SAURASHTRA UNIVERSITY

Accredited Grade 'A'

by NAAC

FACULTY OF PHARMACY

Doctor of Pharmacy (Pharm. D.)
Ordinances and Regulations
Effective from
June 2018

(Six-Year full-time equivalent to PG Course)

Department of Pharmaceutical Sciences
Saurashtra University
Rajkot - 360 005
www.saurashtrauniversity.edu

PROGRAMME OUTCOMEs

POs of Doctor of Pharmacy (Pharm. D.)

The following outcomes reflect the terminal skills that all Pharm D graduates should be able to demonstrate upon program completion.

PO1: Medical and Science Knowledge:

Demonstrate mastery and application of core knowledge and skills of physiology, anatomy, biochemistry, biomedical, clinical, epidemiological and social-behavioral sciences.

PO2: Practice Based Learning and Improvement:

Effectively utilize information, informatics and technology to optimize learning and patient care. Promote continuous improvement in one's own patient care and pharmacy services

PO3:Community Pharmacy knowledge:

Impart skills such as dispensing of drugs, ensure safe medication usage, patient counseling and improve patient care in community pharmacy set up.

PO4: Patient counseling and Pharmaceutical Care:

Provide high quality, evidence-based, patient-centered care in cooperation with patients, prescribers and members of the inter-professional health care team and Promote health and wellness and disease prevention.

PO5: The Clinical Pharmacist and society:

Participation in hospital camps, disease awareness programs will inculcate the social responsibility of the clinical pharmacists.

PO6: Ethics:

Understand the clinical aspects of drug development, such as phases, ethical issues, and roles and responsibilities of clinical trial personnel, design of clinical study documents, data management and safety monitoring in clinical trials.

PROGRAMME SPECIFIC OUTCOMES

PSOs of Doctor of Pharmacy (Pharm. D.)

After completion of the program students are able:

PSO1: Understanding of various drug distribution methods; knowledge of the professional practice management skills in hospital pharmacies.

PSO2: Reorganization of unbiased drug information to the healthcare providers, appreciates practice-based research methods, and appreciates stores management and inventory control.

PSO3: Preparation of personalized therapeutic strategies based on diagnosis, through identification of options, observing treatment, time-course of clinical and laboratory indices of therapeutic response and adverse effects.

PSO4: Interpretation of specific laboratory results of disease states, analyze and formulate medicine information.

PSO5: Explanation of the drug utilization review, prescription monitoring, risk management and pharmacoeconomic evaluation.

PSO6: Understanding of the toxicological aspects of individual class of drugs.

PSO7: Elucidate patient care in performing medication history, interpretations of laboratory data, categorizing potential-medicine related impacts of Pharmacotherapy.

DEPARTMENT OF PHARMACEUTICAL SCIENCES

Course Structure and Scheme of Examination

(With Effective from June 2018)

FIRST YEAR

Subject Code	Title of theCourse	Course Credits	No. of Hours per Week	Weightage for Internal Examination	Weightage for End Examination	Total Marks	Duration of Semester End Exams in Hrs.
PD -101	Human Anatomy and Physiology (Theory)	3	3	30	70	100	3
PD -102	Human Anatomy and Physiology (Practical)	3	3	30	70	100	3
PD -103	Pharmaceutics (Theory)	2	2	30	70	100	3
PD -104	Pharmaceutics (Practical)	3	3	30	70	100	3
PD -105	Medicinal Biochemistry (Theory)	3	3	30	70	100	3
PD -106	Medicinal Biochemistry (Practical)	3	3	30	70	100	3
PD -107	Pharmaceutical Organic Chemistry (Theory)	3	3	30	70	100	3
PD -108	Pharmaceutical Organic Chemistry (Practical)	3	3	30	70	100	3

PD -109	**Pharmaceutical Inorganic Chemistry (Theory)**	**2**	**2**	**30**	**70**	**100**	**3**
PD -110	**Pharmaceutical Inorganic Chemistry (Practical)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -111	**Remedial Mathematics/ Biology (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD - 112	**Biology (Practical)**	**3**	**3**	**30**	**70**	**100**	**3**
Total		**34**				**1200**	

SECOND YEAR

Subject Code	Title of theCourse	Course Credits	No. of Hours per Week	WeightageforInternal Examination	Weightagefor End Examination	Total Marks	Duration of Semester End Exams in Hrs.
PD -201	**Pathophysiology (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -202	**Pharmaceutical Microbiology (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -203	**Pharmaceutical Microbiology (Practical)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -204	**Pharmacognosy & Phytopharmaceuticals (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -205	**Pharmacognosy & Phytopharmaceuticals**	**3**	**3**	**30**	**70**	**100**	**3**

	(Practical)						
PD -206	**Pharmacology-I (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -207	**Community Pharmacy (Theory)**	**2**	**2**	**30**	**70**	**100**	**3**
PD -208	**Pharmacotherapeutics (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -209	**Pharmacotherapeutics (Practical)**	**3**	**3**	**30**	**70**	**100**	**3**
Total		**26**				**900**	

THIRD YEAR

Subject Code	Title of theCourse	Course Credits	No. of Hours per Week	Weightagefor Internal Examination	Weightagefor End Examination	Total Marks	Duration of Semester End Exams in Hrs.
PD -301	**Pharmacology-II (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -302	**Pharmacology-II (Practical)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -303	**Pharmaceutical Analysis (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -304	**Pharmaceutical Analysis (Practical)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -305	**Pharmaco therapeutics (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**

PD -306	**Pharmaco therapeutics (Practical)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -307	**Pharmaceutical Jurisprudence (Theory)**	**2**	**2**	**30**	**70**	**100**	**3**
PD -308	**Medicinal Chemistry (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -309	**Medicinal Chemistry (Practical)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -310	**Pharmaceutical Formulations (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -311	**Pharmaceutical Formulations (Practical)**	**3**	**3**	**30**	**70**	**100**	**3**
Total		**32**				**1100**	

