiology of urinary system	2
	c) Formation of urine	1
	d) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance	1
	e) Clearance tests and micturition	1
12	Endocrine system	
	a) Pituitary gland	2
	b) Adrenal gland	1
	c) Thyroid and Parathyroid glands	1
	d) Pancreas and gonads	1
13	Reproductive system	
	a) Male and female reproductive system	2
	b) Their hormones – Physiology of menstruation	1
	c) Spermatogenesis & Oogenesis	1
	d) Sex determination (genetic basis)	1
	e) Pregnancy and maintenance and parturition	1
	f) Contraceptive devices	1
14	Sense organs	
	a) Eye	2
	b) Ear	2
	c) Skin	1
	d) Tongue & Nose	1
15	Skeletal muscles	
	a) Histology	1
	b) Physiology of Muscle contraction	1
	c) Physiological properties of skeletal muscle and their disorders (definitions)	1
16	Sports physiology	
	Muscles in exercise, Effect of athletic training on muscles and muscle performance,	1
	Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,	1
	Drugs and athletics	1
	Total =	75

Human Anatomy & Physiology (Practical)

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

Course materials:

Text books

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

Reference books

1. Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune

Anderson Experimental Physiology, Latest edition, Publisher: NA

Sl No **List of Experiments**

1. Study of tissues of human body (i) Epithelial tissue (ii) Muscular tissue.
2. Study of tissues of human body (i) Connective tissue (ii) 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 (i) Erythrocyte Sedimentation Rate.
   (ii) Hemoglobin content of Blood.
   (iii) Bleeding time &Clotting time.
8. Determination of (i) Blood Pressure (ii) Blood group.

Study of various systems with the help of charts, models & specimens.

9. Skeleton system part I-axial skeleton.
10. Skeleton system part II- appendicular skeleton.
11. Cardiovascular system.
12. Respiratory system
13. Digestive system
14. Urinary system
15. Nervous system
16. Special senses
17. Reproductive system.
18. Study of different family planning appliances.
19. To perform pregnancy diagnosis test.
20. Study of appliances used in experimental physiology.
21. To record simple muscle curve using gastroenemius sciatic nerve preparation.
22. To record simple summation curve using gastroenemius sciatic nerve preparation.
23. To record simple effect of temperature using gastroenemius sciatic nerve preparation.
24. To record simple effect of load & after load using gastroenemius sciatic nerve preparation.
25. To record simple fatigue curve using gastroenemius sciatic nerve preparation.

Scheme of Practical Examination

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

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

1.2 Pharmaceutics (Theory)

1. **Scope and objectives**: This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.

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

1. to know the formulation aspects of different dosage forms
2. to do different pharmaceutical caluculation involved in formulation
3. to formulate different types of dosage forms
4. to appreciate the importance of good formulation for effectiveness.

2. 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

3. **Lecture wise programme :**

	TOPICS	**Hrs**
1.	a. Introduction to dosage forms classification and definitions	-2
	b. Prescription: definition, parts and handling	-2
	c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.	-1
2.	Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief	-2
3	Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.	-3
4.	Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.	-3
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
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	- 2 - 5
7.	Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.	- 7

8. Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation - 4
9. Galenical: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts. -5
10. -Pharamaceutical calculation -5
11. Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages. -3
12. Incompatibilities: Introduction, classification and methods to overcome the incompatibilities. - 5

Total = 55

Pharmaceutics – Practicals

List of Experiments

1	Syrups	a. Simple Syrup I.P
		b. Syrup of Ephedrine Hcl NF
2		a. Syrup Vasaka IP
		b. Syrup of ferrous Phosphate IP
3		a. Orange Syrup
	Elixir	b. Piperizine citrate elixir BP
4		a. Cascara elixir BPC
		b. Paracetamol elixir BPC
5	Linctus	*a. Simple Linctus BPC*
		b. Pediatric simple Linctus BPC
6	Solutions	a. Solution of cresol with soap IP
		b. Strong solution of ferric chloride BPC
7		a. Aqueous Iodine Solution IP
		b. Strong solution of Iodine IP
8		a. Strong solution of ammonium acetate IP
9	Liniments	a. Liniment of turpentine IP*
		b. Liniment of camphor IP
10	Suspensions*	a. Calamine lotion
11		a. Magnesium Hydroxide mixture BP
12	Emulsions*	a. Cod liver oil emulsion
13		a. Liquid paraffin emulsion
14	Powders♣	a. Eutectic powder
		b. Explosive powder
15		a. Dusting powder
		b. Insufflations
16	Suppositories♣	Boric acid suppositories
17		Chloral suppositories
18 to 20	Incompatibilities	Mixtures with Physical
		Chemical & Therapeutic incompatibilities

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

Scheme of Practical Examination

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

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

1.3 MEDICAL BIOCHEMISTRY

Theory : 50 hours **Practicals: 75 Hrs.** **Tutorials :**

Scope of the Subject: (4-6 lines)**:** 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.

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

1. Able to understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases.
2. Able to know the metabolic process of boimolecules in health and illness (metabolic disorders)
3. Able to understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism.
4. Able to know the biochemical principles of organ function tests of kidney, liver and endocrine gland.
5. Able to do the qualitative analysis and determination of biomolecules in the body fluids.

Text books (Theory)

1. Harpers review of biochemistry - Martin
2. Text book of biochemistry – D.Satyanarayana
3. Text book of clinical chemistry- Alex kaplan &Laverve L.Szabo

Reference books (Theory)

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

Detailed syllabus and lecture wise schedule

No.	Title of the topic	No.of hours
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.	**4Hrs**
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.	**6Hrs**
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.	**6Hrs**
4.	**Lipid metabolism:** Oxidation of saturated (β-oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolmiea).	**5Hrs**
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;	**3Hrs**
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.	**5Hrs**
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.	**6Hrs**
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)	**3Hrs**

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.	**4Hrs**
11	**Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides	**2Hrs**
12	**Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases. Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)	**3Hrs**
13	**Electrolytes:** Body water, compartments, water balance, and electrolyte distrubution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.	**3Hrs**
	Total	**50hrs**

Practicals

No	***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- Minimum & Maximum number of pages
  - It shall be computer draft copy
  - Reference(s) shall be included at the end.
  - Name and signature of the student
  - Assignment can be a combined presentation at the end of the academic year
  - Time allocated for presentation may be 8+2 Min

