# Scheme and Syllabus PHARM. D. & PHARM. D. (PB)

# **Batch 2019 onwards**



By Board of Studies Pharmay Department of Academics

**IK Gujral Punjab Technical University** 

# **Duration of the course**

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

# **Eligibility**

# A. Pharm. D. Course: A pass in any one of the following examinations -

- 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following subjects: Mathematics or Biology.
- A pass in D.Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.
- Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations. Provided that a student should complete the age of\17 years on or before 31st December of the year of admission to the course. Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

# B. Pharm. D. (Post Baccalaureate) Course:

- A pass in B. Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act
- Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

# First Year

Course	Course Name	L+T	P	Marks			Credits
Code				Internal	External	Total	
PD101T-19	Human Anatomy and Physiology	3+1		30	70	100	4
PD102T-19	Pharmaceutics	2+1		30	70	100	3
PD103T-19	Medicinal Biochemistry	3+1		30	70	100	4
PD104T-19	Pharmaceutical Organic Chemistry	3+1		30	70	100	4
PD105T-19	Pharmaceutical Inorganic Chemistry	2+1		30	70	100	3
PD106RM T-19/ PD106RBT -19	Remedial Mathematics#\$/Biology*\$	3+1		30	70	100	4
PD107P-19	Human Anatomy and Physiology		3	30	70	100	2
PD108P-19	Pharmaceutics		3	30	70	100	2
PD109P-19	Medicinal Biochemistry		3	30	70	100	2
PD110P-19	Pharmaceutical Organic Chemistry		3	30	70	100	2
PD111P-19	Pharmaceutical Inorganic Chemistry		3	30	70	100	2
PD112RBP	Remedial Biology*\$		3	30	70	100	2
	Total	22	15 <sup>#</sup> /18 <sup>*</sup>	330#/360*	770 <sup>#/</sup> 840*	1100#/1200*	32 <sup>#</sup> /34 <sup>*</sup>

- # Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM) course
- \*Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB) course
- \$ Non-University Examination (NUE)

# **Second Year**

Course	Course Name	L+T	P		Marks		Credits
Code				Internal	External	Total	
PD201T- 19	Pathophysiology	3+1		30	70	100	4
PD202T- 19	Pharmaceutical Microbiology	3+1		30	70	100	4
PD203T- 19	Pharmacognosy & Phytopharmaceuticals	3+1		30	70	100	4
PD204T- 19	Pharmacology-I	3+1		30	70	100	4
PD205T- 19	Community Pharmacy	2+1		30	70	100	3
PD206T- 19	Pharmacotherapeutics-I	3+1		30	70	100	4
PD207P- 19	Pharmaceutical Microbiology		3	30	70	100	2
PD208P- 19	Pharmacognosy & Phytopharmaceuticals		3	30	70	100	2
PD209P- 19	Pharmacotherapeutics-I		3	30	70	100	2
PD210P- 19	Pharmacology-I		3	30	70	100	2
	Total	23	12	300	700	1000	31

# Third Year

Course	Course Name	L+T	P		Marks		
Code				Internal	External	Total	
PD301T- 19	Pharmacology-II	3+1		30	70	100	4
PD302T- 19	Pharmaceutical Analysis	3+1		30	70	100	4
PD303T- 19	Pharmacotherapeutics-II	3+1		30	70	100	4
PD304T- 19	Pharmaceutical Jurisprudence	2		30	70	100	2
PD305T- 19	Medicinal Chemistry	3+1		30	70	100	4
PD306T- 19	Pharmaceutical Formulations	2+1		30	70	100	3
PD307P- 19	Pharmacology-II		3	30	70	100	2
PD308P- 19	Pharmaceutical Analysis		3	30	70	100	2
PD309P- 19	Pharmacotherapeutics-II		3	30	70	100	2
PD310P- 19	Medicinal Chemistry		3	30	70	100	2
PD311P- 19	Pharmaceutical Formulations		3	30	70	100	2
	Total	21	15	330	770	1100	31

# Fourth Year

Course	Course Name	L+T	P	Marks			Credits
Code				Internal	External	Total	
PD401T- 19	Pharmacotherapeutics-III	3+1		30	70	100	4
PD402T- 19	Hospital Pharmacy	2+1		30	70	100	3
PD403T- 19	Clinical Pharmacy	3+1		30	70	100	4
PD404T- 19	Biostatistics & Research Methodology	2+1		30	70	100	3
PD405T- 19	Biopharmaceutics & Pharmacokinetics	3+1		30	70	100	4
PD406T- 19	Clinical Toxicology	2+1		30	70	100	3
PD407T- 19	Pharmacotherapeutics I & II*	3+1		30	70	100	4
PD408P- 19	Pharmacotherapeutics-III		3	30	70	100	2
PD409P- 19	Hospital Pharmacy		3	30	70	100	2
PD410P- 19	Clinical Pharmacy		3		70	100	2
PD411P- 19	Biopharmaceutics & Pharmacokinetics		3	30	70	100	2
PD412P- 19	Pharmacotherapeutics I & II*		3	30	70	100	2
	Total	21/25*	12/15*	300/360*	700/840*	1000/1200*	29/35*

<sup>• \*</sup>Applicable ONLY for Pharm. D (Post Baccalaureate) Students

# Fifth Year

Course	Course Name	L+T	P		Marks		
Code				Internal	External	Total	
PD501T- 19	Clinical Research	3+1		30	70	100	4
PD502T- 19	Pharmacoepidemiology & Pharmacoeconomics	3+1		30	70	100	4
PD503T- 19	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2+1		30	70	100	3
PD504P- 19	Clerkship*\$		10	30	70	100	5
PD505P- 19	Project Work (Six Months) **		20		100	100	10
	Total	11	30	120	380	500	26

- \*Attending ward rounds on daily basis
- \*\* 30 marks viva-voce (oral) and 70 marks Thesis work
- \$ Non-University Examination (NUE)

#### Sixth Year

It is a phase of training wherein students is exposed to actual pharmacy practice or clinical pharmacy services and acquire skills under supervision so that he or she may become capable of functioning independently. Internship includes posting in specialty units. Student should independently provide clinical pharmacy services to the allotted wards. The training includes posting for six months in internal medicine wards & two months each in any three other specialty departments as prescribed by the pharmacy council of India (PCI). Interns should follow at least minimum of eight cases per week right from the day of patients' admission until discharge.

- 1. Internship or residency training including postings in speciality units
- 2. Student should independently provide the clinical pharmacy services to the allotted wards
  - 2.1 Six months in General Medicine department, and
  - 2.2 Two months each in three other speciality departments

# **Assessment of Internship**

- 1. The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practioner) under whom he/she works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him/her eligible for it.
- 2. Satisfactory completion of internship shall be determined on the basis of the following:

Assesment Criteria	Maximum Score*
Proficiency of knowledge required for each case management	05
The competency in skills expected for providing Clinical Pharmacy	05
Services	
Responsibility, punctuality, workup of case, involvement in patient care	05
Ability to work in a team (behaviour with other healthcare professionals	05
including medical doctors, nursing staff and colleagues)	
Initiative, participation in discussions, research aptitude	05

As per Pharm D Regulation 2008 under section 10 of Pharmacy Act, 1948(8 of 1948)

# Letter grades and grade points equivalent to score of internship and performances

**Evaluation Criterion:** Intern's performance is evaluated using the following scoring system

Performance of internship							
Score of internships		Letter Grade	Grade Point	Performance			
Absent	0	AB	0	Fail			
Poor	0	F	0	Fail			
Fair	1	F	0	Fail			
Below Average	2	F	0	Fail			
Average	3	В	8	Good			
Above average	4	A	9	Excellent			
Excellent	5	O	10	Outstanding			

# **Evaluation Criterion**

Intern's performance is evaluated using the following scoring system:

- A candidate has to score minimum of grade 03 in each of the assessment criteria as specified above
- A score of Grade 03 and above represents satisfactory completion of internship for award of degree as per PharmD Regulation 2008. Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948).
- However, if the candidates work is not satisfactory and the scoring is less than 03, he/she has to continue the internship to the satisfaction of the Preceptors.
- A Score of less than 03 in any of above items will represent unsatisfactory completion of internship.

# **Other Details**

- 1. All parts of the internship shall be done, as far as possible, ininstitutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.
- 2. Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee, a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.
- 3. Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

# **Semester Wise Credit Distribution**

Year	Credit Points
First	32#/34*
Second	31
Third	31
Fourth	29/35\$
Fifth	26
Sixth	Internship or residency training
Total Credit Points for the program	149#/151*/61\$

- # Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM) course
- \*Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB) course
- \$ Applicable ONLY for Pharm. D (Post Baccalaureate) Students

# Eligibility for appearing Examination

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

# **Mode of examinations**

- Theory examination shall be of three hours and practical examination shall be of four hours duration.
- A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.
- Practical examination shall also consist of a viva –voce (Oral) examination.
- Clerkship examination Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

#### Minimum marks for passing examination

- A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks.
- The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm. D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class
- Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt

# Eligibility for promotion to next year

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

# **Internship**

- Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.
- Every student has to undergo one year internship as per prescribed format to these regulations

# **Practical Training**

# 1. Hospital posting

• Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.

# 2. Project work

- To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher.
- The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth-year classes.
- Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
- Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

# **Objectives of Project Work**

The main objectives of the project work are to:

- Show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and
- Develop the students in data collection, analysis and reporting and interpretation skills.