FOURTH YEAR

Subject Code	Title of the Course	Course Credits	No. of Hours per Week	Weightage for Internal Examination	Weightage for End Examination	Total Marks	Duration of Semester End Exams in Hrs.
PD -401	Pharmacotherapeutics-III (Theory)	3	3	30	70	100	3
PD -402	Pharmacotherapeutics-III (Practical)	3	3	30	70	100	3
PD -403	Hospital Pharmacy (Theory)	2	2	30	70	100	3
PD –404	Hospital Pharmacy (Practical)	3	3	30	70	100	3
PD -405	Clinical Pharmacy (Theory)	3	3	30	70	100	3
PD -406	Clinical Pharmacy (Practical)	3	3	30	70	100	3
PD -407	Biostatistics & Research Methodology (Theory)	2	2	30	70	100	3
PD -408	Biopharmaceutics & Pharmacokinetics (Theory)	3	3	30	70	100	3
PD -409	Biopharmaceutics & Pharmacokinetics (Practical)	3	3	30	70	100	3
PD -410	Clinical Toxicology (Theory)	2	2	30	70	100	3
Total		27				1000	

FIFTH YEAR

Subject Code	Title of theCourse	Course Credits	No. of Hours per Week/	Weightage for Internal Examination	Weightage for End Examination	Total Marks	Duration of Semester End Exams in Hrs.
PD -501	**Clinical Research (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -502	**Pharmacoepidemiology and Pharmacoeconomics (Theory)**	**3**	**3**	**30**	**70**	**100**	**3**
PD -503	**Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring (Theory)**	**2**	**2**	**30**	**70**	**100**	**3**
PD –504	**Clerkship ***	**-**	**-**	**30**	**70**	**100**	**3**
PD -505	**Project work (Six Months)**	**20**	**20 Hospital posting ***	**--**	**100 ****	**100**	**3**
Total		**28**				**500**	

Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral)

70 marks – Thesis work

SIXTH YEAR

Internship or residency training including postings in specialty units.

Student should independently provide the clinical pharmacy services to the allotted wards.

- Six months in General Medicine department, and
- Two months each in three other specialty departments

First Year

PD – 101: HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

Scope:

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.

Course outcomes :(COs)

CO1: Describe the structure (gross and histology) and functions of various organs of the human body;

CO2: Describe the various homeostatic mechanisms and their imbalances of various systems;

CO3: Identify the various tissues and organs of the different systems of the humanbody;

CO4: Perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;

CO5: Appreciatecoordinatedworkingpatternofdifferentorgansofeachsystemand

CO6: Appreciate the interlinked mechanisms in the maintenance of normal (homeostasis) of human body

Course materials:

Text books

1. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins College NewYork.
2. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburg.

Reference books

1. Guyto narthur, C.*Physiology of human body*. Publisher: Holts aunders.
2. Chatterjee, C.C.*Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
3. PeterL. Williams, Roger Warwick, Mary Dysonand Lawrence, H.
4. *Gray'sanatomy.* Publisher: Churchill Livingstone, London.

Course content

Unit 1

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

Unit 2

Structure of cell – its components and their functions.

Unit 3

Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics

Unit 4

a) Osseous system-structure, composition and functions of the Skeleton(done in practical classes- 6hrs)
b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

Unit 5

Haemopoetic System

a) Composition and functions of blood
b) Haemopoesis and disorders of blood components (definition of disorder)
c) Blood groups
d) Clotting factors and mechanism
e) Platelets and disorders of coagulation

Unit 6

Lymph

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

Unit 7

Cardiovascular system

a) Anatomy and functions of heart
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
c) Electro cardiogram(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

Unit 8

Respiratory system

a) Anatomy of respiratory organs and functions

b) Mechanism/physiology of respiration and regulation of respiration

c) Transport of respiratory gases

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

Unit 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)

Unit 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 midbrain

e) Thalamus, hypothalamus and Basal Ganglia

f) Spinal cord: Structure & reflexes–mono-poly-planter

g) Cranial nerves – names and functions

h) ANS–Anatomy & functions of sympathetic & parasympathetic N.S.

Unit 11

Urinary system

a) Anatomy and physiology of urinary system

b) Formation of urine

c) Renin Angiotensin system–Juxta Glomerular apparatus-acid base Balance

d) Clearance tests and micturition

Unit 12

Endocrine system

a) Pituitary gland
b) Adrenal gland
c) Thyroid and Parathyroid glands
d) Pancreas and gonads

Unit 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

Unit 14

Sense organs

a) Eye
b) Ear
c) Skin
d) Tongue & Nose

Unit 15

Skeletal muscles

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

Unit 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

PD – 102: HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical: 3 Hrs./Week

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

Course materials:

Text books

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

Reference books

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

List of Experiments:

1. Study of tissues of human body
   (a) Epithelial tissue.
   (b) Muscular tissue.
2. Study of tissues of human body
   (a) Connective tissue.
   (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
   (a) Erythrocyte Sedimentation Rate.
   (b) Hemoglobin content of Blood.
   (c) Bleeding time & Clotting time.
8. Determination of
   (a) Blood Pressure.
   (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
   (a) Skeleton system part I-axial skeleton.
   (b) Skeleton system part II- appendicular skeleton.
   (c) Cardio vascular system.
   (d) Respiratory system.
   (e) Digestive system.

(f) Urinary system.

(g) Nervous system.

(h) Special senses.

(i) Reproductive system.

10. Study of different family planning appliances.

11. To perform pregnancy diagnosis test.

12. Study of appliances used in experimental physiology.

13. To records imple muscle curve using gastroenemiussciaticnervepreparation.

14. Torecordsimplesummationcurveusinggastroenemiussciaticnervepreparation.

15. To record simple effect of temperature using gastroenemius sciatic nerve preparation.

16. To record simple effect of load & after load using gastroenemius sciatic nerve preparation.

17. Torecordsimplefatiguecurveusinggastroenemiussciaticnervepreparation.

Scheme of Practical Examination:

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

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

PD – 103: PHARMACEUTICS (THEORY)

Theory: 2 Hrs. /Week

Scope:

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.