Scheme of Practical Examination

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

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

1.4 Pharmaceutical Organic Chemistry- I
Theory 75 hrs Practical 75hrs

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
   b. Free radical/ nucleophyllic [alkyl/ acyl/ aryl] /electrophyllic substitution, free radical/ nucleophyllic / electrophyllic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds.
   c. Some named organic reactions with mechanisms
   d. 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

2. Lecture wise programme:

	TOPICS	hr
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	-4
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
3	Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability	- 1
4	Alicyclic compounds: Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.	-3
5	Nuclophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN_2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents	- 5
6	Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation	- 3
7	Electrophillic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydin formation, mechanism of free radicals additon, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.	- 3
8	Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes,	- 4
9	orientation and reactivity, allylic rearrangements Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substituion 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	- 4
10	Elecrophilic 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	-5
11	chain halogination of alkyl benzene, resonance stabilization of benzyl radical	-3
	Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.	
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.	- 3
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	- 3
14	reaction, Reimer tieman's reactions	
15	Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.	- 3
16	Oxidation reduction reaction	- 2
	Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihyrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate, saccharin sodium, mephensin	- 6
	Total =	55

Pharmaceutical Organic chemistry-I – Practicals

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

1. *Acetanilde / aspirin (Acetylation)*
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)

5. 1-Phenylazo-2-napthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Antharaquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotolune
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by
Systematic qualitative organic analysis including preparation of derivatives
Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitro compounds

III Introduction to the use of stereo models
Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination

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

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

1.5 Pharmaceutical Inorganic Chemistry
Theory 50hrs **Practicals 75hrs**

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.

Upon completion of the course student shall be able
1. To under stand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals.
2. To know the analysis of the inorganic pharmaceuticals their applications.
3. To appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

2. 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. Pharmaaceutical 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

3. Lecture wise programme:

NO	TOPICS	HOURS
1	Errors	03
2	Volumetric analysis	02
3	*Acid-base titrations*	06
4	Redox titrations	06
5	Non aqueous titrations	02
6	Precipitation titrations	03
7	Complexometric titrations	03
8	Theory of indicators	03
9	Gravimetry	06
10	Limit tests	03
11	Medicinal gases	03
12	Acidifiers	01
13	Antacids	06
14	Cathartics	02
15	Electrolyte replenishers	05
16	Essential Trace elements	02
17	Antimicrobials	06
18	Pharmaceutical aids	02
19	Dental Products	03
20	Miscellaneous compounds	02
21	Radio Pharmaceuticals	05
	Total =	74

Pharmaceutical Inorganic chemistry – Practicals

I. Limit test (6 exercises) 18 hrs

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

II. Assays (10 exercises) 30 hrs

1. Ammonium chloride- Acid-base titration
2. Ferrous sulphate- Cerimetry
3. Copper sulpahte- Iodometry
4. Calcilugluconate- Complexometry
5. Hydrogen peroxide – Permanganometry

6. Sodium benzoate – Nonaqueous titration
7. Sodium chloride – Modified volhard's method
8. Assay of KI – KIO_3 titration
9. Gravimetric estimation of barium as barium sulphate
10. Sodium antimony gluconate or antimony potassium tartarate

III. Estimation of mixture (Any two exercises) 06 hrs

1. Sodium hydroxide and sodium cabonate
2. Boric acid and Borax
3. Oxalic acid and sodium oxalate

IV Test for identity (Any three exercises) 09 hrs

1. Sodium bicorbonate
2. Barium sulphate
3. Ferrous sulphate
4. Potassium chloride

V Test for purity (Any two exercises) 06 hrs

1. Swelling power in Bentonite
2. Acid neutralising capacity in aluminium hydroxide gel
3. Ammonium salts in potash alum
4. Adsorption power heavy Kaolin
5. Presence of Iodates in KI

VI Preparations (Any two exercises) 06 hrs

1. Boric acids
2. Potash alum
3. Calcium lactate
4. Magnesium suphate

Scheme of Practical Examination

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment1&2	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

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

1.6 Mathematics

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

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

- Know Trignometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications

- solve the problems of different types by applying theory
- appreciate the important applications of mathematics in pharmacy

2. Course materials:

Text books

a. Differential calculus By Shantinarayan
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

3. Lecture wise programme :

NO	TOPICS	HOURS
1	**Algebra :** Determinants, Matrices	15
2	**Trigonometry :** Sides and angles of a triangle, solution of triangles	05
3	**Analytical Geometry :**Points, Straight line, circle, parabola	10
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	15
5	**Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.	08
6	**Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.	14
7	**Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.	08
	Total =	75

1.6 Biology

Theory 75hrs

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 introduces 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.

1. 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.

2. Lecture wise programme :

NO	TOPIC	Hrs
	PART – A	
01	Introduction	01
02	General organization of plants and its inclusions	03
03	Plant tissues	02
04	Plant kingdom and its classification	02
05	Morphology of plants	02
06	Root, Stem, Leaf and Its modifications	04
07	Inflorescence and Pollination of flowers	03
08	Morphology of fruits and seeds	02
09	Plant physiology	03
10	Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae	06
11	Study of Fungi, Yeast, Penicillin and Bacteria	02
	PART-B	
01	Study of Animal cell	01
02	Study animal tissues	02
03	Detailed study of frog	07
04	Study of Pisces, Raptiles, Aves	04
05	Genearal organization of mammals	04
06	Study of poisonous animals	02

Biology – Practicals

	Title	Hours
1.	Introduction of biology experiments	02
2.	Study of cell wall constituents and cell inclusions	04
3.	Study of Stem modifications	04
4.	Study of Root modifications	04
5.	Study of Leaf modifications	04
6.	Identification of Fruits and seeds	02
7.	Preparation of Permanent slides	02
8.	T.S. of Senna, Cassia, Ephedra, Podophyllum.	06
9.	Simple plant physiological experiments	04
10.	Identification of animals	02
11.	Detailed study of Frog	12
12.	Computer based tutorials	04
	Total =	100

Scheme of Practical Examination

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

* 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)

Scope of the Subject: (4-6 lines) 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.

Objectives of the Subject

Upon completion of the subject student shall be able to

(Know, do, and appreciate)

1. Describe the etiology and pathogenesis of the selected disease states
2. Name the signs and symptoms of the diseases.
3. Mention the complications of the diseases.