#### Methodology

To complete the project work following methodology shall be adopted, namely:

- Students shall work in groups of not less than *two* and not more than *four* under an authorised teacher
- Project topic shall be approved by the Head of the Department or Head of the Institution
- Project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics
- Project work shall be approved by the institutional ethics committee;
- Student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
- Two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

# Reporting

- Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution
- Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.
- Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

#### **Evaluation**

The following methodology shall be adopted for evaluating the project work:

- Project work shall be evaluated by internal and external examiners
- Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students)
- Three seminars presented by students shall be evaluated for thirty marks each and the average of best two shall be forwarded to the university with marks of other subjects.
- Evaluation shall be done on the following items:

S.No.	Criteria	Maximum Marks
1	Write up of the seminar	7.5
2	Presentation of work	7.5
3	Communication skills	7.5
4	Question and answer skills	7.5
	Total	30

# Final evaluation of project work shall be done on the following items:

S.No.	Criteria	Maximum Marks
1	Write up of the seminar	17.5
2	Presentation of work	17.5
3	Communication skills	17.5
4	Question and answer skills	17.5
	Total	70

**Note:** For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers 2, 3 and 4 mentioned above.

# **Scheme of Practical Examination**

Criteria	Internal	External
Synopsis	08	20
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Regularity, promptness, and record	10	-
maintenance		
Max Marks	30	70
Duration	03hrs	04hrs

# FIRST YEAR

<b>Course Code</b>	Course	L+T	P	Marks distribution		Credits	
				External	Internal	Total	
PD101T-19	Human Anatomy and Physiology	3+1	-	70	30	100	4

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

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

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

#### **Course Materials**

#### **Textbooks**

- 1. Gerard J. Tortora and Bryan Derrickson. Principles of anatomy and physiology, Publisher: Harpercollins College New York
- 2. Anne Waught & Allison Grant. Ross and Wilson's foundations of Anatomy and Physiology in Health and Ilness. Publisher: Churchill Livingstone, Edinburg

#### Reference Books

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

# **Lecture Wise Program**

1. **Scope** of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)

- 2. **Structure of cell** its components and their functions.
- 3. **Elementary tissues of the human body**: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
- 4. **Osseous system** Structure, composition and functions of the Skeleton. (done in practical classes) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

# 5. Haemopoetic System

- a. Composition and functions of blood
- b. Process of haemopoiesis and disorders of blood components (definition of disorder)
- c. Blood groups
- d. Clotting factors and mechanism of blood clotting
- e. Platelets and disorders of coagulation (definition only)

# 6. Lymph

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

# 7. Cardiovascular system

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

# 8. Respiratory system

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

#### 9. Digestive system

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

#### 10. Nervous system

a. Definition and classification of nervous system

- b. Anatomy, physiology and functional areas of cerebrum
- c. Anatomy and physiology of cerebellum
- d. Anatomy and physiology of mid brain
- e. Thalamus, hypothalamus and Basal Ganglia
- f. Spinal card: Structure & reflexes mono-poly-planter
- g. Cranial nerves names and functions
- h. ANS Anatomy & functions of sympathetic & parasympathetic N.S.

# 11. Urinary system

- a. Anatomy and physiology of urinary system
- b. Physiology of formation of urine
- c. Renin Angiotensin system Juxtaglomerular apparatus acid base balance
- d. Clearance tests and micturition

# 12. Endocrine system

- a. Pituitary gland and their functions
- b. Adrenal gland and their functions
- c. Thyroid and Parathyroid glands and their functions
- d. Pancreas and gonads and their functions

# 13. Reproductive system

- a. Male and female reproductive system
- b. Their hormones Physiology of menstruation
- c. Spermatogenesis & Oogenesis
- d. Sex determination (genetic basis)
- e. Pregnancy and maintenance and parturition
- f. Contraceptive devices

# 14. Sense organs

- a. Eye
- b. Ear
- c. Skin
- d. Tongue & Nose

#### 15. Skeletal muscles

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

# 16. Sports physiology

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

<b>Course Code</b>	Course	L+T	P	Marks	Credits		
				External	Internal	Total	
PD102T-19	Pharmaceutics	2+1	-	70	30	100	3

**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:

- a. Know the formulation aspects of different dosage forms;
- b. Do different pharmaceutical calculation involved in formulation;
- c. Formulate different types of dosage forms; and
- d. Appreciate the importance of good formulation for effectiveness.

#### **Course Materials**

#### **Textbooks**

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

#### **Reference Books**

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

# **Lecture Wise Program**

- 1. a. Introduction to dosage forms classification and definitions
  - b. Prescription: definition, parts and handling
  - c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
- 2. History of profession of Pharmacy in India in relation to pharmacy education, industry and organization in brief.
- 3. Development of Indian Pharmacopoeia. Salient features of latest edition of IP (IP 2008) and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian National formulary.
- 4. Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions.
- 5. Powders and Granules: Classification advantages and disadvantages, Preparation of

- simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
- 6. Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like Vehicles, Organoleptic additives and Stabilizers, with examples. Study of Monophasic liquids (formulation aspects and examples) like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.
- 7. Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification and formulation of Suspensions and Emulsions. Test for the type of emulsion and stability problems in emulsions.
- 8. Suppositories: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
- 9. Galenicals: Definition, of different extraction processes like infusion, Decoction, Maceration and Percolation. Study of Maceration and Percolation processes.
- 10. Surgical aids: Surgical dressings, sutures, ligatures and preparation of surgical catgut.
- 11. Incompatibilities: Introduction, classification, Examples and methods to overcome Physical and therapeutic incompatibilities.

<b>Course Code</b>	Course	L+T	P	Marks	Marks distribution				
				External	Internal	Total			
PD103T-19	Medicinal Biochemistry	3+1	-	70	30	100	4		

**Scope and Objectives:** Biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells in normal and abnormal state. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment and prevention of diseases. The objective of the present course is providing biochemical facts and the principles to the students of pharmacy.

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

- a. Understand the catalytic activity of enzymes and importance of enzymes in diagnosis of diseases and therapeutic agents;
- b. Know the metabolic pathways of biomolecules in health and illness (metabolic disorders);
- c. Understand the genetic organization of mammalian genome, protein synthesis, replication, mutation and repair mechanism.
- d. Know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- e. Do the qualitative analysis and determination of biomolecules in the body fluids and their clinical significance.

# **Course Materials**

#### **Textbooks**

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

#### **Reference Books**

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

# **Lecture Wise Program**

- 1. **Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance
- 2. Enzymes: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity;

Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases

- 3. Carbohydrate metabolism: Glycolysis, citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, glycogenesis gluconeogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose tolerance test and its significance; hormonal regulation of carbohydrate metabolism
- 4. **Lipid metabolism:** Beta-Oxidation of saturated fatty acid; Ketogenesis and ketolysis; biosynthesis of fatty acids and lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolmiea)
- 5. **Biological oxidation:** Enzymes and Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture, regulation and inhibition); Oxidative phosphorylation and uncouplers of ETC.
- 6. **Protein and amino acid metabolism:** protein turn over; nitrogen balance; general reactions of catabolism of amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphorias, jaundice. Metabolic disorder of Amino acids
- 7. **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; DNA damage and repair mechanism; DNA replication (semi conservative)
- 8. The kidney function tests: Role of kidney; Laboratory tests for normal function includes
- a. Urine analysis (macroscopic and physical examination, quantitative and semi quantitative tests)
- b. Test for NPN constituents. (Creatinine /urea clearance, determination of blood/
- c. urine creatinine, urea and uric acid)
- d. Urine concentration test
- e. Urinary tract calculi (stones)
- 9. **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
  - e. Selected enzyme activity determination tests
- 10. **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides

- 11. **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)
- 12. **Electrolytes:** Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids

<b>Course Code</b>	Course	L+T	P	Marks distribution			Credits
				External	Internal	Total	
PD104T-19	Pharmaceutical Organic Chemistry	3+1	-	70	30	100	4

Scope and objectives: This course is designed to impart a very good knowledge about

- a. IUPAC/Common systems of nomenclature of simple organic compounds belonging to different classes of organic compounds
- b. Some important physical properties of organic compounds
- c. Free radical/ nucleophylic [alkyl/ acyl/ aryl] /electrophylic- substitution, free radical/ nucleophylic / electrophylic- addition, elimination, oxidation and reduction reactions with mechanism, orientation, order of reactivity, stability of compounds
- d. Some named organic reactions with mechanisms
- e. Uses of organic compounds in pharmacy.

# At the end of the course, the student should be able to:

- a. Name, write the structure of organic compound
- b. Name the type of isomerism
- c. Compare physical properties
- d. Tell the name, class of reaction
- e. Tell the method of conversion of compounds
- f. Account for reactivity, orientation of reactions
- g. Prepare organic compounds
- h. Identify, confirm the identification of organic compound

#### **Course Materials**

#### **Textbooks**

- 1. Organic chemistry- T.R.Morrison and R. Boyd
- 2. Text book of Pharmaceutical chemistry Bentley and Driver
- 3. Organic chemistry, the fundamentals of chemistry I.L.Finar
- 4. Organic chemistry P.L.Soni
- 5. Text book of organic chemistry B.S.Bahl and Arun Bahl

#### **Reference Books**

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

#### **Lecture Wise Program**

Note to emphasise also on definition, examples, uses in pharmacy, mechanisms of reactions

#### 1. Classification and Nomenclature

Different types of classification of organic compounds

- a. Common- IUPAC systems of nomenclature of following classes of open chain compounds. Hydrocarbons, halohydrocarbons, alcohols, aldehydes, ketones, carboxylic acids, carboxylic acid halides, carboxylic acid amides, carboxylic acid esters, acid anhydrides, amines, ethers
- b. Nomenclature of alicyclic compounds and aromatic compounds (non heterocyclic)

#### 2. Isomerism

- a. Structural isomerism, chain isomerism, positional isomerism, functional isomerism, metamerism, tautomerism
- b. Stereo isomerism, optical isomerism, geometrical isomerism
- c. specification of configuration, conformational isomerism

# 3. Structure and Properties

- a. Polar molecules, nonpolar molecules, protic molecules, aprotic molecules
- b. Inter molecular forces
- c. Melting point, boiling point of organic compounds, solubility of organic compounds

#### 4. Alkanes

Free radical substitution reactions of alkanes- reactivity, inhibition. Reaction between methane, ethane, propane and halogens

# 5. Alkenes

- a. i. Dehydrohalogenation reactions of alkyl halides- kinetics, rearrangement of carbo cations, reactivity, orientation
  - ii. Dehydration of alcohols reactions- kinetics, rearrangement of carbo cations, reactivity, orientation
  - iii. E1 versus E2 reactions
- b. Electrophylic addition reactions of alkenes- orientation, rearrangement of carbo cations, reactivity
- c. Free radical addition reactions of alkenes- orientation, reactivity

# 6. Alkyl halides

Preparation of alkyl halides from alcohols by Nucleophylic substitution reactions Nucleophylic substitution reactions of alkyl halides- kinetics, reactivity, rearrangement of carbocations, solvent effect, stereochemistry, SN<sup>1</sup> versus SN<sup>2</sup> reactions.