Course outcomes :(COs)

CO1: Know the formulation aspects of different dosage forms;

CO2: Do different pharmaceutical calculation involved in formulation;

CO3: Formulate different types of dosage forms.

CO4: Appreciate the importance of good formulation for effectiveness.

Course materials:

Text books

1. Cooper and Gunns Dispensing for pharmacy students.
2. A textbook 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.

Course content

Unit 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.

Unit 2

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

Unit 3

a. Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as

b. BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.

Unit 4

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

Unit 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.

Unit 6

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

Unit 7

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

Unit 8

Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.

Unit 9

Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.

Unit 10

Pharmaceutical calculations.

Unit 11

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

Unit 12

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

PD – 104: PHARMACEUTICS (PRACTICAL)

Practical: 3 Hrs. /Week List of Experiments:

1. Syrups
   a. Simple Syrup I.P
   b. Syrup of Ephedrine HclNF
   c. Syrup Vasaka IP
   d. Syrup of ferrous Phosphate IP
   e. OrangeSyrup
2. Elixir
   a. Piperizine citrate elixir BP
   b. Cascara elixir BPC
   c. Paracetamol elixir BPC
3. Linctus
   a. Simple Linctus BPC
   b. Pediatric simple Linctus BPC
4. Solutions
   a. Solution of cresol with soap IP
   b. Strong solution of ferric chloride BPC
   c. Aqueous Iodine Solution IP
   d. Strong solution of Iodine IP
   e. Strong solution of ammonium acetate IP
5. Liniments
   a. Liniment of turpentine IP*
   b. Liniment of camphor IP
6. Suspensions*
   a. Calamine lotion
   b. Magnesium Hydroxide mixture BP
7. Emulsions*
   a. Cod liver oil emulsion
   b. Liquid paraffin emulsion
8. Powders
   a. Eutectic powder
   b. Explosive powder
   c. Dusting powder
   d. Insufflations

9. Suppositories
    a. Boric acid suppositories
    b. Chloral suppositories
10. Incompatibilities
    a. Mixtures with Physical
    b. Chemical & Therapeutic incompatibilities

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

Scheme of Practical Examination:

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

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

PD – 105: MEDICINAL BIOCHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

Scope:

Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

Course outcomes (COs):-

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

CO1: Understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;

CO2: Know the metabolic process of biomolecules in health andillness (metabolic disorders);

CO3: the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;

CO4: Know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and

CO5: Dothequalitativeanalysisanddeterminationofbiomoleculesinthebodyfluids.

Text books (Theory)

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

Reference books (Theory)

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

Course content

Unit 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.

Unit 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.

Unit 3

Carbohydrate metabolism: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

Unit 4

Lipid metabolism: Oxidation of saturated (β-oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolemia).

Unit 5

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

Unit 6

Protein and amino acid metabolism: protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.

Unit 7

Nucleic acid metabolism: Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semi conservative /onion peel models) and DNA repair mechanism.

Unit 8

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

Unit 9

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 and urine creatinine, urea and uric acid)

c. Urine concentration test

d. Urinary tract calculi (stones)

Unit 10

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

a. Test for hepatic dysfunction – Bile pigments metabolism.

b. Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.

c. Dye tests of excretory function.

d. Tests based upon abnormalities of serum proteins. Selected enzyme tests.

Unit 11

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

Unit 12

Immunochemical techniques for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.

Radio Immuno-Assay (RIA) and Enzyme Linked Immuno-Sorbent Assay (ELISA)

Unit 13

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

PD – 106: MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week Title of the Experiment:

1. Qualitativeanalysisofnormalconstituentsofurine.*

2. Qualitativeanalysisofabnormalconstituentsofurine.*

3. Quantitative estimation of urine sugar by Benedict's reagent method. **

4. Quantitative estimation of urine chlorides by Volhard's method. **

5. Quantitative estimation of urine creatinine by Jaffe'smethod.**

6. Quantitative estimation of urine calcium by precipitation method. **

7. QuantitativeestimationofserumcholesterolbyLibermannBurchard'smethod. **

8. PreparationofFolinWufiltratefromblood.*

9. Quantitative estimation of blood creatinine. **

10. Quantitative estimation of blood sugar Folin - Wutubemethod. **

11. Estimation of SGOT in serum. **

12. Estimation of SGPT in serum. **

13. Estimation of Urea in Serum. **

14. Estimation of Proteins in Serum. **

15. Determination of serum bilirubin**
16. Determination of Glucose by means of Glucoseoxidase. **
17. Enzymatic hydrolysis of Glycogen/Starch by Amylases. **
18. Study of factors affecting Enzyme activity. (pH &Temp.)**
19. Preparation of standard buffer solutions and its pH measurements (any two)*
20. Experiment on lipid profile tests**
21. Determination of sodium, calcium and potassium in serum. **

** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

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

Scheme of Practical Examination:

	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).

PD – 107: PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

Course outcomes (COs):-

This course is designed to impart a very good knowledge about

CO1: IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;

CO2: Some important physical properties of organic compounds;

CO3: Free radical/ nucleophyllic [alkyl/ acyl/ aryl] /electrophyllic substitution, free radical/ nucleophyllic / electrophyllic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability ofcompounds;

CO4: Some named organic reactions with mechanisms

CO5: Methods of preparation test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

Course materials:

Text books

1. T.R. Morrison and R. Boyd – Organic chemistry,
2. Bentley and Driver-Textbook of Pharmaceutical chemistry
3. I.L. Finer - Organic chemistry, the fundamentals of chemistry

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

Course Content

Unit 1

Structures and Physical properties:

a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, nonionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
b. Acids and bases, Lowry Bronsted and Lewis theories
c. Isomerism

Unit 2

Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes,

Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides and Cycloalkanes.