Text books (Theory)

i) Pathologic basis of disease by- Cotran, Kumar, Robbins
ii) Text book of Pathology- Harsh Mohan
iii) Text book of Pathology- Y.M. Bhinde

Reference books (Theory)

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

Detailed syllabus and lecture wise schedule

No.	Title of the topic	Hours
1.	**Introduction to basic pathology;** Definition of pathology, terminologies used in pathology and subdivisions of pathology	1hr
2.	**Basic Principles of cell injury and adaptation** Definition, Etiology, Pathogenesis and morphology of cell injury	3hrs
3.	**Inflammation** 1. Definition, types and etiology of Inflammation 2. Pathogenesis of acute and chronic inflammation 3. Repairs of wounds in the skin, factors influencing healing of wounds	3 hrs
4.	**Hypersensitivity** Definition and classification of hypertension; Hypersensitivity type I, II, III, IV with examples Biological significance of hypersensitivity Allergy due to food	4hrs
5.	**Autoimmunity** 1. Definition of autoimmunity 2. Classifications of autoimmune diseases in man with examples, 3. Mechanism of autoimmunity	2 hrs
6.	**Pathophysiology of common diseases** (Definition, Types, Etiology, Pathogenesis, signs and symptoms and Complications of following diseases) 1. Hypertension 2. Stroke 3. Angina	 1hr 1hr 1hr 1hr

	4. CCF 5. Atherosclerosis 6. Myocardial Infarction 7. Diabetes 8. Thyroid disorders 9. Peptic ulcer 10. Hepatitis - infective hepatitis, Alcoholic liver diseases 11. Acute and chronic renal failure 12. Asthma 13. Chronic obstructive Pulmonary disease (COPD) 14. Rheumatoid arthritis 15. Epilepsy 16. Depression and Mania 17. Parkinson's Disease 18. Schizophrenia 19. Anemia	1hr 1hr 1hr 1hr 1hr 2hr 2hr 1hr 1hr 1hr 1hr 1hr 1hr 1hr 1hr
7.	**Pathophysiology of Infectious diseases** (Definition, Etiology, Pathogenesis, signs and symptoms of following diseases) 1. AIDS 2. Urinary tract infections (UTI)1hr 3. Pneumonia 4. Tuberculosis 5. Leprosy 6. Malaria 7. Dysentery: Bacterial and Amoebic dysentery	 1hr 1hr 1hr 1hr 1hr 1hr 1hr
8.	**Neoplasia** Classification, differences between benign and malignant Tumors Etiology and pathogenesis of cancer Invasions and metastasis, patterns of spread of cancer, disturbances of growth of cells, general biology of tumors, spread of malignant tumors,	8 hrs
	Total =	48

50hrs

Assignments

No	***Title of the Experiment***
1.	Chemical Mediators of inflammation
2	Drug Hypersensitivity
3	Cigarette smoking & its ill effects
4	Biological Effects of Radiation
5	Etiology and hazards of obesity
6	Complications of diabetes
7	Diagnosis of cancer
8	Disorders of vitamins
9	Methods in Pathology-Laboratory values of clinical significance
10	Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Assignments

Format of the assignment

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

Pharmaceutical Microbiology

Theory 75 hrs **Practical 75hrs**

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.

Objectives of the Subject

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

- **To know**
- The anatomy, identification, growth factors and sterilization of microorganisms
- The mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect

- **To do**
- Estimation of RNA and DNA and there by identifying the source.
- Cultivation and identification of the microorganisms in the laboratory.
- Identification of diseases by performing the diagnostic tests.

- **To appreciate**
- The behavior of motility and behavioral characteristics of microorganisms.

Text books (Theory)

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

Reference books (Theory)

1) Prescot L.M., Jarley G.P Klein D.A "Microbiology" 2nd- edition Mc Graw Hill Company Inc
2) Rawlins E.A."Bentley's Text Book of Pharmaceutics" B ailliere Tindals 24-28

London 1988
3) Forbisher " Fundamentals of Microbiology" Philidelphia W.B. Saunders.
4) Prescott L.M. Jarley G.P., Klein.D.A. " Microbiology."2nd edition WMC Brown Publishers, Oxford. 1993
5) War Roitt, Jonathan Brostoff, David male, " Immunology"3rd edition 1996, Mosby-year book Europe Ltd, London.
6) Pharmacopoeia of India, Govt of India, 1996.

Detailed syllabus and lecture wise schedule

No.	Title of the topic	No.of hours
1.	Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.	2 hrs
2.	Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.	10 hrs
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.	8 hrs
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.	8 hrs
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.	7 hrs
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	6 hrs
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	10 hrs
8.	Diagnostic tests: Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite	6 hrs
9.	Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B_2 and B_{12}. Standardisation of vaccines and sera.	8 hrs
10	Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV	10 hrs
	Total	**75 Hours**

Practicals

No	***Title of the Experiment***
1.	Study of apparatus used in experimental microbiology*.
2	Sterilisation of glass ware's. Preparation of media and sterilisation.*
3	Staining techniques – Simple staining ; Gram's staining ; Negative staining**
4	Study of motility characters*.
5	Enumeration of micro-organisms (Total and Viable)*
6	Study of the methods of isolation of pure culture.*
7	Bio chemical testing for the identification of micro*-organisms.
8	Cultural sensitivity testing for some micro-organisms.*
9	Sterility testing for powders and liquids.*
10	Determination of minimum inhibitory concentration.*
11	Microbiological assay of antibiotics by cup plate method.*
12	Microbiological assay of vitamins by Turbidometric method**
13	Determination of RWC.**
14	Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments

- Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same
- Visit to milk dairies (Pasturization) and microbial laboratories(other sterization methods) & study the activities and equipment/instruments used and reporting the same
- Library assignments
  1. Report of recent microbial techniques developed in diagnosing some common diseases
  2. Latest advancement developed in identifying, cultivating & handling of microorganisms.
- Format of the assignment- Minimum & Maximum number of pages
  - It shall be computer draft copy
  - Reference(s) shall be included at the end.
  - Name and signature of the student
  - Assignment can be a combined presentation at the end of the academic year
  - Time allocated for presentation may be 8+2 Min

Scheme of Practical Examination

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

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

2.3 PHARMACOGNOSY & PHYTO PHARMACEUTICALS

Theory 75 hrs **Practical 75hrs**

1. **Scope and objectives**: This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