#### 7. Alicyclic compounds

- a. Baeyer's strain theory, Sachse Mohr theory
- b. General methods of preparation

#### 8. Dienes

Classification, stability, eases of formation of conjugated dienes, electrophylic and free radical addition reactions of conjugated dienes

# 9. Aromatic compounds

- a) Evidences in the derivation of structure of Benzene, aromatic characters
- b) i. Electrophylic substitution reactions of Benzene- nitration, sulfonation, halogenations, reactivity of halogens, Friedel craft's alkylation, reactivity of alkyl halides and limitation of Friedel crafts alkylation reactions, Friedel crafts acylationbreactions.
  - ii. Classification of substituents
  - iii. Orientation of mono substituted Benzene compounds towards electrophylic substitution reactions.
- c). Nucleophilic aromatic substitution reactions- reactivity, comparison with aliphatic nucleophylic substitution reactions

#### 10. Carbonyl compounds

- a. Nucleophylic addition reactions, reactions between carbonyl compounds and hydrogen cyanide, Sodium bisulphite, hydroxyl amine, hydrazine, phenyl hydrazine, 2,4- dinitro phenyl hydrazine, alcohol
- b. Aldol, crossed aldol, Cannizaro, crossed Cannizaro, Benzoin, Perkin reactions

# 11. Carboxylic acids and derivatives

- a. Acidity of carboxylic acids and effect of substituents on it.
- b. Nucleophylic acyl substitution reactions, esterification.
- c. Comparison of alkyl nucleophylic substitution with nucleophylic acyl substitution reactions

#### 12. Amines

- a. Basicity of amines
- b. Hoffmanns degradation of amides, diazotization reactions, coupling reactions, replacement reactions of aromatic diazonium salts

#### 13. Phenols

- a. Acidity of phenols
- b. Kolbe's synthesis, Riemer tiemann reactions, pthalein reaction, Schotten Bauman reaction, Libermann's nitrosation reaction

# 14. Heterocyclic compounds

Classification, nomenclature of mono and bicyclic compounds, medicinal uses of some important heterocyclic compounds

# 15. Carbohydrates

Classification, qualitative tests

# 16. Amino acids and proteins

- a. Classification of amino acids, qualitative tests for amino acids
- b. Classification, structure, colour reactions of proteins. Qualitative tests for proteins

<b>Course Code</b>	Course	L+T	P	M	Credits		
				External	Internal	Total	
PD105T-19	Pharmaceutical	2+1	-	70	30	100	3
	Inorganic						
	Chemistry						

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

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

- a. Understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceutical;
- b. Know the analysis of the inorganic pharmaceuticals their applications
- c. Appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

#### **Course Materials**

#### **Textbooks**

- 1. A.H. Beckett & J.B. Stenlake's -Practical Pharmaceutical Chemistry Vol I & II, Stahl one Press of University of London
- 2. Text Book of Quantitative Inorganic analysis by Vogel
- 3. Inorganic Pharmaceutical Chemistry III-Edition P. Gundu Rao

#### **Reference Books**

- 1. A textbook of Inorganic medicinal Chemistry by Surendra N. Pandey
- 2. Inorganic pharmaceutical Chemistry by M.L Schroff
- 3. Bentely and Driver's Textbook of Pharmaceutical chemistry
- 4. Pharmaceutical Analysis Vol I, Dr. A.V. Kasture et al., Nirali Prakashan
- 5. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
- 6. Analytical chemistry principles by John H. Kennedy
- 7. I.P.1985, 1996, 2008 Govt. of India, Ministry of Health

# **Lecture Wise Program**

#### 1. Errors

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

# 2. Volumetric analysis

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

#### 3. Acid-base titrations

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

#### 4. Redox titrations

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

# 5. Non aqueous titration

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

# 6. Precipitation titrations

Introduction, types of precipitation titrations, end point detection.

# 7. Complexometric titrations

Introduction, principle, types of titrations, endpoint detection.

# 8. Theory of Indicators

# 9. Gravimetry

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

#### 10. Limit tests

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

#### 11. Medicinal Gases

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

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

#### 12. Acidifiers

Dilute hydrochloric acid, Sodium phosphate, Ammonium chloride.

#### 13. Antacids

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

trisilicate, light and heavy magnesium carbonate, Calcium carbonate, Magaldrate and Bismuth carbonate.

#### 14. Cathartics

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

# 15. Electrolyte replenisher

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

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

#### 16. Essential Trace elements

Definition, Physiological role of Iron, Copper, Zinc,

Chromium, Manganese, Molybdenum, Selenium, Sulphur and Iodine.

#### 17. Antimicrobials

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

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

# 19. Dental products

Anti-caries Agents: Role of Fluorides as anti-caries agents, Sodium fluoride. Dentifrices: Calcium carbonate, dibasic calcium phosphate, Zinc chloride.

#### 20. Miscellaneous compounds

Sclerosing agents: Hypertonic saline, Sodium tetra decyl sulphate.

Expectorants: Potassium citrate and Potassium iodide.

Sedative: Potassium bromide.

Antidotes: Sodium nitrite, Sodium thiosulphate and Charcoal

Respiratory stimulant: Ammonium carbonate.

# 21. Radiopharmaceuticals

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

<b>Course Code</b>	Course	L+T	P	M	Credits		
				External	Internal	Total	
PD106RMT- 19	Remedial Mathematics	3+1	-	70	30	100	4

#### For PCB students

**Scope and objectives**: This is an introductory course in mathematics. This subject deal 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:**

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

#### **Course Materials**

#### **Textbooks**

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

#### **Reference Books**

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

# **Lecture Wise Program**

- 1. Algebra: Matrices: Definition, Addition, Subtraction and Multiplication of matrices, Determinants: Determinants of order two and three, Properties of determinants (without Proof). Inverse of square Matrices, Adjoint of square matrix, Solution of linear equation by Matrix method, Cramer's rule, Characteristic equation, Statement of Cayley-Hamilton Theorem (Without Proof) Pharmaceutical examples
- **2. Trigonometry:** Relation between Sides and angles of a triangle, solution of triangles Simple problems
- 3. Analytical Geometry: Points, Straight line, Types of straight lines -Y = mx + c, (y-y1) = m\*(x-x1), (y-y1) = ((y2-y1)/(x2-x1))\*(x-x1) Parallel and Perpendicular straight lines, Angle between two lines, Perpendicular distance from a point to the line, distance between parallel lines, Circle: General equation of circle, finding centre and radius of the circle, Parabola: Equation of the parabola y2 = 4ax, Simple problems

- **4. Differential calculus:** Function, Limit, Differentiation, Differentiation of sum, Product, Quotient, Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, simple problems.
- **5. Integral Calculus:** Partial fractions, Definition of integration, integration by substitution and integration by parts, Properties of definite integrals, Simple problems.
- **6. Differential equations:** Definition, order, degree, variable separable, homogeneous differential equation, linear differential equation, exact differential equation, Simple problems
- **7. Laplace transform:** Definition, Laplace transform of elementary functions, linearity and shifting property, simple problems

<b>Course Code</b>	Course	L+T	P	M	Credits		
				External	Internal	Total	
PD106RBT- 19	Remedial Biology	3+1	-	70	30	100	4

#### For PCM students

**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 introducing 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.

#### **Course Materials**

#### **Textbooks**

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

#### Reference books

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

#### **Lecture Wise Program**

#### PART - A

- 1. Introduction
- 2. General organization of plants and its inclusions
- 3. Plant tissues
- 4. Plant kingdom and its classification
- 5. Morphology of plants
- 6. Root, Stem, Leaf and Its modifications
- 7. Inflorescence and Pollination of flowers
- 8. Morphology of fruits and seeds
- 9. Plant physiology
- 10. Taxonomy of Leguminosae, Umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
- 11. Study of Fungi, Yeast, Penicillin and Bacteria

#### **PART-B**

1. Study of Animal cell

- 2. Study animal tissues
- 3. Detailed study of frog
- 4. Study of Pisces, Reptiles, Aves
- 5. General organization of mammals
- 6. Study of poisonous animals

<b>Course Code</b>	Course	L+T	P	Mark	Credits		
				External	Internal	Total	
PD107P-19	Human Anatomy &	-	3	70	30	100	2
	Physiology						

**General Requirements:** Laboratory napkin, muslin cloth, record, observation book (100pages), stationary items, and blood lance

#### **Course Materials**

#### **Textbooks**

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

#### Reference books

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

# **List of Experiments:**

- 1. Study of compound microscope
- 2. Study of tissues of human body
  - (a) Epithelial tissue
  - (b) Muscular tissue
- 3. Study of tissues of human body
  - (a) Connective tissue
  - (b) Nervous tissue
- 4. Study of appliances used in haematological experiments
- 5. Determination of total WBC count of blood
- 6. Determination of total RBC count of blood
- 7. 7Determination of differential leukocyte count of blood
- 8. Determination of
  - (a) Erythrocyte Sedimentation Rate (ESR)
  - (b) Hemoglobin content of blood
  - (c) Bleeding time & clotting time
  - (d) Blood pressure
  - (e) Blood group
- 9. Study of various systems with the help of charts, models & specimens
  - (a) Skeleton system part I-axial skeleton
  - (b) Skeleton system part II- appendicular skeleton
  - (c) Cardiovascular system
  - (d) Respiratory system
  - (e) Digestive system
  - (f) Urinary system
  - (g) Nervous system
  - (h) Special senses

- (i) Reproductive system
- 10. Study of different family planning appliances
- 11. Study of pregnancy diagnosis test
- 12. Study of appliances used in experimental physiology
- 13. Study of record of simple muscle curve using gastrocnemius sciatic nerve preparation
- 14. Study of simple summation curve using gastrocnemius sciatic nerve preparation
- 15. Study of simple effect of temperature using gastrocnemius sciatic nerve preparation
- 16. Study of simple effect of load & after load using gastrocnemius sciatic nerve preparation
- 17. Study of fatigue curve using gastrocnemius sciatic nerve preparation

<b>Course Code</b>	Course	L+T	P	Mai	Marks distribution				
				External	Internal	Total			
PD108P-19	Pharmaceutics	-	3	70	30	100	2		