Unit 3

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

Unit 4

Alicyclic compounds: Preparations of cycloalkanes, Bayer strain theory and orbital picture of angle strain.

Unit 5

Nuclophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

Unit 6

Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.

Unit 7

Electrophillic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydin formation, mechanism of free radicals additon, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.

Unit 8

Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

Unit 9

Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substitution in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical

addition to conjugated dienes.

Unit 10

Elecrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogination of alkyl benzene, resonance stabilization of benzyl radical.

Unit 11

Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acidto acid chloride, esters, amide and anhydride. Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

Unit 12

Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.

Unit 13

Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.

Unit 14

Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.

Unit 15

Oxidation reduction reaction.

Unit 16

Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihyrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

PD – 108: PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

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

1. Acetanilde/aspirin (Acetylation)
2. Benzanilide/Phenylbenzoate (Benzoylation)
3. P-bromoacetanilide/2,4,6–tribromoaniline (Bromination)
4. Dibenzylideneacetone (Condensation)
5. 1-Phenylazo-2-napthol (Diazotisationandcoupling)
6. Benzoicacid/salicylicacid (Hydrolysisofester)
7. M-dinitro benzene(Nitration)
8. 9, 10 – Antharaquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene)/ Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotolune
14. Preparation of cyclohexanone from cyclohexanol

2. Identification of organic compounds belonging to the following classes by Systematicqualitativeorganicanalysisincludingpreparationofderivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones,Alcohols, esters, hydrocarbons, anilides, nitro compounds.

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

Scheme of Practical Examination:

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

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

PD – 109: PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory: 2 Hrs. /Week

Scope:

This course mainly deals with fundamentals of Analytical chemistryandalsothestudyofinorganicpharmaceuticalsregardingtheirmonographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.

Course outcomes (COs):-

CO1: Understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;

CO2: Know the analysis of the inorganic pharmaceuticals their applications; and

CO3: Appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

Course materials:

Text books

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

Reference books

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

Course content

Unit 1: Errors

Unit 2: Volumetric analysis

Unit 3: Acid-base titrations

Unit 4: Redox titrations

Unit 5: Non aqueous titrations

Unit 6: Precipitation titrations

Unit 7: Complexometric titrations

Unit 8: Theory of indicators

Unit 9: Gravimetry

Unit 10: Limit tests

Unit 11: Medicinal gases

Unit 12: Acidifiers

Unit 13: Antacids

Unit 14: Cathartics

Unit 15: Electrolyte replenishers

Unit 16: Essential Trace elements

Unit 17: Antimicrobials

Unit 18: Pharmaceutical aids

Unit 19: Dental Products

Unit 20: Miscellaneous compounds

Unit 21: Radio Pharmaceuticals

PD – 110: PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical: 3 Hrs. /Week

1. Limit test (6exercises)

a. Limit test for chlorides
b. Limit test for sulphates
c. Limit test for iron
d. Limit test for heavy metals
e. Limit test for arsenic
f. Modified limit tests for chlorides and sulphates

2. Assays (10exercises)

a. Ammonium chloride- Acid-base titration
b. Ferrous sulphate - Cerimetry
c. Copper sulpahte - Iodometry
d. Calcilum gluconate - Complexometry
e. Hydrogen peroxide –Permanganometry

f. Sodium benzoate–Non-aqueoustitration
g. Sodium chloride–Modifiedvolhard'smethod
h. Assay of KI – KIO_3titration
i. Gravimetric estimation of barium as bariumsulphate
j. Sodium antimony gluconate or antimony potassium tartarate

3. Estimation of mixture (Anytwoexercises)
a. Sodium hydroxide and sodium carbonate
b. Boric acid and Borax
c. Oxalic acid and sodium oxalate

4. Test for identity (Any three exercises)
a. Sodium bicorbonate
b. Barium sulphate
c. Ferrous sulphate
d. Potassium chloride

5. Test for purity (Any two exercises)
a. Swelling power in Bentonite
b. Acid neutralizing capacity in aluminium hydroxide gel
c. Ammonium salts in potash alum
d. Adsorption power heavy Kaolin
e. Presence of Iodates in KI

6. Preparations (Any two exercises)
a. Boric acids
b. Potash alum
c. Calcium lactate
d. Magnesium suphate

Scheme of Practical Examination:

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

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

PD – 111: REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory: 3 Hrs. /Week

REMEDIAL MATHEMATICS:

Scope:

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

Course outcomes (COs):-

CO1: Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;

CO2: Solve the problems of different types by applying theory; and

CO3: Appreciate the important applications of mathematics in pharmacy.

Course materials:

Text books

1. Differential calculus By Shantinarayan
2. TextbookofMathematicsforsecondyearpre-universitybyProf.B.M.Sreenivas

Reference books

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

Course content

Unit 1

Algebra: Determinants, Matrices

Unit 2

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

Unit 3

Analytical Geometry: Points, Straight line, circle, parabola

Unit 4

Differential calculus: Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables

Unit 5

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

Unit 6

Differential equations: Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.

Unit 7

Laplace transform: Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

BIOLOGY

Scope:

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

Coursematerials:

Text books

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

Reference books

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

Course Content

PART- A

Unit 1

Introduction

Unit 2

General organization of plants and its inclusions

Unit 3

Plant tissues

Unit 4

Plant kingdom and its classification

Unit 5

Morphology of plants

Unit 6

Root, Stem, Leaf and Its modifications

Unit 7

Inflorescence and Pollination of flowers

Unit 8

Morphology of fruits and seeds

Unit 9

Plant physiology

Unit 10

Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae

Unit 11

Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

Unit 1

Study of Animal cell

Unit 2

Study animal tissues

Unit 3

Detailed study of frog

Unit 4

Study of Pisces, Raptiles, Aves

Unit 5

General organization of mammals

Unit 6

Study of poisonous animals

PD- 112: BIOLOGY (PRACTICAL)

Practical: 3 Hrs./Week Title:

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

Scheme of Practical Examination:

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

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

SECOND YEAR

PD – 201: PATHOPHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

Scope:

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.