2. Upon completion of the course student shall be able

1. To under stand the basic principles of cultivation, collection and storage of crude drugs.
2. To know the source, active constituents and uses of crude drugs.
3. To 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
c. Pharmacognosy by M.A. Iyengar

4. Lecture wise programme :

No	Topics	Hours
1	Introduction.	1
2	Definition, history, and scope of Pharmacognosy.	1
3	Classification of crude drugs.	4
4	Cultivation, collection, processing and storage of crude drugs.	4
5	Detailed method of cultivation of crude drugs	4
6	Study of cell wall constituents and cell inclusions.	2
7	Microscopical and powder Microscopical study of crude drugs.	8
8	Study of natural pesticides.	2
9	Detailed study of various cell constituents	2
10	Carbohydrates and related products	4
11	Detailed study carbohydrates containing drugs.(11 drugs)	5
12	Definition sources, method extraction, chemistry and method Of analysis of lipids	4
13	Detailed study of oils	3
14	Definition, classification, chemistry and method of analysis of protein	2
15	Study of plants fibers used in surgical dressings and related products	2
16	Different methods of adulteration of crude drugs	2
	Total =	50

Pharmacognosy – Practicals

General Requirements: Laboratory Napkin, Observation Book 150pages 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.
20) *Determination of ester value.*
21) *Determination of Acid value.*
22) Chemical test for Acacia.
23) Chemical test for Tragacanth.
24) Chemical test for Agar.
25) Chemical test for Starch.
26) Chemical test for Lipids. (castor oil,sesame oil, shark liver oil,bees wax)
27) Chemical test for Gelatin.

Scheme of Practical Examination

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

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

2.4 Pharmacology – I

Theory: 75hrs

Scope of the Subject: (4-6 lines): 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.

Objectives of the Subject

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

1. To understand the pharmacological aspects of drugs falling under the above mentioned chapters.
2. To handle and carry out the animal experiments.
3. To appreciate the importance of pharmacology subject as a basis of therapeutics.
4. To correlate and apply the knowledge therapeutically.

Text books (Theory) *(Author, Title, Edition, Publication Place, Publisher, Year of Publication)*

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

Reference books (Theory) *(Author, Title, Edition, Publication Place, Publisher, Publication Year)*

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

Practical

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

Reference books (Practical)

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

3. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
4. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
5. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

Detailed syllabus and lecture wise schedule

No.	Title of the topic	No.of hours
1.	General Pharmacology	
	a) Introduction, definitions and scope of pharmacology	1
	b) Routes of administration of drugs	1
	c) Pharmacokinetics (absorption, distribution, metabolism and excretion)	6
	d) Pharmacodynamics	4
	e) Factors modifying drug effects	1
	f) Drug toxicity - Acute, sub- acute and chronic toxicity.	2
	g) Pre-clinical evaluations	1
	h) Drug interactions	1
	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	5
	b) Cholinergic and anticholinergic drugs	5
	c) Neuromuscular blockers	1
	d) Mydriactics and miotics	1
	e) Drugs used in myasthenia gravis	1
	f) Drugs used in Parkinsonism	1
		1
3.	Pharmacology of drugs acting on cardiovascular system	
	a) Antihypertensives	2
	b) Anti-anginal drugs	2
	c) Anti-arrhythmic drugs	2
	d) Drugs used for therapy of Congestive Heart Failure	2
	e) Drugs used for hyperlipidaemias	1
4.	Pharmacology of drugs acting on Central Nervous System	
	a) General anesthetics	2
	b) Sedatives and hypnotics	3
	c) Anticonvulsants	2
	d) Analgesic and anti-inflammatory agents	4
	e) Psychotropic drugs	5
	f) Alcohol and methyl alcohol	2
	g) CNS stimulants and cognition enhancers	2
	h) Pharmacology of local anaesthetics	1

5.	Pharmacology of Drugs acting on Respiratory tract a)Bronchodilators, b)Mucolytics, c)expectorants, d)Antitussives, e)NasalDecongestants	4
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	 2 2 2 1
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	 1 1 1
	Total:	**75hrs**

2.5 Community Pharmacy

Theory 50 hrs

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 counselling, health screening services for improved patient care in the community set up.

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 counselling & provide health screening services to public in community pharmacy
- Respond to minor ailments and provide appropriate medication.
- Show empathy and sympathy to patients
- Appreciate the concept of Rational drug therapy

Text Books:

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

Reference books:

a. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins

Special requirements:

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

Scheme of evaluation (For 80 Marks)

1. Synopsis 10
2. Major Experiment 30
   (Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion)
3. Minor Experiment (Ability to measure B.P/ CBG / Lung function) 15
4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management) 15
5. Viva – Voce 10

Community Pharmacy (50hrs.)

S.No	Lecture wise programme	No. of Hrs.
1	**Definition, scope, of community pharmacy** **Roles and responsibilities of Community pharmacist**	**2**
2	**Community Pharmacy Management** i) Selection of site, Space layout, and design ii) Staff, Materials- coding, stocking iii) Legal requirements iv) Maintenance of various registers iv) Use of Computers: Business and health care soft wares	**6**
3	Prescriptions – parts of prescription, legality & identification of medication related problems like drug interactions.	**2**
4	**Inventory control in community pharmacy** Definition, various methods of Inventory Control **ABC, VED, EOQ, Lead time, safety stock**	**2**
5	**Pharmaceutical care** Definition and Principles of Pharmaceutical care.	**2**
6	**Patient counselling** Definition, outcomes, various stages, barriers, Strategies to overcome barriers Patient information leaflets- content, design, & layouts, advisory labels	**5**
7	**Patient medication adherence** Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.	**2**
8	**Health screening services** Definition, importance, methods for screening Blood pressure/ blood sugar/ lung function And Cholesterol testing	**3**
9	***OTC Medication- Definition, OTC medication list & Counselling***	***1***
10	**Health Education** WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients. Commonly occurring Communicable Diseases, causative agents, Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS Balance diet, and treatment & prevention of deficiency disorders Family planning – role of pharmacist	**17**

11	**Responding to symptoms of minor ailments**	**5**
	Relevant pathophysiology, common drug therapy to, Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms, worms infestations.	
12	**Rational drug therapy**	**2**
	Role of community pharmacist	
13	**Code of ethics for community pharmacists**	**1**
	Total =	**45**

2.6 Therapeutics-I

Theory: 75 Hrs **Practicals: 75 Hrs.**

Scope of the Subject: (4-6 lines)**:** 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.