# **List of Experiments**

# 1. Syrups

- a. Simple Syrup I.P
- b. Syrup of Ephedrine Hydrochloride NF
- c. Orange Syrup

#### 2. Elixir

- a. Piperizine citrate elixir BP
- b. Paracetamol elixir BPC

#### 3. Linctus

- a. Simple linctus BPC
- b. Pediatric simple linctus BPC

#### 4. Solutions

- a. Solution of cresol with soap IP
- b. Aqueous Iodine Solution IP
- c. Strong solution of Iodine IP
- d. Strong solution of ammonium acetate IP

# 5. Liniments

- a. Liniment of turpentine IP\*
- b. Liniment of camphor IP

# 6. Suspensions\*

- a. Calamine lotion
- b. Magnesium Hydroxide mixture BP

#### 7. Emulsions\*

- a. Cod liver oil emulsion
- b. Liquid paraffin emulsion

# 8. Powders\*

- a. Eutectic powder
- b. Dusting powder
- c. Insufflations

# 9. Suppositories\*

- a. Boric acid suppositories
- b. Chloral suppositories

# 10. Incompatibilities

Preparations having with Physical Incompatibilities (3 Nos)

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

<b>Course Code</b>	Course	L+T	P	Mar	tion	Credits	
				External	Internal	Total	
PD109P-19	Medicinal Biochemistry	-	3	70	30	100	2

## **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 chlorides by Volhard's method
- 4. Quantitative estimation of urine creatinine by Jaffe's method
- 5. Quantitative estimation of urine calcium by precipitation method
- 6. Quantitative estimation of serum cholesterol
- 7. Preparation of Folin Wu filtrate from blood
- 8. Quantitative estimation of blood creatinine
- 9. Quantitative estimation of blood sugar Folin-Wu tube method
- 10. Estimation of SGOT in serum
- 11. Estimation of SGPT in serum
- 12. Estimation of Urea in Serum
- 13. Estimation of Proteins in Serum
- 14. Determination of serum bilirubin
- 15. Determination of Glucose by means of Glucoseoxidase
- 16. Enzymatic hydrolysis of Glycogen/Starch by Amylases
- 17. Study of factors affecting Enzyme activity. (pH & Temp.)
- 18. Preparation of standard buffer solutions and its pH measurements (any two)
- 19. Experiment on lipid profile tests
- 20. Determination of sodium/calcium / potassium in serum

<b>Course Code</b>	Course	L+T	P	Mar	tion	Credits	
				External	Internal	Total	
PD110P-19	Pharmaceutical Organic Chemistry	-	3	70	30	100	2

#### **Course Materials**

- 1. Practical organic chemistry Mann and Saunders
- 2. Introduction to organic laboratory techniques Pavia, Lampman, Kriz
- 3. Text book of Practical Organic Chemistry Vogel

# Title of the experiment

- 1. Recrystallization of organic compounds
- 2. Preparation of simple non-hetero cyclic organic compounds and recrystallization of compounds prepared.

(Minimum of 08 compounds)

Aspirin/Benzanilide/Phenyl benzoate/Acetanilide by acylation

2,4,6-Tribromo aniline/Para bromo acetanilide by halogenations

5-Nitro salicylic acid/Meta di nitro benzene by nitration

Dibenzal acetone from benzaldehyde by Claisen Schmidt

Benzoic acid from benzyl chloride by oxidation

Benzoic acid/Salicylic acid by hydrolysis

1- Phenyl azo -2- napthol from aniline by diazotization and coupling

Benzophenone oxime from benzophenone

- **3.** Systematic qualitative analysis of unknown organic compounds for preliminary and Lassaigns tests
- **4.** Systematic qualitative analysis of unknown organic compounds for functional groups (for preliminary / Lassaigns / solubility / functional group tests)

Following classes of compounds may be analysed

Phenols, amide/ urea, carbohydrate, amine, carboxylic acid, aldehyde, ketone, alcohol, carboxylic acid ester, hydrocarbon, halohydrocarbon, nitrocompound, anilide

- 5. Determination of melting and boiling points of organic compounds
- **6.** Preparation of suitable solid derivatives from organic compounds
- 7. Introduction to the use of stereomodels Methane, Ethane, Ethane, Ethene, Acetylene, Cyclo hexane, Benzene (Students to prepare the ball and stick stereomodels using china clay, plastic sticks individually and to explain the formation of bonds& bond angles, bond lengths)

<b>Course Code</b>	Course	L+T	P	Mar	Credits		
				External	Internal	Total	
PD111P-19	Pharmaceutical Inorganic Chemistry	-	3	70	30	100	2

(Following experiments to be covered in 25 different practical classes)

- 1. Limit tests (7 exercises)
  - a. Limit test for chlorides
  - b. Limit test for sulphate
  - c. Limit test for Iron
  - d. Limit test for heavy metals
  - e. Limit test for Arsenic
  - f. Modifications in limit tests for chloride and sulphates in potassium permanganate,
  - g. sodium bicarbonate, sodium benzoate and sodium Salicylate
- 2. Preparation and standardization of the following (3 exercises)
  - a. 0.IN NaOH
  - b. 0.IN KMnO4
  - c. 0.IN Cerric ammonium sulphate
  - d. 0.IN HClO4
  - e. 0.05M Di sodium EDTA
  - f. 0.IN Sodium thiosulphate
- 3. Assay of the following compounds
  - a. Ammonium chloride-acid base titration (Formal titration)
  - b. Ferrous sulphate- (redox) Ceric ammonium sulphate titration
  - c. Copper sulphate- (redox) Iodometry
  - d. Calcium gluconate-complexometry
  - e. Hydrogen peroxide- (redox -Permanganometry)
  - f. Sodium benzoate-nonaqueous titration
  - g. Sodium chloride-Modified Volhard's method
  - h. Assay of KI-KIO3 titration
  - i. Assay of Zinc oxide (acid base back titration)
- 4. Test for identify for the following (2 exercises)
  - a. Sodium bicarbonate
  - b. Ferrous sulphate
  - c. Potassium iodide.
  - d. Calcium chloride
- 5. Test for purity for the following (2 exercises)
  - a. Swelling power in Bentonite

- b. Ammonium salts in Potash alum.
- c. Presence of Iodates in KI
- 6. Preparation of inorganic pharmaceuticals (2 exercises)
  - a. Boric acid
  - b. Potash alum
  - c. Magnesium hydroxide
  - d. Magnesium sulphate

<b>Course Code</b>	Course	L+T	P	Mai	ıtion	Credits	
				External	Internal	Total	
PD112RBP- 19	Remedial Biology	-	3	70	30	100	2

# For PCM students

# **List of Experiments**

- 1. Introduction of biology experiments (section cutting techniques,
- 2. Mounting and staini9ng, permanence slide preparation and Microscope)
- 3. Study of cell wall constituents and cell inclusions
- 4. Study of Stem modifications
- 5. Study of Root modifications
- 6. Study of Leaf modifications
- 7. Identification of Fruits and seeds
- 8. Preparation of Permanent slides
- 9. Simple plant physiological experiments
- 10. Identification of animals
- 11. Detailed study of Frog by using computer models
- 12. Computer based tutorials

# SECOND YEAR

<b>Course Code</b>	Course	L+T	P	Marks distribution			Credits
				External	Internal	Total	
PD201T-19	Pathophysiology	3+1	-	70	30	100	4

**Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.

Objectives of the Subject: Upon completion of the subject student shall be able to

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

# **Course Materials**

#### **Textbooks**

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

#### **Reference Books**

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

#### **Lecture Wise Program**

# 1. Basic principles of cell injury and Adaptation

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

#### 2. Inflammation

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

#### 3. Diseases of Immunity

- a) Introduction to T and B cells
- b) MHC proteins or transplantation antigens
- c) Immune tolerance, Hypersensitivity
- d) Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
- e) Autoimmunity: criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
- Acquired immune deficiency syndrome (AIDS)
- Amyloidosis

- 4. Cancer: differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer
- 5. Types of shock, mechanisms, stages and management
- 6. Biological effects of radiation
- 7. Environmental and nutritional diseases
  - i) Air pollution and smoking- SO2, NO, NO2, and CO
  - ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation

# 8. Pathophysiology of common diseases

- a. Parkinsonism
- b. Schizophrenia
- c. Depression and mania
- d. Hypertension,
- e. Stroke (ischaemic and hemorrhage)
- f. Angina, CCF, Atherosclerosis, Myocardial infarction
- g. Diabetes Mellitus
- h. Peptic ulcer and inflammatory bowel diseases
- i. Cirrhosis and Alcoholic liver diseases
- j. Acute and chronic renal failure
- k. Asthma and chronic obstructive airway diseases
- 9. **Infectious diseases:** sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

#### **Assignments**

#### Title of the Experiment

- 1. Chemical Mediators of inflammation
- 2. Drug Hypersensitivity
- 3. Cigarette smoking & its ill effects
- 4. Biological Effects of Radiation
- 5. Etiology and hazards of obesity
- 6. Complications of diabetes
- 7. Diagnosis of cancer
- 8. Disorders of vitamins
- 9. Methods in Pathology-Laboratory values of clinical significance
- 10. Pathophysiology of Dengue Hemorrhagic Fever (DHF)

#### Format of the assignment

1. Minimum & Maximum number of pages.

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

<b>Course Code</b>	Course	L+T	P	Marks distribution			Credits
				External	Internal	Total	
PD202T-19	Pharmaceutical Microbiology	3+1	-	70	30	100	4

**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. It's 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

- a) Know the anatomy, identification, growth factors and sterilization of microorganisms;
- b) Know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- c) Do estimation of RNA and DNA and there by identifying the source;
- d) Do cultivation and identification of the microorganisms in the laboratory;
- e) Do identification of diseases by performing the diagnostic tests; and
- f) Appreciate the behaviour of motility and behavioural characteristics of microorganisms.