Course outcomes (COs):-

CO1: Describe the etiology and pathogenesis of these lected disease states;

CO2: Name the signs and symptoms of the diseases; and

CO3: Mention the complications of the diseases.

Text books (Theory)

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 (Theory)

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

Course Content

Unit 1

Basic principles of cell injury and Adaptation

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

Unit 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

Unit 3

Diseases of Immunity

a. Introduction to T and B cells
b. MHC proteins or transplantation antigens
c. Immune tolerance

Hypersensitivity

Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs

Autoimmunity

Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.

Acquired immune deficiency syndrome (AIDS)

Amylodosis

Unit 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.

Unit 5

Types of shock, mechanisms, stages and management

Unit 6

Biological effects of radiation

Unit 7

Environmental and nutritional diseases

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

Unit 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

Unit 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 acombined 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+2Min.

PD – 202: PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory: 3 Hrs. /Week

Scope:

Microbiology has always been an essential component of pharmacycurriculum.Thisisbecauseoftherelevanceofmicrobiologytopharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug products cenario in the future.

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

Course outcomes (COs):-

CO1: Knowtheanatomy,identification, growth factors and sterilization of microorganisms;

CO2: Know the mode of transmission of disease-causing microorganism, symptoms of disease, and treatment aspect;

CO3: Do estimation of RNA and DNA and there by identifying the source;

CO4: Do cultivation and identification of the microorganisms in the laboratory;

CO5: Do identification of diseases by performing the diagnostic tests; and

CO6: Appreciatethebehaviorofmotilityandbehavioralcharacteristicsofmicroorganisms.

Text books (Theory)

1. Vanitha Kale and Kishor Bhusari– Applied Microbiology I Himalaya Publishing houseMumbai.
2. Mary Louis Turgeon–Immunology and Serology in Laboratory Medicines ‖2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
3. Harsh Mohan, – Text book of Pathology‖ 3rdedition, 1998, B-3 Ansari road Daryaganj N.Delhi.

Reference books (Theory)

1. PrescotL.M.,JarleyG.PKleinD.A–Microbiology‖2nd-edition Mc Graw Hill Company Inc
2. Rawlins E.A.‖Bentley's Text Book of Pharmaceutics‖ B aillereTindals24-28 London1988
3. Forbisher– Fundamentals of Microbiology‖ Philidelphia W.B.Saunders.
4. Prescott L.M. Jarley G.P., Klein.D.A. – Microbiology.2ndedition WMC Brown Publishers, Oxford.1993

5. War Roitt, Jonathan Brostoff, David male, -Immunology‖3rd edition 1996, Mosby- year book Europe Ltd,London.
6. Pharmacopoeia of India, Govt ofIndia, 1996.

Course content

Unit 1

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

Unit 2

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

Unit 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.

Unit 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.

Unit 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.

Unit 6

Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents' factors affecting their activation and mechanism of action.

Evaluation of bactericidal, bacteriostatic, virucidal activities, evaluation of preservatives in pharmaceutical preparations.

Unit 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 andendotoxins. Significance of toxoids in active immunity, Immunization program, and importance of booster dose.

Unit 8

Diagnostic tests: Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC,

Mantaux Peripheral smear. Study of malaria parasite.

Unit 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. Standardization of vaccines and sera.

Unit 10

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

PD – 203: PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical: 3 Hrs./Week

Title of the Experiment:

1. Study of apparatus used in experimental microbiology*.
2. Sterilization of glass wares. Preparation of media and sterilisation.*
3. Staining techniques – Simple staining; Gram's staining; Negative staining**
4. Study of motility characters*.
5. Enumeration of micro-organisms (Total andViable)*
6. Study of the methods of isolation of pureculture.*
7. Biochemical testing for the identification of micro*-organisms.
8. Cultural sensitivity testing for some micro-organisms.*
9. Sterility testing for powders and liquids.*
10. Determination of minimum inhibitory concentration.*
11. Microbiological assay of antibiotics by cup plate method.*
12. Microbiological assay of vitamins by Turbidometric
13. Determination of RWC. **
14. Diagnostic tests for some common diseases, Widal, malarial parasite. **

* Indicate minor experiment & ** indicate major experiment

Assignments:

1. Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasteurization) and microbial laboratories (other sterilization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments

a. Report of recent microbial techniques developed in diagnosing some common diseases.

b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

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

Scheme of Practical Examination:

	Sessionals	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

PD – 204: PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory: 3 Hrs. /Week

Scope:

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, medicinaluses,identificationtests,preservationmethods,substitutesandadulterants.

Course outcomes (COs):-

CO1: understand the basic principles of cultivation, collection and storage of crude drugs;

CO2: know the source, active constituents and uses of crude drugs; and 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 & Tyler.E.
2. Pharmacognosy by T.E.Wallis.
3. Pharmacognosy by C.S. Shah & Qadery.
4. Pharmacognosy by M.A.Iyengar.

Course content

Unit 1: Introduction.

Unit 2: Definition, history and scope of Pharmacognosy.

Unit 3: Classification of crude drugs.

Unit 4: Cultivation, collection, processing and storage of crude drugs.

Unit 5: Detailed method of cultivation of crude drugs.

Unit 6: Study of cell wall constituents and cell inclusions.

Unit 7: Microscopical and powder Microscopical study of crude drugs.

Unit 8: Study of natural pesticides.

Unit 9: Detailed study of various cell constituents.

Unit 10: Carbohydrates and related products.