Objectives:

At completion of this subject it is expected that 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)

TEXT BOOKS

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

REFERENCE BOOKS

1. Pathologic basis of disease - Robins SL, W.B.Saunders publication
2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
3. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication

4. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
5. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
6. Relevant review articles from recent medical and pharmaceutical literature.

Detailed syllabus and lecture wise schedule

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

No.	Title of the topic	No. of hours
1.	1.1 Cardiovascular system Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias	30 [6+5+6+5+3+ 5]
2	1.2 Respiratory system Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases	12 [1+5+4+2]
	Endocrine system Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis	20 [6+5+3+3+3]
3	General prescribing guidelines for 2.1 Paediatric patients 2.2 Geriatric patients 2.3 Pregnancy and breast feeding	10 [2+3+5]
4	Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial	3
5	Introduction to rational drug use Definition, Role of pharmacist Essential drug concept Rational drug formulations	3 1+1+1
	Total =	78

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.

Assignments

Format of the assignment

- Minimum & Maximum number of pages
- Reference(s) shall be included at the end.
- Assignment can be a combined presentation at the end of the academic year
- It shall be computer draft copy
- Name and signature of the student
- 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
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

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

Third Year

3.1 Pharmacology - II

Theory: 75 Hrs. **Practicals: 75 Hrs.**

Scope of the Subject: (4-6 lines): This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autocoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamines, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

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

1. To understand the pharmacological aspects of drugs falling under the above mentioned chapters.
2. To carry out the animal experiments confidently.
3. To appreciate the importance of pharmacology subject as a basis of therapeutics.
4. To correlate and apply the knowledge therapeutically.

Text books (Theory)

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

Reference books (Theory)

1. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
2. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
3. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
4. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

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

Reference books (Practical)

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

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

Detailed syllabus and lecture wise schedule

No.	Title of the topic	Hours
1.	Pharmacology of Drugs acting on Blood and blood forming agents a) Anticoagulants b) Thrombolytics and antiplatelet agents c) Haemopoietics and plasma expanders	 2 2 1
2.	Pharmacology of drugs acting on Renal System a) Diuretics b) Antidiuretics	 2 1
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)	 1 1 6 2 4 2 1 2 3 2 2 1 4
4	Immunopharmacology a) Pharmacology of immunosuppressants and stimulants	 2
5.	Principles of Animal toxicology Acute, sub acute and chronic toxicity	 2
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.	16

	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. d) RNA processing: rRNA, tRNA and mRNA processing. Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events e) Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes. f) 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	16

Total: 75hrs

Books:

1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition
3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
4 Genes VIII by Lewin, B., (2004)
5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

3.2 Pharmaceutical Analysis

Theory 75 hrs **Practicals 75 hrs**

1. **Quality Assurance:** **8 hr.**
   - 1.1 Introduction, sources of quality variation, control of quality variation.
   - 1.2 Concept of statistical quality control.
   - 1.3 Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
   - 1.4 GLP, ISO 9000.
   - 1.5 Total quality management, quality review and documentation.
   - 1.6 ICH- international conference for harmonization-guidelines.
   - 1.7 Regulatory control

2. **Chromatography:** **15 hr.**

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.

2.1 **Column Chromatography**: Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.

2.2 **TLC**: Introduction, principle, techniques, R_f value and applications.

2.3 **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.

2.4 **Ion-exchange chromatography**: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.

2.5 **HPLC**: Introduction, theory, instrumentation, and applications.

2.6 **HPTLC**: Introduction, theory, instrumentation, and applications.

2.7 **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.

2.8 **Electrophoresis**: Principles of separation, equipment for paper and gel electrophoresis, and application.

2.9 **Gel filtration** and **affinity chromatography**: Introduction, technique, applications.

3. **Electrometric Methods:** **10 hr.**

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

3.1 **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.

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

3.3 **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.

3.4 **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:

4.1 A. **Absorption Spectroscopy:** **15 hr.**

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.

B. **Infrared Spectroscopy**: Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectro-meter – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors–Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

C. **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry. **4 hr.**

4.2 **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications. **3 hr.**

4.3 **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications. **3 hr.**

4.4 **Atomic Emission Spectroscopy**: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection. **2 hr.**

4.5 **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications. **4 hr.**

4.6 **Mass Spectroscopy**: (**Introduction only**) – Fragmentation, types of ions produced mass spectrum and applications. **2 hr.**

4.7 **Polarimetry: (Introduction only**) – Introduction to optical rotatory dispersion, circular dichroism, polarimeter. **2 hr.**

4.8 **X-RAY Diffraction: (Introduction only**) – Theory, reciprocal lattice concept, diffraction patterns and applications. **2 hr.**

4.9 **Thermal Analysis**: Introduction, instrumentation, applications, and DSC and DTA. **2 hr.**

Total = 66

PRACTICALS (75 hr.)

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.

5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of a acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC
19. Demonstration of HPTLC
20. Demonstration of GC-MS
21. Demonstration of DSC
22. Interpretation of NMR spectra of any one compound.

Reference 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. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.

Practicals

No	*Title of the Experiment*
1	Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.**
2	To study the effects of drugs on intestinal motility using frog's esophagus model*
3	To study the effects of drugs using rat uterus preparation.**
4	To study the anticonvulsant property of drugs (any one model).*
5	To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
6	To study the apomorphine-induced compulsive behaviour (stereotypy) in mice.*
7	To study the muscle relaxant property of diazepam in mice using rotarod apparatus.*
8	To study the antiinflammatory property of indomethacin against carrageenan-induced paw oedema.**
9	To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.**
10	To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
11	To study the effect of anthelmintics on earthworms.
12	To study the taming effect of chlorpromazine.*
13	To study the effects of drugs on vas deferense of the male rat.**
14	To study the effect of drugs on pesticide toxicity using rats as model.
15	To study the effect of drugs on heavy metal toxicity.

** indicate major experiment & * indicate minor experiment

Scheme of Practical Examination

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

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

3.3 Pharmacotherapeutics-II

Theory: 75 hrs **Practical: 75 Hrs**

Scope of the Subject: (4-6 lines) **:** 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.