#### **Course Materials**

#### **Textbooks**

- 1. Vanitha Kale and Kishor Bhusari —Applied Microbiology, Himalaya Publishing house Mumbai
- 2. Mary Louis Turgeon —Immunology and Serology in Laboratory Medicines, Mosby- Year book Inc St. Louis Missouri
- 3. Harsh Mohan,— Text book of Pathology New Delhi

#### **Reference Books**

- 1. Prescot L.M., Jarley G.P Klein D.A, Microbiology, Mc Graw Hill Company Inc
- 2. Rawlins E.A. Bentley's Text Book of Pharmaceutics Bailliere Tindals London
- 3. Forbisher —Fundamentals of Microbiology Philidelphia, W.B. Saunders
- 4. Prescott L.M. Jarley G.P., Klein.D.A. —Microbiology, WMC Brown Publishers, Oxford
- 5. War Roitt, Jonathan Brostoff, David male, —Immunology, Mosby-year book Europe Ltd, London
- 6. Pharmacopoeia of India, Govt of India

#### **Lecture Wise Program**

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

- 2. Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes
- 3. Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures
- 4. Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques
- 5. Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations. Brief information on Validation
- 6. Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agent's factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, virucidal activities, evaluation of preservatives in pharmaceutical preparations
- 7. Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity (active and passive). Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose
- 8. Diagnostic tests: Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malaria parasite
- 9. Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B2 and B12. Standardisation of vaccines and sera
- 10. Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV

<b>Course Code</b>	Course	L+T	P	Mark	ion	Credits	
				External	Internal	Total	
PD203T-19	Pharmacognosy &	3+1	-	70	30	100	4
	Phytopharmaceuticals						

**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.

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

- a. Understand the basic principles of cultivation, collection and storage of crude drugs;
- b. Know the source, active constituents and uses of crude drugs; and
- c. Appreciate the applications of primary and secondary metabolites of the plant.

#### **Course materials**

#### **Text**books

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

#### **Reference Books**

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

# **Lecture Wise Program**

- 1. Introduction
- 2. Definition, history and scope of Pharmacognosy
- 3. Classification of crude drugs
- 4. Cultivation, collection, processing and storage of crude drugs
- 5. Detailed method of cultivation of crude drugs
- 6. Study of cell wall constituents and cell inclusions
- 7. Microscopical and powder Microscopical study of crude drugs
- 8. Study of natural pesticides
- 9. Detailed study of various cell constituents
- 10. Carbohydrates and related products
- 11. Detailed study carbohydrates containing drugs. (11 drugs)
- 12. Definition sources, method extraction, chemistry and method of analysis of lipids
- 13. Detailed study of oils
- 14. Definition, classification, chemistry and method of analysis of protein
- 15. Study of plants fibers used in surgical dressings and related products
- 16. Different methods of adulteration of crude drugs

<b>Course Code</b>	Course	L+T	P	Marks	Marks distribution			
				External	Internal	Total		
PD204T-19	Pharmacology – I	3+1	-	70	30	100	4	

**Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, and route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be 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) –

- a. Understand the pharmacological aspects of drugs falling under the above-mentioned chapters
- b. Handle and carry out the animal experiments
- c. Appreciate the importance of pharmacology subject as a basis of therapeutics
- d. Correlate and apply the knowledge therapeutically

#### **Course Materials**

#### **Textbooks**

- 1. Tripathi, K. D. Essentials of medical pharmacology, Publisher: Jaypee, Delhi.
- 2. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and Pharmacotherapeutics, Publisher: Popular, Dubai
- 3. Rang, H.P. & Dale, M.M. Pharmacology, Publisher: Churchill Living stone

#### Reference Books

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

# **Lecture Wise Program**

#### 1. General Pharmacology

- a) Introduction, definitions and scope of pharmacology
- b) Routes of administration of drugs
- c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
- d) Pharmacodynamics

- e) Factors modifying drug effects
- f) Drug toxicity Acute, sub- acute and chronic toxicity
- g) Pre-clinical evaluations
- h) Drug interactions

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

# 2. Pharmacology of drugs acting on ANS

- a) Adrenergic and antiadrenergic drugs
- b) Cholinergic and anticholinergic drugs
- c) Neuromuscular blockers
- d) Mydriactics and miotics
- e) Drugs used in myasthenia gravis
- f) Drugs used in Parkinsonism

# 3. Pharmacology of drugs acting on cardiovascular system

- a) Antihypertensive
- b) Anti-anginal drugs
- c) Anti-arrhythmic drugs
- d) Drugs used for therapy of Congestive Heart Failure
- e) Drugs used for hyperlipidaemias

# 4. Pharmacology of drugs acting on Central Nervous System

- a) General anaesthetics
- b) Sedatives and hypnotics
- c) Anticonvulsants
- d) Analgesic and anti-inflammatory agents
- e) Psychotropic drugs
- f) Alcohol and methyl alcohol
- g) CNS stimulants and cognition enhancers
- h) Pharmacology of local anaesthetics

# 5. Pharmacology of Drugs acting on Respiratory tract

- a) Bronchodilators
- b) Mucolytic
- c) Expectorants
- d) Antitussives
- e) Nasal Decongestants

#### 6. Pharmacology of Hormones and Hormone antagonists

- a) Thyroid and Antithyroid drugs
- b) Insulin, Insulin analogues and oral hypoglycaemic agents
- c) Sex hormones and oral contraceptives
- d) Oxytocin and other stimulants and relaxants

# 7. Pharmacology of autocoids and their antagonists

- a) Histamines and Antihistaminic
- b) 5-Hydroxytryptamine and its antagonists
- c) Lipid derived autacoids and platelet activating factor

<b>Course Code</b>	Course	L+T	P	Mark	Marks distribution			
				External	Internal	Total		
PD205T-19	Community Pharmacy	2+1	-	70	30	100	3	

**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 –

- a) Know pharmaceutical care services;
- b) Know the business and professional practice management skills in community pharmacies;
- c) Do patient counselling & provide health screening services to public in community pharmacy
- d) Respond to minor ailments and provide appropriate medication;
- e) Show empathy and sympathy to patients; and
- f) Appreciate the concept of rational drug therapy

#### **Course Materials**

#### **Textbooks**

- 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**

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

#### **Special requirements**

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

#### **Scheme of evaluation**

Synopsis-10

Major Experiment- 30

Minor Experiment (ability to measure B.P/CBG / Lung function) - 30

Prescription Analysis (analysing the prescriptions for probable drug interaction and ability to tell the management) - 15

Viva – Voce- 15

# **Lecture Wise Program**

# 1. Definition, scope, of community pharmacy Roles and responsibilities of Community pharmacist

# 2. Community Pharmacy Management

- a) Selection of site, Space layout, and design
- b) Staff, Materials- coding, stocking
- c) Legal requirements
- d) Maintenance of various registers
- e) Use of Computers: Business and health care soft wares

# 3. Prescriptions

a) Parts of prescription, legality & identification of medication related problems like drug interactions

# 4. Inventory control in community pharmacy

a) Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock

#### 5. Pharmaceutical care

a) Definition and Principles of Pharmaceutical care

#### 6. Patient counselling

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

#### 7. Patient medication adherence

a) Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence

# 8. Health screening services

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

#### 9. OTC Medication

a) Definition, OTC medication list & Counselling

#### 10. Health Education

- a) WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients
- b) Commonly occurring Communicable Diseases, causative agents, Clinical presentations and prevention of communicable diseases Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS, Balance diet, and treatment & prevention of deficiency disorders Family planning role of pharmacist

- 11. Responding to symptoms of minor ailments
  - a) Relevant pathophysiology, common drug therapy to, Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhoea, constipation), Pyrexia, Opthalmic symptoms, worm's infestations
- 12. Essential Drugs concept and Rational Drug Therapy, Role of community pharmacist
- 13. Code of ethics for community pharmacists

<b>Course Code</b>	Course	L+T	P	Marks	ion	Credits	
				External	Internal	Total	
PD206T-19	Pharmacotherapeutics - I	3+1	-	70	30	100	4

**Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

**Objectives:** At completion of this subject, it is expected that students will be able to understand:

- a. The pathophysiology of selected disease states and the rationale for drug therapy
- b. The therapeutic approach to management of these diseases
- c. The controversies in drug therapy
- d. The importance of preparation of individualised therapeutic plans based on diagnosis
- e. Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects)
- f. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy
- g. Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence
- h. Discuss the controversies in drug therapy
- i. Discuss the preparation of individualised therapeutic plans based on diagnosis
- j. 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)

#### **Course Materials**

#### **Textbooks**

- 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 e. Avery's Drug Treatment, Adis International Limited
- 5. Relevant review articles from recent medical and pharmaceutical literature

# **Lecture Wise Program**

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

- 1. **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias , Electrophysiology of heart and Arrhythmias
- 2. **Respiratory system:** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
- 3. **Endocrine system :** Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
- 4. General prescribing guidelines for
- a) Paediatric patients
- b) Geriatric patients
- c) Pregnancy and breast feeding
- 5. Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial
- 6. Introduction to rational drug use
- a) Definition, role of pharmacist, essential drug concept, rational drug formulations

<b>Course Code</b>	Course	L+T	P	Marl	Credits		
				External	Internal	Total	
PD207P-19	Pharmaceutical Microbiology	-	3	70	30	100	2

# **Title of the Experiment**

- 1. Study of apparatus used in experimental microbiology\*
- 2. Sterilisation of glassware's
- 3. Preparation of media and sterilisation \*
- 4. Staining techniques Simple staining; Gram's staining; Negative staining\*\*
- 5. Study of motility characters\*
- 6. Enumeration of micro-organisms (Total and Viable) \* 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 microorganisms\*
- 9. Sterility testing for powders and liquids\*
- 10. Determination of minimum inhibitory concentration\*
- 11. Microbiological assay of antibiotics by cup plate method\*
- 12. Microbiological assay of vitamins by Turbidometric method\*\*
- 13. Determination of RWC\*\*
- 14. Diagnostic tests for some common diseases, Widal, malarial parasite\*\*

# \* Indicate minor experiment & \*\* indicate major experiment

#### **Assignments**

- 1. Visit to some pathological laboratories and study the activities and equipment/instruments used and reporting the same
- 2. Visit to milk dairies (pasturization) and microbial laboratories (other sterilization 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

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

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

<b>Course Code</b>	Name of Subject	L+T	P	Marks distribution			Credit
				Externa	Interna	Total	s
				l	l		
PD208P -19	Pharmacognosy &	-	3	70	30	100	2
	Phytopharmaceuticals						