Unit 11: Detailed study carbohydrates containing drugs.(11 drugs)

Unit 12: Definition sources, method extraction, chemistry and methodof analysis of lipids.

Unit 13: Detailed study of oils.

Unit 14: Definition, classification, chemistry and method of analysis of protein.

Unit 15: Study of plants fibers used in surgical dressings and related products.

Unit 16: Different methods of adulteration of crude drugs.

PD – 205: PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical: 3 Hrs. /Week

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

List of experiments:

1. Introduction of Pharmacognosy laboratory and experiments.
2. Study of cell wall constituents and cell inclusions.
3. Macro, powder and microscopic study of Datura.
4. Macro, powder and microscopic study of Senna.
5. Macro, powder and microscopic study of Cassia. Cinnamon.
6. Macro, powder and microscopic study of Cinchona.
7. Macro, powder and microscopic study of Ephedra.
8. Macro, powder and microscopic study of Quassia.
9. Macro, powder and microscopic study of Clove
10. Macro, powder and microscopic study of Fennel.
11. Macro, powder and microscopic study of Coriander.
12. Macro, powder and microscopic study of Isapgol.
13. Macro, powder and microscopic study of Nux vomica.
14. Macro, powder and microscopic study of Rauwolfia.
15. Macro, powder and microscopic study of Liquorice.
16. Macro, powder and microscopic study of Ginger.
17. Macro, powder and microscopic study ofPodophyllum.

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, beeswax)
27. Chemical tests for Gelatin.

Scheme of Practical Examination:

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

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

PD – 206: PHARMACOLOGY – I (THEORY)

Theory: 3 Hrs. /Week

Scope:

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.

Course outcome (COs):–

CO1: Understand the pharmacological aspects of drugs falling under the above-mentioned chapters;

CO2: Handle and carry out the animal experiments;

CO3: Appreciate the importance of pharmacology subject as a basis of therapeutics; and correlate an apply the knowledge therapeutically.

Text books (Theory)

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

Reference books (Theory

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

Text books (Practical) :

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

Reference books (Practical)

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

Course content

Unit 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.

Unit 2

Pharmacology of drugs acting on ANS

- **a.** Adrenergic and anti adrenergic drugs
- **b.** Cholinergic and anti cholinergic drugs
- **c.** Neuromuscular blockers
- **d.** Mydriactics and miotics
- **e.** Drugs used in myasthenia gravis
- **f.** Drugs used in Parkinsonism

Unit 3

Pharmacology of drugs acting on cardiovascular system

- **a.** Anti hypertensives
- **b.** Anti-anginal drugs
- **c.** Anti-arrhythmic drugs

d. Drugs used for therapy of Congestive Heart Failure

e. Drugs used for hyper lipidaemias

Unit 4

Pharmacology of drugs acting on Central Nervous System

a. General anesthetics

b. Sedatives and hypnotics

c. Anticonvulsants

d. Analgesic and anti-inflammatory agents

e. Psychotropic drugs

f. Alcohol and methyl alcohol

g. CNS stimulants and cognition enhancers

h. Pharmacology of local anaesthetics

Unit 5

Pharmacology of Drugs acting on Respiratory tract

a. Bronchodilators
b. Mucolytics
c. Expectorants
d. Antitussives
e. Nasal Decongestants

Unit 6

Pharmacology of Hormones and Hormone antagonists

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

Unit 7

Pharmacology of autocoids and their antagonists

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

PD – 207: COMMUNITY PHARMACY (THEORY)

Theory: 2 Hrs. /Week

Scope:

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

Course outcome (COs):-

CO1: know pharmaceutical care services;

CO2: know the business and professional practice management skills in community pharmacies;

CO3: do patient counseling & provide health screening services to public in community pharmacy;

CO4: respond to minor ailments and provide appropriate medication;

CO5: show empathy and sympathy to patients

CO6: appreciate the concept of rational drug therapy.

Text Books:

1. Health Education and Community Pharmacy by N.S.Parmar.
2. WHO consultative group report?
3. Drugstore & 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 counseling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

Scheme of evaluation (80 Marks)

1	Synopsis	10
2	Major Experiment	30
	(Counseling of patients with specific diseases – emphasis should be	

	given on Counseling: introduction, content, process and conclusion)	
3	Minor Experiment (Ability to measure B.P/CBG/Lung function)	15
4	Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management)	15
5	Viva– Voce	10
Total		80

Course content

Unit 1

Definition, scope of community pharmacy Roles and responsibilities of Community pharmacist

Unit 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

Unit 3

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

Unit 4

Inventory control in community pharmacy

Definition, various methods of Inventory Control

ABC, VED, EOQ, Lead time, safety stock

Unit 5

Pharmaceutical care

Definition and Principles of Pharmaceutical care.

Unit 6

Patient counseling Definition,

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

Unit 7

Patient medication adherence

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

Unit 8

Health screening services

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

Unit 9

OTC Medication

Definition, OTC medication list & Counseling Unit 10 Health Education WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients. Commonly occurring Communicable Diseases, causative agents, Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS Balance diet, and treatment & prevention of deficiency disorders Family planning – role of pharmacist

Unit 11

Responding to symptoms of minor ailments

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

Unit 12

Essential Drugs concept and Rational Drug Therapy, Role of community pharmacist

Unit 13

Code of ethics for community pharmacists

PD – 208: PHARMACOTHERAPEUTICS – I (THEORY)

Theory: 3 Hrs. /Week

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.

Course outcome (Cos):-

CO1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO2: The therapeutic approach to management of these diseases;

CO3: The controversies in drug therapy;

CO4: The importance of preparation of individualized therapeutic plans based on diagnosis;

CO5: 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);

CO6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO7: Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO8: Discuss the controversies in drug therapy;

CO9: Discuss the preparation of individualized therapeutic plans based on diagnosis;

CO10: Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

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

Reference Books

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

5. Avery's Drug Treatment, 4thEdn, 1997, Adis International Limited.
6. Relevant review articles from recent medical and pharmaceutical literature.
7.