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

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)

Text book (Theory)

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

Reference books (Theory)

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

Detailed syllabus and lecture wise schedule

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases

No.	Title of the topic	No. of hours
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, Gonarrhoea and Syphillis	**39** [2+3+3+5+4+2 +2+3+2+6+2+ 3+2]
2	**Musculoskeletal disorders** Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.	**10** [3+3+2+1+1]
3	**Renal system** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders	**9** [3+2+2+2]
4	**Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis	**12** [2+2+3+3+2]
5	**Dermatology:** Psoriasis, Scabies, Eczema, Impetigo	**4**
	Total =	**74**

PRACTICALS

Hospital postings for a period of at least one month 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.

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

- Minimum & Maximum number of pages
- Reference(s) shall be included at the end.
- Assignment can be a combined presentation at the end of the academic year
- It shall be computer draft copy
- Name and signature of the student
- 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
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

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

3.4 PHARMACEUTICAL JURISPRUDENCE

Theory 50 hrs

Scope of the Subject: (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The D and C 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.

Objectives of the Subject

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

1. To Practice the Professional ethics.
2. To understand the various concepts of the pharmaceutical legislation in India.
3. To know the various parameters in the Drug and Cosmetic Act and rules.
4. To know the Drug policy, DPCO, Patent and design act.
5. To understand the labeling requirements and packaging guidelines for drugs & cosmetics.
6. To be able to understand the concepts of Dangerous drugs act, Pharmacy Act and Excise duties act.
7. Other laws as prescribed by the PCI from time to time including International Laws.

Text books (Theory)

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

Reference books (Theory)

1. **Si**ngh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics**.** Allahabad: Law Book House; 1984.
2. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
3. Reports of the Pharmaceutical enquiry Committee
4. I.D.M.A., Mumbai. DPCO 1995

5. Various reports of Amendments.
6. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
7. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

Detailed syllabus and lecture wise schedule

No.	Title of the topic	hours
1.	Pharmaceutical Legislations – A brief review.	03
2.	Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.	02
3.	Drugs and Cosmetics Act, 1940,and its rules 1945. Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, E1, F&F1, F2, F3, FF, G, H, M, N, P, R, W, X. 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.	 07 07 02 02 02
4.	Pharmacy Act –1948. Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.	05
5.	Medicinal and Toilet Preparation Act –1955. Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations.	04
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.	05
7.	Study of Salient Features of Drugs and magic remedies Act and its rules.	02
8.	Study of essential Commodities Act Relevant to drugs price control Order.	01
9.	Drug Price control Order & National Drug Policy (Current).	04
10	Prevention Of Cruelty to animals Act-1960.	01
11	Patents & design Act-1970.	01
12	Brief study of prescription and Non-prescription Products.	01
	Total =	49

Assignments

Format of the assignment

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

1. Case studies relating to D and C Act and rules along with its amendments, Dangerous drugs act, medicinal and toilet preparation Act, new drug policy, professional ethics, DPCO, patent and design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories
4. Diagnostic aids and appliances available in the market.

3.5 Medicinal Chemistry

THEORY 75 hrs **Practical 75 Hrs**

I. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationaship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules. **4 hr.**

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

II. Anti-infective agents
   a) Local anti-infective agents **3 hr.**
   b) Preservatives **1 hr.**
   c) Antifungal agents **2 hr.**
   d) Urinary tract anti-infectives **2 hr.**
   e) Antitubercular agents **3 hr.**
   f) Antiviral agents and Anti AIDS agents **2 hr.**
   g) Antiprotozoal agents **2 hr.**
   h) Anthelmentics **2 hr.**
   i) Antiscabies and Antipedicular agents **1 hr.**

III. Sulphonamides and sulphones **4 hr.**
IV. Antimalarials **4 hr.**
V. Antibiotics **11 hr.**
VI. Antineoplastic agents **5 hr.**
VII. Cardiovascular agents
   a) Antihypertensive agents **4 hr.**
   b) Antianginal agents and vasodilators **3 hr.**
   c) Antiarrhythmic agents **3 hr.**
   d) Antihyperlipidemic agents **2 hr.**
   e) Coagulants and Anticoagulants **3 hr.**
   f) Hypoglycemic agents **2 hr.**
   g) Thyroid and Antithyroid agents **2 hr.**
VIII. Diureties **4 hr.**
IX. Diagnostic agents **2 hr.**
X. Steroidal Hormones and Adrenocorticoids **4 hr.**

Total = 75 hr.

PRACTICALS (75 hr.) **3 hr./week**

I. Assays of important drugs from the course content.
II. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
III. Monograph analysis of important drugs.
IV. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Reference Books:

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

3 .6 Pharmaceutical dosage forms

Theory 50hrs. **Practicals 50hrs**

Scope of the Subject: (4-6 lines) Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.

Objectives of the Subject

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

1.To understand the principle involved in formulation of various pharmaceutical dosage forms
2.To prepare various pharmaceutical formulation
3.To perform evaluation of pharmaceutical dosage forms
4.To understand & appreciate concept of bioavailability & bioequivalence, their role in clinical situations

Text books (Theory)

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

Reference books (Theory)

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

Detailed syllabus and lecture wise schedule

No.	Title of the topic	hours
1.	Pharmaceutical dosage form- concept and classification	01
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.	10
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.	08
4.	**Liquid orals**: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations	05
5.	**Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization	10
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	05
7.	Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parentral, trans dermal, buccal, rectal, nasal, implants, ocular	11
	Total	**50 hours**

Fourth Year

4.1 PHARMACOTHEAPEUTICS -III

Theory: 75 Hrs **Practical: 75 Hrs.**

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.