**General Requirements:** Laboratory napkin, observation book 150 pages zero brush, needle, blade, and matchbox

# List of experiments:

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

<b>Course Code</b>	Name of Subject	L+T	P	Marks distribution			Credits
				External	Internal	Total	
PD209P-19	Pharmacotherapeutics - I	-	3	70	30	100	2

#### **Practicals**

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

# **Assignments**

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

# Format of the assignment

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

<b>Course Code</b>	Course	L+T	P	Marks distribution			Credits
				External	Interna	l Total	
PD210P-19	Pharmacology - I	-	3	70	30	100	2

# **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 oesophagus 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 anti-inflammatory 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 anthelmintic 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

*Note:* \*\* indicate major experiment & \* indicate minor experiment

#### **Textbooks**

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

#### Reference books

1. Macleod, L.J. Pharmacological experiments on intact preparations, Publisher: Churchill livingstone

# THIRD YEAR

<b>Course Code</b>	Course	L+T	P	Marks distribution			Credits
				External	Internal	Total	
PD301T-19	Pharmaceutical Analysis	3+1	-	70	30	100	4

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

# Objectives of the Subject Upon completion of the subject student shall be able to:

- a) Understand the pharmacological aspects of drugs falling under the abovementioned chapters
- b) Carry out the animal experiments confidently
- c) Appreciate the importance of pharmacology subject as a basis of therapeutics
- d) Correlate and apply the knowledge therapeutically

#### **Course Material**

#### **Textbooks**

- 1. Tripathi, K. D. Essentials of medical pharmacology, Publisher: Jaypee, Delhi
- 2. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics, Publisher: Popular, Dubai
- 3. Rang, H.P. and Dale, M.M. Pharmacology, Publisher: Churchill Living stone

#### **Reference Books**

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

# **Lecture Wise Program**

# 1. Pharmacology of Drugs acting on Blood and blood forming agents

- a) Anticoagulants
- b) Thrombolytics and antiplatelet agents
- c) Haemopoietics and plasma expanders

# 2. Pharmacology of drugs acting on Renal System

- a) Diuretics
- b) Antidiuretics

# 3. Chemotherapy

- a) Introduction
- b) Sulfonamides and co-trimoxazole
- c) Penicillins and Cephalosporins
- d) Tetracyclins and Chloramphenicol
- e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
- f) Quinolines and Fluroquinolines
- g) Antifungal antibiotics
- h) Antiviral agents
- i) Chemotherapy of tuberculosis and leprosy
- j) Chemotherapy of Malaria
- k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
- 1) Pharmacology of Anthelmintic drugs
- m) Chemotherapy of cancer (Neoplasms)

# 4. Immunopharmacology

a) Pharmacology of immunosuppressants and stimulants

#### 5. Principles of Animal Toxicology

b) Acute, subacute and chronic toxicity

# 6. The dynamic cell: The structures and functions of the components of the cell

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

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

a) Gene structure: Organization and elucidation of genetic code

- b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families
- c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes. RNA processing: rRNA, tRNA and mRNA processing. Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events
- d) Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes. The gene sequencing, mapping and cloning of human disease genes. Introduction to gene therapy and targeting
- e) Recombinant DNA technology: principles, processes (gene transfer technology) and applications

#### **Books**

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

<b>Course Code</b>	Course	L+T	P	Marks distribution			Credits
				External	Internal	Total	
PD302T-19	Pharmaceutical Analysis	3+1	-	70	30	100	4

**Scope:** This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

- 1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis.
- 2. Understand the chromatographic separation and analysis of drugs.
- 3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

#### **Course Material**

#### **Textbooks**

- 1. Instrumental Methods of Chemical Analysis by B.K Sharma
- 2. Organic spectroscopy by Y.R Sharma
- 3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
- 4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
- 5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
- 6. Organic Chemistry by I. L. Finar
- 7. Organic spectroscopy by William Kemp
- 8. Quantitative Analysis of Drugs by D. C. Garrett
- 9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
- 10. Spectrophotometric identification of Organic Compounds by Silverstein

#### **Lecture Wise Program**

# 1. Quality Assurance

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

#### 2. Chromatography

• Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of

- pharmaceutical products involving principles and techniques of separation of drugs from excipients
- a) Column Chromatography: Adsorption column chromatography, Operational technique, frontal, analysis and elution, analysis. Factors affecting column efficiency, applications and partition chromatography
- b) Thin Layer Chromatography: Introduction, principle, techniques, Rf value and applications
- c) Paper chromatography: Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications
- d) Ion-exchange Chromatography: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications
- e) High Pressure Liquid Chromatography: Introduction, theory, instrumentation, and applications
- f) High Pressure Thin Layer Chromatography: Introduction, theory, instrumentation, and applications
- g) Gas Chromatography: Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors-Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
- h) Electrophoresis: Principles of separation, equipment for paper and gel electrophoresis, and application
- i) Gel filtration and affinity chromatography: Introduction, technique, applications

#### 3. Electrometric Methods

- Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.
- a) Potentiometry: Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
- b) Conductometry: Introduction, conductivity cell, conductometric titrations and applications
- c) Polarography: Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
- d) Amperometric Titrations: Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of amperometry over potentiometry. Pharmacy applications.

# 4. Spectroscopy

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

#### a) Absorption Spectroscopy

- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra
- Instrumentation Photometer, U.V.-Visible spectrophotometer sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations
- Infrared Spectroscopy: Vibrational transitions, frequency structure correlations, Infrared absorption bands, Instrumentation–IR spectro-meter sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy
- Fluorimetric Analysis: Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry
- b) Flame Photometry: Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications
- c) Atomic Absorption Spectrometry: Introduction, Theory, types of electrodes, instrumentation and applications
- d) Atomic Emission Spectroscopy: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection
- e) NMR & ESR (introduction only): Introduction, theoretical aspects and applications
- f) Mass Spectroscopy (introduction only): Fragmentation, types of ions produced mass spectrum and applications
- g) Polarimetry (introduction only): Introduction to optical rotatory dispersion, circular dichroism, polarimeter
- h) X-RAY Diffraction (introduction only): Theory, reciprocal lattice concept, diffraction patterns and applications
- i) Thermal Analysis: Introduction, instrumentation, applications, and DSC and DTA

<b>Course Code</b>	Course	L+T	P	Marks distribution			Credits
				External	Internal	Total	
PD303T-19	Pharmacotherapeutics – II	3+1	-	70	30	100	4

**Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

# Objectives of the Subject Upon completion of the subject student shall be able to:

- a) Know the pathophysiology of selected disease states and the rationale for drug therapy
  - Know the therapeutic approach to management of these diseases
- b) Know the controversies in drug therapy
- c) Know the importance of preparation of individualised therapeutic plans based on diagnosis
- d) Appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects)

#### **Course Material**

#### **Textbooks**

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

#### Reference books

- 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

#### **Lecture Wise Program**

- Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases:
- 1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis
- **2. Musculoskeletal disorders:** rheumatoid arthritis, osteoarthritis, gout, spondylitis, systemic lupus erythematosus

- **3. Renal system:** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders
- 4. **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia Management of chemotherapy nausea and emesis
- 5. Dermatology: Psoriasis, Scabies, Eczema, Impetigo

<b>Subject Code</b>	Name of Subject	L+T	P	Mark	Marks distribution			
				External	Internal	Total		
PD304T	Pharmaceutical	2	-	70	30	100	2	
	Jurisprudence							

**Scope**: This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments is the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.

**Objectives of the Subject:** Upon completion of the subject student shall be able to:

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

### **Course Materials**

#### **Textbooks**

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

#### **Reference Books**

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

## **Lecture Wise Program**

1. Pharmaceutical Legislations – A brief review

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

## **Assignments**

## Format of the assignment

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

## Case studies relating to

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

<b>Course Code</b>	Course	L+T	P	Mark	Marks distribution			
				External	Internal	Total		
PD305T-19	Medicinal Chemistry	3+1	1	70	30	100	4	

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

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

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

#### **Course Materials**

## **Textbooks**

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

## **Lecture Wise Program**

- 1. 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. 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.
- 2. Anti-infective agents
  - a) Local anti-infective agents
  - b) Preservatives
  - c) Antifungal agents
  - d) Urinary tract anti-infectives
  - e) Antitubercular agents
  - f) Antiviral agents and Anti AIDS agents

- g) Antiprotozoal agents
- h) Anthelmentics
- i) Antiscabies and Antipedicular agents
- 3. Sulphonamides and sulphones
- 4. Antimalarials
- 5. Antibiotics
- 6. Antineoplastic agents
- 7. Cardiovascular agents
  - a) Antihypertensive agents
  - b) Antianginal agents and vasodilators
  - c) Antiarrhythmic agents
  - d) Antihyperlipidemic agents
  - e) Coagulants and Anticoagulants
  - f) Endocrine
- 8. Hypoglycemic agents
- 9. Thyroid and Antithyroid agent
- 10. Diureties
- 11. Diagnostic agents
- 12. Steroidal Hormones and Adrenocorticoids

<b>Course Code</b>	Course	L+T	P	Mark	on	Credits	
				External	Internal	Total	
PD306T-19	Pharmaceutical	2+1	-	70	30	100	3
	Formulations						

**Scope of the Subject:** 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:

- a) Understand the principle involved in formulation of various pharmaceutical dosage forms
- b) Prepare various pharmaceutical formulation
- c) Perform evaluation of pharmaceutical dosage forms
- d) Understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations

#### **Course Materials**

#### **Textbooks**

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

#### Reference Books

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

## **Lecture Wise Program**

- 1. Pharmaceutical dosage form- concept and classification
- 2. **Tablets**: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet
- 3. Capsules: Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules
- 4. **Liquid orals**: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
- 5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
- 6. **Ophthalmic preparations (Semi Solids)**: Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging

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

<b>Course Code</b>	Course	L+T	P	Marks distribution			Credits
				External	Interna	l Total	
PD307P-19	Pharmacology – II	-	3	70	30	100	2

#### **Course Materials**

#### **Textbooks**

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

#### **Reference Books**

- 1. Macleod, L.J. Pharmacological experiments on intact preparations, Publisher: Churchill livingstone
- 2. Ghosh, M.N. Fundamentals of experimental pharmacology, Publisher: Scientific book agency, Kolkata
- 3. Ian Kitchen. Textbook of in vitro practical pharmacology, Publisher: Black well Scientific