Course content

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Unit 1

Cardiovascular system: Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias , Electrophysiology of heart and Arrhythmias

Unit 2

Respiratory system: Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

Unit 3

Endocrine system: Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis

Unit 4

General prescribing guidelines for

a. Pediatric patients
b. Geriatric patients
c. Pregnancy and breastfeeding

Unit 5

Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial

Unit 6

Introduction to rational drug use

Definition, Role of pharmacist Essential drug concept Rational drug Formulations

PD – 209: PHARMACO THERAPEUTICS - I (PRACTICAL)

Practical: 3 Hrs. /Week 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	**03 hrs**	**04 hrs**

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

Third Year

PD – 301: PHARMACOLOGY – II (THEORY)

Theory: 3 Hrs. /Week

Scope:

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, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autocoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamines, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

Course outcome (COs):-

CO1: Understand the pharmacological aspects of drugs falling under the above-mentioned chapters,

CO2: Carry out the animal experiments confidently,

CO3: Appreciate the importance of pharmacology subject as a basis of therapeutics, and

CO4: Correlate and apply the knowledge therapeutically.

Text books (Theory)

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

Reference books (Theory)

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

Text books (Practical)

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

Reference books (Practical):

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

Course content

Unit 1

Pharmacology of Drugs acting on Blood and blood forming agents

- **a.** Anti coagulants
- **b.** Thrombolytics and anti platelet agents
- **c.** Haemopoietics and plasma expanders

Unit 2

Pharmacology of drugs acting on Renal System

- **a.** Diuretics
- **b.** Anti diuretics

Unit 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.** Anti fungal antibiotics
- **h.** Anti viral agents
- **i.** Chemotherapy of tuberculosis and leprosy
- **j.** Chemotherapy of Malaria

k. Chemotherapy of protozoal infections (amoebiasis, Giardiasis)

l. Pharmacology of Anthelmintic drugs

m. Chemotherapy of cancer (Neoplasms)

Unit 4

Immuno pharmacology

a. Pharmacology of immune suppressants and stimulants

Unit 5

Principles of Animal toxicology

a. Acute, sub-acute and chronic toxicity

Unit 6

The dynamic cell: The structures and functions of the components of the cell

a. Cell and macromolecules: Cellular classification, sub cellular organelles, macromolecules, large macromolecular assemblies

b. Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.

c. DNA replication: General, bacterial and eukaryotic DNA replication.

d. The cell cycle: Restriction point, cell cycle regulators and modifiers.

e. Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

The Gene: Genome structure and function:

a. Gene structure: Organization and elucidation of genetic code.

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

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

RNA processing: rRNA, tRNA and mRNA processing.

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

Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, tri nucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes.

The gene sequencing, mapping and cloning of human disease genes. Introduction to gene therapy and targeting.

Recombinant DNA technology: principles. Processes (gene transfer technology) and

applications

Books:

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

PD – 302: PHARMACOLOGY – II (PRACTICAL)

Practical: 3 Hrs./Week List of Experiments:

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

a) Analgesic property of drug using analgesiometer.

b) Antiinflammatory effect of drugs using rat-paw edema method.

c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.

d) Anti depressant activity of drugs using poleclimbing apparatus and pentobarbitone induced sleeping time methods.

e) Locomotor activity evaluation of drugs using actophotometer and rotorod.

f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

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

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

PD – 303: PHARMACEUTICAL ANALYSIS (THEORY)

Theory: 3 Hrs. /Week

Scope:

This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

Course Outcome (Cos):

CO1: Understand the principles of volumetric and electro chemical analysis

CO2: Carryout various volumetric and electrochemical titrations

CO3: Develop analytical skills

Course content

Unit 1

Quality Assurance:

1. Introduction, sources of quality variation, control of quality variation.
2. Concept of statistical quality control.
3. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
4. GLP, ISO 9000.
5. Total quality management, quality review and documentation.
6. ICH- international conference for harmonization-guidelines.
7. Regulatory control.

Unit 2

Chromatography:

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

1. **Column Chromatography**: Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
2. **TLC**: Introduction, principle, techniques, R_f value and applications.
3. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
4. **Ion-exchange chromatography**: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
5. **HPLC**: Introduction, theory, instrumentation and applications.

6. **HPTLC**: Introduction, theory, instrumentation and applications.
7. **Gas Chromatography**: Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors- Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
8. **Electrophoresis**: Principles of separation, equipment for paper and gel electrophoresis and application.
9. **Gel filtration** and **affinity chromatography**: Introduction, technique, applications.

Unit 3

Electrometric Methods:

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

1. **Potentiometry**: Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischertitration.
2. **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications.
3. **Polarography**: Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographicwave, Polarographic maxima and suppressors and applications.
4. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

Unit 4

Spectroscopy:

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

1. **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 byfluorimetry.

2. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceuticalapplications.
3. **Atomic Absorption Spectrometry:** Introduction, Theory,types ofelectrodes, instrumentation and applications.
4. **Atomic Emission Spectroscopy**: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.
5. **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications.
6. **Mass Spectroscopy**: (**Introduction only**) – Fragmentation, types of ions produced mass spectrum and applications.
7. **Polarimetry: (Introduction only**) – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.
8. **X-RAY Diffraction: (Introduction only**) – Theory, reciprocal lattice concept, diffraction patterns and applications.
9. **Thermal Analysis**: Introduction, instrumentation, applications, and DSC and DTA.

PD – 304: PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical: 3 Hrs. /Week List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of an acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.

10. Colourimetric estimation of Supha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colouri metry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nephelo turbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pHmeter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot.D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett &Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D.Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practice GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.