Objectives:
At completion of this subject it is expected that 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. Summarize 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)

TEXT BOOKS

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

REFERENCE BOOKS

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

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

No.	Title of the topic	No. of hours
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.	19 [6+4+6+3]
2	**Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.	12 6+4+2
3	**Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,	16 [6+4+4+2]
4	**Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders	14 [4+5+3+1+1]
5	Pain management including Pain pathways, neuralgias, headaches.	8 3+1+4
6	Evidence Based Medicine	5
	Total =	**74**

Text books

1. Clinical Pharmacy and Therapeutics: Roger Walker and Clive Edwards. 3rd Edn. Churchill Livingstone, Edinburgh, 2003.
2. Textbook of therapeutics, Drug and disease management: Eric T Herfindal. 7th Edn. Williams & Wilkins Publications 2003.
3. Pharmacotherapy, A Pathophysiologic Approach: Joseph T Dipiro. 5th Edn. McGraw-Hill Medical publishing division 2002.
4. Applied therapeutics: Mary Anne Koda-Kimble, Lloyd Yee Young et al, 8th Edn. Lippincott Williams and Wilkins publications 2005.
5. Avery's Drug Treatment: Trevor M Speight, Nicholas HG et al, 4th Edn. Adis International Ltd. 1997.
6. Basic and Clinical Pharmacology: Bertram G Katzung, 9th Edn. Lange Medical Publications, 2004.
7. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

Reference books:

1. Principles of Internal Medicine: Harrisons: Braunwald et al, 16th Edn. Mc Graw Hill Publications, 2005
2. Pathological Basis of Disease: Robins SL, 7th Edn. WB Saunders Publications, 2004
3. Current Medical Diagnosis Treatment: Tierney et al, 44th Edn. Lange Medical Publications, 2005.
4. American Hospital Formulary Services: GK Mc Evoy, Published by American Society of Hospital Pharmacists, 2004.
5. Davidsons Principles and Practice of Medicine: Christopher Haslett, et al, 19th Edn. Churchill Living stone Publicatios, 2002.
6. Journals relevant to respective therapeutic areas.

4. 2 Hospital Pharmacy

Theory 50 hrs **Practical 75hrs**

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 counselling, 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
- Know the professional practice management skills in hospital pharmacies.
- Provide unbiased drug information to the doctors
- Know the manufacturing practices of various formulations in hospital set up.
- Appreciate the practice based research methods.
- Appreciate the stores management and inventory control.

Textbooks: (latest editions)

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

References:

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

S.No	Lecture wise programme	No. of Hrs.
1	Hospital - its Organisation and functions	2
2	Hospital pharmacy-Organisation and management	7
	a) Organizational structure-Staff, Infrastructure & work load statistics	4
	b) Management of materials and finance	2
	c) Roles & responsibilities of hospital pharmacist	1
3	The Budget – Preparation and implementation	2
4	Hospital drug policy	7
	a) Pharmacy and Therapeutic committee (PTC)	1
	b) Hospital formulary	1
	c) Hospital committees- infection committee -Research and ethical committee	2
	d) developing therapeutic guidelines	2
	e) Hospital pharmacy communication - Newsletter	1
5	Hospital pharmacy services	11
	a) Procurement & warehousing of drugs and Pharmaceuticals	3
	b) Inventory control	4
	Definition, various methods of Inventory Control	
	ABC, VED, EOQ, Lead time, safety stock	

	c) Drug distribution in the hospital	2
	i) Individual prescription method	
	ii) Floor stock method	
	iii) Unit dose drug distribution method	
	d) Distribution of Narcotic and other controlled substances	1
	e) Central sterile supply services – Role of pharmacist	1
6	Manufacture of Pharmaceutical preparations	15
	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	1
	Education and training	
8	Radio Pharmaceuticals – Handling and packaging	2
10	Professional Relations and practices of hospital pharmacist	2

Practicals

(3 hours / week)

1. Assessment of drug interactions in the given prescriptions	4
2. Manufacture of parenteral formulations, powders.	8
3. Drug information queries.	4
4. Inventory control	2
Total =	**88**

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

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

Scheme of Practical Examination

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

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

4.3 Clinical Pharmacy

Theory-75 Hrs **Practicals: 75 Hrs**

Objectives of the Subject

Upon completion of the subject student shall be able to

(Know, do, appreciate)

1. Monitor drug therapy of patient through medication chart review and clinical review
2. Obtain medication history interview and counsel the patients
3. Identify and resolve drug related problems
4. Detect, assess and monitor adverse drug reaction
5. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
6. Retrieve, analyse, interpret and formulate drug/medicines information

Text books (Theory)

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

REFERENCES

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

Detailed syllabus and lecture wise schedule

No	Title of the topic	No.of hours
1.	**Definitions, development and scope of clinical pharmacy**	**3**
2.	**Introduction to daily activities of a clinical pharmacist** • Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions) • Ward round participation • Adverse drug reaction management • Drug information and poisons information • Medication history • Patient counselling • Drug utilisation evaluation (DUE) and review (DUR) * Quality assurance of clinical pharmacy services	**13** [3+1+1+ 1+2+2+2 +1]

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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.	**3**
4.	**Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results** • Haematological, Liver function, Renal function, thyroid function tests • Tests associated with cardiac disorders • Fluid and electrolyte balance • Microbiological culture sensitivity tests • Pulmonary Function Tests	**15** [2+2+2+ 1+2+2+2 +2]
5.	**Drug & Poison information**	**8**
	• Introduction to drug information resources available, • Systematic approach in answering DI queries • Critical evaluation of drug information and literature • Preparation of written and verbal reports • Establishing a Drug Information Centre • Poisons information- organization & information resources	[1+1+1+ 1+2 +2]
6	• **Pharmacovigilance** Scope, definition and aims of pharmacovigilance • Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used], • Reporting, evaluation, monitoring, preventing & management of ADRs • Role of pharmacist in management of ADR.	**10**
7	• Communication skills, including patient counselling techniques, medication history interview, presentation of cases.	**10**
8	• Pharmaceutical care concepts	**4**
9	• Critical evaluation of biomedical literature	**6**
10	• Medication errors	**3**
	Total =	**75**

PRACTICALS

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

Answering drug information questions (4 Nos)

Patient medication counselling (4 Nos)

Case studies related to laboratory investigations (4 Nos)

Patient medication history interview (3 Nos)

ASSIGNMENT

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

Drug information, Patient medication history interview, Patient medication counselling, Problem solving in Clinical Pharmacokinetics, Therapeutic drug monitoring and Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment

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

4.4 Biostatistics and Research Methodology

Theory: 50 Hr

Detailed syllabus and lecture wise schedule

1	**Research Methodology**	**10**
	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**	**25**
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.	5
2.2	**Data graphics:** Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarthimic plots	2
	Basics of testing hypothesis	
2.3	a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.	14
	b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)	
	c)Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test,	

Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)

d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient.

e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 **Statistical methods in epidemiology** Incidence and prevalence, relative risk, attributable risk 4

3 **Computer applications in pharmacy** **10**

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 6

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy 3

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval 1

Total = 80

Reference books:

1.Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.