## **List of Experiments**

- 1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea
- 2. pigs, e. Rabbits)
- 3. Study of physiological salt solutions used in experimental pharmacology Study of laboratory appliances used in experimental pharmacology
- 4. Study of use of anaesthetics in laboratory animals
- 5. To record the dose response curve of ACH using isolated ileum/rectus abdominis muscle preparation
- 6. To carry out bioassay of ACH using isolated ileum/rectus abdominis muscle preparation by interpolation method
- 7. To carry out bioassay of ACH using isolated ileum/rectus abdominis muscle preparation by three-point method
- 8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation
- 9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation
- 10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method
- 11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three-point method
- 12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
- 13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
  - Analgesic property of drug using analgesiometer.
- a) Antiinflammatory effect of drugs using rat-paw edema method

- b) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods
- c) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods
- d) Locomotor activity evaluation of drugs using actophotometer and rotorod
- e) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations

<b>Course Code</b>	Course	L+T	P	Marl	Credits		
				External	Interna	l Total	
PD308P-19	Pharmaceutical Analysis	-	3	70	30	100	2

## **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 Assay of Salicylic Acid by colourimetry
- 12. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method
- 13. Determination of Na/K by Flame Photometry
- 14. Determination of pKa using pH meter
- 15. Determination of specific rotation
- 16. Comparison of the IR spectrum of a compound with that of its derivatives Demonstration of HPLC
- 17. Demonstration of HPTLC
- 18. Demonstration of GC-MS Demonstration of DSC
- 19. 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 Undergraduate Instrumental Analysis by James. E., CBS Publishers
- 4. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras

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

<b>Course Code</b>	Course	L+T	P	Marks distribution			Credits
				External	Interna	l Total	
PD309P-19	Pharmacotherapeutics – II	-	3	70	30	100	2

#### **Practicals**

- Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.
- The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.
- A minimum of 20 cases should be presented and recorded covering most common diseases.

## **Assignments**

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

## Format of the assignment

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

Course	Course	L+T	P	Marl	ks distrib	ution	Credits
Code				External	Internal	l Total	
PD310P-19	Medicinal Chemistry	-	3	70	30	100	2

## **List of Experiments**

- 1. Assays of important drugs from the course content
- 2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs
- 3. Monograph analysis of important drugs
- 4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis

#### **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
- 5. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi
- 6. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi
- 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

Course	Course	L+T	P	Marl	Marks distribution			
Code				External	Interna	l Total		
PD311P-19	Pharmaceutical	-	3	70	30	100	2	
	Formulations							

## **List of Experiments**

## 1. Manufacture of Tablets

- a) Ordinary compressed tablet-wet granulation
- b) Tablets prepared by direct compression.
- c) Soluble tablet
- d) Chewable tablet

## 2. Formulation and filling of hard gelatin capsules

## 3. Manufacture of parenterals

- a) Ascorbic acid injection
- b) Calcium gluconate injection
- c) Sodium chloride infusion
- d) Dextrose and Sodium chloride injection/infusion

## 4. Evaluation of Pharmaceutical formulations (QC tests)

- a) Tablets
- b) Capsules
- c) Injections

## 5. Formulation of two liquid oral preparations and evaluation by assay

- a) Solution: Paracetamol Syrup
- b) Antacid suspensions- Aluminum hydroxide gel

## 6. Formulation of semisolids and evaluation by assay

- a) Salicyclic acid and benzoic acid ointment
- b) Gel formulation Diclofenac gel

## 7. Cosmetic preparations

- a) Lipsticks
- b) Cold cream and vanishing cream
- c) Clear liquid shampoo
- d) Tooth paste and tooth powders

## 8. Tablet coating (demonstration)

# FOURTH YEAR

<b>Course Code</b>	Course	L+T	P	Marks	ion	Credits	
				External	Internal	Total	
PD401T-19	Pharmacotherapeutics -	3+1	1	70	30	100	4
	III						

**Scope:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

**Objectives:** At completion of this subject, it is expected that students will be able to understand:

- a) The pathophysiology of selected disease states and the rationale for drug therapy
- b) The therapeutic approach to management of these diseases
- c) The controversies in drug therapy
- d) The importance of preparation of individualised therapeutic plans based on diagnosis
- e) Needs to identify the patient-specific parameters relevant in initiating drug therapy,
- f) and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects)
- g) Describes the pathophysiology of selected disease states and explain the rationale for drug therapy
- h) To summarize the therapeutic approach to management of these diseases including reference to the latest available evidence
- i) To discuss the controversies in drug therapy
- j ) To discuss the preparation of individualised therapeutic plans based on diagnosis; and
- k) Identify the patient-specific parameters relevant in initiating drug therapy, and
- 1) monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects)

## **Course Materials**

#### **Textbooks**

- 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

## **Lecture Wise Program**

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

<b>Course Code</b>	Course	L+T	P	Marks	Credits		
				External	Internal	Total	
PD402T-19	Hospital Pharmacy	2+1	-	70	30	100	3

**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:

- a) Know various drug distribution methods
- b) Know the professional practice management skills in hospital pharmacies
- c) Provide unbiased drug information to the doctors
- d) Know the manufacturing practices of various formulations in hospital set up
- e) Appreciate the practice-based research methods
- f) Appreciates the stores management and inventory control

#### **Course Materials**

#### **Textbooks**

- 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

## Reference Books

- 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

## **Lecture Wise Programme**

## 1. Hospital - its Organisation and functions

## 2. Hospital pharmacy-Organisation and management

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

## 3. The Budget – Preparation and implementation

## 4. Hospital drug policy

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

## 5. Hospital pharmacy services

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

## 6. Manufacture of Pharmaceutical preparations

- a) Sterile formulations large and small volume parenteral
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition
- 7. Continuing professional development programs: Education and training
- 8. Radio Pharmaceuticals Handling and packaging
- 9. Professional Relations and practices of hospital pharmacist

<b>Course Code</b>	Course	L+T	P	Marks	tion	Credits	
				External	Internal	Total	
PD403T-19	Clinical Pharmacy	3+1	-	70	30	100	4

**Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

## Objectives of the Subject: Upon completion of the subject, student shall be able to

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

#### **Course Materials**

#### **Textbooks**

- 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 textbook of Clinical Pharmacy Practice; Essential concepts and skills, G. Parthasarathi, Orient Orient Langram Pvt. Ltd.

## **References Books**

- 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.

## **Lecture Wise Program**

## 1. Definitions, development and scope of clinical pharmacy

## 2. Introduction to daily activities of a clinical pharmacist

- a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
- b. Ward round participation
- c. Adverse drug reaction management
- d. Drug information and poisons information e. Medication history
- e. Patient counseling
- f. Drug utilisation evaluation (DUE) and review (DUR)
- g. Quality assurance of clinical pharmacy services

## 3. Patient data analysis

a. The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices

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

- a. Haematological, Liver function, Renal function, thyroid function tests
- b. Tests associated with cardiac disorders
- c. Fluid and electrolyte balance
- d. Microbiological culture sensitivity tests
- e. Pulmonary Function Tests

#### 5. Drug & Poison information

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

## 6. Pharmacovigilance

- a. Scope, definition and aims of pharmacovigilance
- b. Adverse drug reactions Classification, mechanism, predisposing factors, causality assessment [different scales used]

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

<b>Course Code</b>	Course	L+T	P	Marks	Credits		
				External	Internal	Total	
PD404T-19	Biostatistics & Research	2+1	-	70	30	100	3
	Methodology						

**Scope:** To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

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

- a. Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- b. Know the various statistical techniques to solve statistical problems
- c. Appreciate statistical techniques in solving the problems

#### **Course Materials**

#### Reference Books

- 1. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton, Publisher Marcel Dekker Inc. New York
- 2. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich, McGraw Hill Publications

## **Lecture Wise Program**

## 1. Research Methodology

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

#### 2. Biostatistics

- 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

## 3. Data graphics

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

## 4. Basics of testing hypothesis

- a. Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals
- b. Level of significance (Parametric data)- Students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c. Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)
- d. Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient
- e. Introduction to statistical software: SPSS, Epi Info, SAS

## 5. Statistical methods in epidemiology

a. Incidence and prevalence, relative risk, attributable risk

## 6. Computer applications in pharmacy

## 7. Computer System in Hospital Pharmacy

a. 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

## 8. Computer in Community Pharmacy

- a. Computerizing the Prescription Dispensing process
- b. Use of Computers for Pharmaceutical Care in community pharmacy
- c. Accounting and General ledger system

## 9. Drug Information Retrieval & Storage

- a. Introduction Advantages of Computerized Literature Retrieval
- b. Use of Computerized Retrieval

<b>Course Code</b>	Course	L+T	P	Marks distribution		ion	Credits
				External	Internal	Total	
PD405T-19	Biopharmaceutics &	3+1	-	70	30	100	4
	Pharmacokinetics						

**Scope:** This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems raised therein.

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

- a) Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance
- b) Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination
- c) To understand the concepts of bioavailability and bioequivalence of drug products and their significance
- d) Understand various pharmacokinetic parameters, their significance & applications

## **Course Materials**

#### **Textbooks**

- 1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- 2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- 3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU, Prentice-Hall Inernational edition.USA
- 4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
- 5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
- 6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press
- 7. Biopharmaceutics; By Swarbrick
- 8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia
- 9. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania
- 10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel

#### **Reference Books**

1. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

## **Lecture Wise Program**

## 1. Biopharmaceutics

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

#### 2. Pharmacokinetics

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

## 3. One compartment open model

- a) Intravenous Injection (Bolus)
- b) Intravenous infusion

## 4. Multicompartment models

- a) Two compartment open model
- b) IV bolus, IV infusion and oral administration

## 5. Multiple – Dosage Regimens

- a) 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

- a) Introduction
- b) Factors causing Non-linearity
- c) Michaelis-menton method of estimating parameters

## 7. Non-compartmental Pharmacokinetics

- a) Statistical Moment Theory
- b) MRT for various compartment models
- c) Physiological Pharmacokinetic model

## 8. Bioavailability and Bioequivalence

- a) Introduction
- b) Bioavailability study protocol
- c) Methods of Assessment of Bioavailability

<b>Course Code</b>	Course	L+T	P	Marks	distribut	tion	Credits
				External	Internal	Total	
PD406T-19	Clinical Toxicology	2+1	-	70	30	100	3

#### **Course Materials**

#### **Textbooks**

- 1. Matthew J Ellenhorn. ellenhorns medical toxicology diagnosis and treatment of poisoning, Williams and Willkins publication, London
- 2. V Pillay, Handbook of forensic medicine and toxicology, Paras Publication, Hyderabad

## **Lecture Wise Program**

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

- 9. Plants poisoning: Mushrooms, Mycotoxins
- 10. Food poisonings
- 11. Envenomations Arthropod bites and stings
- 12. Substance abuse
- a) Signs and symptoms of substance abuse and treatment of dependence
- b) CNS stimulants: amphetamine
- c) Opioids
- d) CNS depressants
- e) Hallucinogens: LSD
- f) Cannabis group
- g) Tobacco

<b>Course Code</b>	Course	L+T	P	Marks distribution		on	Credits
				External	Internal	Total	
PD407T-19	Pharmacotherapeutics - I & II*	3+1	ı	70	30	100	4

<sup>\*</sup>Applicable ONLY for Pharm. D (Post Baccalaureate) Students

**Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

**Objectives:** At completion of this subject, it is expected that students will be able to understand:

- a) The pathophysiology of selected disease states and the rationale for drug therapy
- b) The therapeutic approach to management of these diseases
- c) The controversies in drug therapy
- d) The importance of preparation of individualised therapeutic plans based on diagnosis Needs to identify the patient-specific parameters relevant in initiating drug therapy,
- e) and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects)
- f) Describe the pathophysiology of selected disease states and explain the rationale for drug therapy
- g) Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence
- h) Discuss the controversies in drug therapy
- i) Discuss the preparation of individualised therapeutic plans based on diagnosis; and
- j) 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).

#### **Course Materials**

#### **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

## **Lecture Wise Program**

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

## 1. Cardiovascular system

- a. Hypertension
- b. Congestive cardiac failure
- c. Angina Pectoris
- d. Myocardial infarction
- e. Hyperlipidaemias
- f. Electrophysiology of heart and Arrhythmias

## 2. Respiratory system

a. Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

## 3. Endocrine system

- a. Diabetes
- b. Thyroid diseases
- c. Oral contraceptives
- d. Hormone replacement therapy
- e. Osteoporosis

## 4. General prescribing guidelines for:

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

## 5. Ophthalmology

- a. Glaucoma
- b. Conjunctivitis- viral & bacterial

## 6. Introduction to rational drug use

- a. Definition, Role of pharmacist Essential drug concept Rational drug formulations
- 7. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis:
- a. Tuberculosis

- b. Meningitis
- c. Respiratory tract infections
- d. Gastroenteritis
- e. Endocarditis
- f. Septicemia
- g. Urinary tract infections
- h. Protozoal infection- Malaria
- i. HIV & Opportunistic infections
- j. Fungal infections
- k. Viral infections
- 1. Gonarrhoea and Syphillis

#### 8. Musculoskeletal disorders

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

## 9. Renal system

- a. Acute Renal Failure
- b. Chronic Renal Failure
- c. Renal Dialysis
- d. Drug induced renal disorders

## 10. Oncology

- a. Basic principles of Cancer therapy
- b. General introduction to cancer chemotherapeutic agents
- c. Chemotherapy of breast cancer, leukemia
- d. Management of chemotherapy nausea and emesis

## 11. **Dermatology**

- a. Psoriasis
- b. Scabies
- c. Eczema
- d.Impetigo

<b>Course Code</b>	Course	L+T	P	Marks distribution		ion	Credits
				External	Internal	Total	
PD408P-19	Pharmacotherapeutics – III	-	3	70	30	100	2

#### **Practicals**

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

## **Assignments**

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

## Format of the assignment

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

## **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

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

<b>Course Code</b>	Course	L+T	P	Marks distribution		on	Credits
				External	Internal	Total	
PD409P-19	Hospital Pharmacy	-	3	70	30	100	2

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

## **List of Assignments**

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

## **Special requirements**

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

#### **Scheme of Practical Examination**

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

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

<b>Course Code</b>	Course	L+T	P	Marks distribution		ion	Credits
				External	Internal	Total	
PD410P-19	Clinical Pharmacy	-	3	70	30	100	2

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

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

## **Assignment**

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

- 1. Drug information
- 2. Patient medication history interview
- 3. Patient medication counselling
- 4. Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue

## Format of the assignment

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

Course	Course	L+T	P	Marks distribution		ion	Credits
Code				External	Internal	Total	
PD411P-19	Biopharmaceutics and	-	3	70	30	100	2
	Pharmacokinetics						

- 1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
- 2. Comparison of dissolution studies of two different marketed products of same drug.
- 3. Influence of polymorphism on solubility and dissolution.
- 4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
- 5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
- 6. Bioavailability studies of some commonly used drugs on animal/human model.
- 7. Calculation of Ka, Ke, t<sub>1</sub>/<sub>2</sub>, Cmax, AUC, AUMC, MRT etc. from blood profile data
- 8. Calculation of bioavailability from urinary excretion data for two drugs.
- 9. Calculation of AUC and bioequivalence from the given data for two drugs.
- 10. In vitro absorption studies.
- 11. Bioequivalency studies on the different drugs marketed (eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
- 12. Absorption studies in animal inverted intestine using various drugs.
- 13. Effect on contact time on the plasma protein binding of drugs.
- 14. Studying metabolic pathways for different drugs based on elimination kinetics data
- 15. Calculation of elimination half-life for different drugs by using urinary elimination
- 16. data and blood level data.
- 17. Determination of renal clearance.

#### References

- 1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- 2. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
- 3. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
- 4. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- 5. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- 6. Biopharmaceutics; By Swarbrick
- 7. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
- 8. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- 9. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- 10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4<sup>th</sup> edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
- 11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

Code				External	Internal	Total	
PD412P-19	Pharmacotherapeutics - I	-	3	70	30	100	2
	& II*						

<sup>\*</sup>Applicable ONLY for Pharm. D (Post Baccalaureate) Students

#### **Practical**

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

## **Assignments**

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

## Format of the assignment

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

### **Scheme of Practical Examination**

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

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

# FIFTH YEAR

<b>Course Code</b>	Course	L+T	P	Marks distribution		ion	Credits
				External	Internal	Total	
PD501T-19	Clinical Research	3+1	-	70	30	100	4

## **Drug development process:** Introduction Various Approaches to drug discovery

- 1. Pharmacological
- 2. Toxicological
- 3. IND Application
- 4. Drug characterization
- 5. Dosage form

## Clinical development of drug: Introduction to Clinical trials

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

#### 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.

<b>Course Code</b>	Course	L+T	P	Marks distribution		tion	Credits
				External	Internal	Total	
PD502T-19	Pharmacoepidemiology and	3+1	-	70	30	100	4
	Pharmacoeconomics						

## A. Pharmacoepidemiology

- 1. **Definition and scope:** Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.
- 2. **Measurement of outcomes in pharmacoepidemiology** Outcome measure and drug use measures. Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.
- 3. Concept of risk in pharmacoepidemiology: Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio.
- 4. **Pharmacoepidemiological methods:** Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross sectional studies, cohort studies, case control studies, case cohort studies, meta analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.
- 5. Sources of data for pharmacoepidemiological studies: Ad Hoc data sources and automated data systems.
- 6. **Selected special applications of pharmacoepidemiology:** Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

#### **B.** Phrmacoeconomics

- 1. Definition, history, needs of pharmacoeconomic evaluations
- 2. Role in formulary management decisions
- 3. **Pharmacoeconomic evaluation:** Outcome assessment and types of evaluation Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost minimization, cost- benefit, cost effectiveness, cost utility

## C. Applications of Pharmacoeconomics

1. Software and case studies

<b>Course Code</b>	Course	L+T	P	Marks distribution			Credits
				External	Internal	Total	
PD503T-19	Clinical Pharmacokinetics	2+1	-	70	30	100	3
	and Pharmacotherapeutic						
	Drug Monitoring						

## 1. Introduction to Clinical pharmacokinetics

## 2. Design of dosage regimens

- (a)Nomograms and Tabulations in designing dosage regimen
- (b)Conversion from intravenous to oral dosing
- (c)Determination of dose and dosing intervalsDrug dosing in the elderly and pediatrics and obese patients.

## 3. Pharmacokinetics of Drug Interaction

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

## 4. Therapeutic Drug monitoring

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

## 5. Dosage adjustment in Renal and hepatic Disease

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

## 6. Population Pharmacokinetics

- (a)Introduction to Bayesian Theory
- (b)Adaptive method or Dosing with feedback
- (c) Analysis of Population pharmacokinetic data

## 7. Pharmacogenetics

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

<b>Course Code</b>	Course	L+T	P	Marks distribution		tion	Credits
				External	Internal	Total	
PD504P-19	Clerkship	-	10	70	30	100	5

Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

<b>Course Code</b>	Course	L+T	P	Marks distribution			Credits
				External	Internal	Total	
PD505P-19	Project work (Six	-	20	70	30	100	10
	Months)						

## **Project Work**

- 1. To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth-year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
- 2. Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

## Objectives of project work

The main objectives of the project work are to:

- 1. Show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner.
- 2. Develop the students in data collection, analysis and reporting and interpretation skills.

#### Methodology

- 1. To complete the project work following methodology shall be adopted, namely:
- 2. Students shall work in groups of not less than *two* and not more than *four* under an authorised teacher
- 3. Project topic shall be approved by the Head of the Department or Head of the Institution
- 4. Project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics
- 5. Project work shall be approved by the institutional ethics committee
- 6. student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work
- 7. Two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

### Reporting

1. Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50

- pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution
- 2. Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.
- 3. Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

**Evaluation of project work:** The following methodology shall be adopted for evaluating the project work:

- 1. Project work shall be evaluated by internal and external examiners.
- 2. Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).
- 3. Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.
- 4. Internal Evaluation shall be done on the following items: Marks

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

5. Final evaluation of project work shall be done on the following items: Marks

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

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