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

Biopharmaceutics and Pharmacokinetics

Theory 75 Hrs **Practical 75 Hrs**

Biopharmaceutics **(15hours)**

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

Pharmacokinetics **(12 hours)**

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

3. One compartment open model. **(8 hours)**
   a. Intravenous Injection (Bolus)

b. Intravenous infusion.

4. Multicompartment models. **(8 hours)**
   a. Two compartment open model.
   b. IV bolus, IV infusion and oral administration
5. Multiple – Dosage Regimens. **(8 hours)**
   a. Repititive Intravenous injections – One Compartment Open Model
   b. Repititive Extravascular dosing – One Compartment Open model
   c. Multiple Dose Regimen – Two Compartment Open Model
6. Nonlinear Pharmacokinetics. **(5 hours)**
   a. Introduction
   b. Factors causing Non-linearity.
   c. Michaelis-menton method of estimating parameters.
7. Noncompartmental Pharmacokinetics. **(6 hours)**
   a. Statistical Moment Theory.
   b. MRT for various compartment models.
   c. Physiological Pharmacokinetic model.
8. Bioavailability and Bioequivalence. **(13 hours)**
   a. Introduction.
   b. Bioavailability study protocol.
   c. Methods of Assessment of Bioavailability

Total = 75 hours

Clinical Toxicology

Theory 50 hrs

a. General principles involved in the management of poisoning **(10 hours)**
b. Antidotes and the clinical applications.
c. Supportive care in clinical Toxicology.
d. Gut Decontamination.
e. Elimination Enhancement.
f. Toxicokinetics.
g. Clinical symptoms and management of acute poisoning with the following agents **(20 hours)**
   i) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
   ii) Opiates overdose.
   iii) Antidepressants
   iv) Barbiturates and benzodiazepines.
   v) Alcohol: ethanol, methanol.
   vi) Paracetamol and salicylates.
   vii) Non-steroidal anti-inflammatory drugs.
   viii) Hydrocarbons: Petroleum products and PEG.
   ix) Caustics: inorganic acids and alkali.
   x) Radiation poisoning

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

i. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
j. Plants poisoning. Mushrooms, Mycotoxins.
k. Food poisonings
l. Envenomations –Arthropod bites and stings.

Substance abuse **(20 hours)**

a) Signs and symptoms of substance abuse and treatment of dependence
   i) CNS stimulants :amphetamine
   ii) Opioids
   iii) CNS depressants
   iv) Hallucinogens: LSD
   v) Cannabis group
   vi) Tobacco

Total = 50

REFERENCES:

Matthew J Ellenhorn. Ellenhorns Medical Toxicology – Diagnosis and Treatment of Poisoning. Second edition. Williams and Willkins publication, London

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

Fifth year

5.1 Clinical Research

Total: 50 hrs

1 Drug development process 10 hrs

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

Total = 50

References

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

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

5.2 Pharmacoepidemiology and pharmacoeconomics

Theory 75hrs

Pharmacoepidemiology:

Definition and scope:
Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications. **6**hrs
[2+2+2]

Measurement of outcomes in pharmacoepidemiology **5**hrs
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 **[2+3]**

Concept of risk in pharmacoepidemiology **4**hrs
Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods **18**hrs
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 **4**hrs
Ad Hoc data sources and automated data systems. **[2+2]**

Selected special applications of pharmacoepidemiology **8**hrs
Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.
[2+2+2+2]

Phrmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations **6** hrs

Role in formulary management decisions [2+4]

Pharmacoeconomic evaluation **18**hrs
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

Applications of Pharmacoeconomics **6 hrs**

Software and case studies 2+4 hrs

Total = 75

5. 3 Clinical Pharmacokinetics and Therapeutic Drug Monitoring

Theory 50hrs

1. **Introduction to Clinical pharmacokinetics. – 1 hour.**

2. **Design of dosage regimens: - 7 hours.**
   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: (3 hours)**
   a. Pharmacokinetic drug interactions
   b. Inhibition and Induction of Drug metabolism
   c. Inhibition of Biliary Excretion.

4. **Therapeutic Drug monitoring: (20 hours)**
   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. (10 hours)**
   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. (5 hours)**
   a. Introduction to Bayesian Theory.
   b. Adaptive method or Dosing with feed back.
   c. Analysis of Population pharmacokinetic Data.

7. **Pharmacogenetics (4 hours)**
   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

Total = 50

Appendix-C

INTERNSHIP

1) **SPECIFICE OBJECTIVES**

i) 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 teachnologies, and evolving biomedical, pharmaceutical, social/behavioral/administrative, and clinical sciences that may impact therapeutic outcomes.

ii) 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) Promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk populations, and other members of an interprofessional team of health care providers.

iv) Demonstrate skills in monitoring of the National Health Programme and schemes, oriented to provide preventive and promotive health care services to the community.

v) Develop leadership qualities to function effectively as a member of the health team organised to deliver the health and family welfare service in existing socio-ecomic, political and cultural environment.

v) Communicate effectively with patient and the community.

2) **OTHER DETAILS**

i) All parts of the internship shall be done as far as possible in institutions of India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on individual merit.

ii) Where an intern is posted to District Hospital for training, there shall be a committee consisting of representatives of the college/university 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/Dean of College.

iii) Every candidate will be required after passing the final Pharm.D. examination to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of 12 months so as to be eligible for the award of the degree of Pharm.D and Pharm.D and full registration.

3. **ASSESSMENT OF INTERNSHIP**

i) The intern shall maintain a record of work which is to be verified and certified by the preceptor medical officer 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/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 shall be determined on the basis of the following:-

(1) Proficiency of knowledge required for each case SCORE 0-5

(2) The competency in skills expected to manage each case:
a) Competency for performance of self performance,
b) of having assisted in Drug information and patient counselling,
c) of having observed. SCORE 0-5

(3) Responsibility, punctuality, work up of case, involvement in treatment, follow-up reports. SCORE 0-5

(4) Capacity to work in a team (Behaviour with colleagues, nursing staff and relationship with paramedicals). 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.

(7) Registration shall only be given by the State Pharmacy Councils on the award of the degree by the university or it declaration that the candidate is eligible for it.