15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia–The Pharm. Press, London.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	**04**	**10**
Major Experiment	**08**	**30**
Minor Experiment	**04**	**10**
Viva	**02**	**10**
Max Marks	**20**	**70**
Duration	**3hrs**	**4hrs**

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

PD – 305: PHARMACOTHERAPEUTICS – II (THEORY)

Theory: 3 Hrs. /Week

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.

Course outcome (Cos):-

CO1: Know the pathophysiologyofselecteddiseasestatesandtherationalefordrugtherapy

CO2: Know the therapeutic approach to management of these diseases;

CO3: Know the controversies in drug therapy;

CO4: Know the importance of preparation of individualized therapeutic plans based on diagnosis;

CO5: 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).

Text books (Theory)

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

Reference books (Theory)

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

Course content

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases

Unit 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

Unit 2

Musculoskeletal disorders

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

Unit 3

Renal system

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

Unit 4

Oncology:

Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management

of chemotherapy nausea and emesis

Unit 5

Dermatology:

Psoriasis, Scabies, Eczema, Impetigo

PD – 306: PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical: 3 Hrs./Week 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.
- The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.
- A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

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

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.

5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	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).

PD – 307: PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory: 2 Hrs. /Week

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.

Course outcome (COs):-

CO1: Practice the Professional ethics;

CO2: Understand the various concepts of the pharmaceutical legislation in India;

CO3: Know the various parameters in the Drug and Cosmetic Act and rules;

CO4: Know the Drug policy, DPCO, Patent and design act;

CO5: Understand the labeling requirements and packaging guidelines for drugs and cosmetics;

CO6: Be able to understand and the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and

CO7: Other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

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

Reference books (Theory)

1. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
2. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
3. Reports of the Pharmaceutical enquiry Committee
4. I.D.M.A., Mumbai. DPCO1995
5. Various reports of Amendments.
6. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
7. Eastern Book Company, The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

Course content

Unit 1

Pharmaceutical Legislations – A brief review.

Unit 2

Principle and Significance of professional ethics. Critical study of the code of Pharmaceutical ethics drafted by PCI.

Unit 3

- Drugs and Cosmetics Act, 1940, and its rules 1945.
- Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
- Sales, Import, labeling and packaging of Drugs and Cosmetics Provisions Relating to Indigenous Systems.
- Constitution and Functions of DTAB, DCC, CDL.
- Qualification and duties –Govt. analyst and Drugs Inspector.

Unit 4

Pharmacy Act –1948.

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

Unit 5

Medicinal and Toilet Preparation Act –1955.

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

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

Unit 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.

Unit 7

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

Unit 8

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

Unit 9

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

Unit 10

Prevention of Cruelty to animals Act-1960.

Unit 11

Patents & design Act-1970.

Unit 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.

PD – 308: MEDICINAL CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

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.

Course outcomes (COs):-

CO1: Understand the chemistry of drugs with respect to their pharmacological activity

CO2: Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs

CO3: Know the Structural Activity Relationship of different class of drugs

CO4: Study the chemical synthesis of selected drugs

Course content

Unit 1

Modern concept of rational drug design:

- A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of anti-sense 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.

Unit 2

Anti-infective agents

a. Local anti-infective agents

b. Preservatives

c. Anti-fungal 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

Unit 3

Sulphonamides and sulphones

Unit 4

Antimalarials

Unit 5

Antibiotics

Unit 6

Antineoplastic agents

Unit 7

Cardiovascular agents

- **a.** Antihypertensive agents
- **b.** Anti anginal agents and vasodilators
- **c.** Anti arrhythmic agents
- **d.** Anti hyperlipidemic agents
- **e.** Coagulants and Anticoagulants
- **f.** Endocrine

Unit 8

Hypoglycemic gents

Unit 9

Thyroid and Ant thyroid agents

Unit 10

Diuretics

Unit 11

Diagnostic agents

Unit 12

Steroidal Hormones and Adrenocorticoids

PD – 309: MEDICINAL CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

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

PD – 310: PHARMACEUTICAL FORMULATIONS (THEORY)

Theory: 2 Hrs. /Week

Scope:

Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.

Course outcomes (COs):-

CO1: Understand the principle involved in formulation of various pharmaceutical dosage forms;

CO2: Prepare various pharmaceutical formulations;

CO3: Perform evaluation of pharmaceutical dosage forms; and

CO4: Understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

Text books (Theory)

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

Reference books (Theory)

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

Course content

Unit 1

Pharmaceutical dosage form- concept and classification

Unit 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.

Unit 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.

Unit 4

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

Unit 5

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

Unit 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

Unit 7

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

PD – 311: PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical: 3 Hrs. /Week List of Experiments:

1. Manufacture of Tablets
   - **a.** Ordinary compressed tablet-wet granulation
   - **b.** Tablets prepared by direct compression.
   - **c.** Soluble tablet.
   - **d.** Chewable tablet.
2. Formulation and filling of hard gelatin capsules
3. Manufacture of parenterals
   - **a.** Ascorbic acid injection
   - **b.** Calcium gluconate injection
   - **c.** Sodium chloride infusion.
   - **d.** Dextrose and Sodium chloride injection/infusion.
4. Evaluation of Pharmaceutical formulations (QC tests)
   - **a.** Tablets
   - **b.** Capsules
   - **c.** Injections
5. Formulation of two liquid oral preparations and evaluation by assay
   - **a.** Solution: Paracetamol Syrup
   - **b.** Antacid suspensions-Aluminum hydroxide gel
6. Formulation of semisolids and evaluation by assay
   - **a.** 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 toothpowders.

8. Tablet coating(demonstration)

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	**03 hrs**	**04 hrs**

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

Fourth Year

PD – 401: PHARMACOTHERAPEUTICS – III (THEORY)

Theory: 3 Hrs. /Week

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.

Course outcomes (COs):-

CO1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO2: The therapeutic approach to management of these diseases;

CO3: The controversies in drug therapy;

CO4: Theimportanceofpreparationofindividualizedtherapeuticplansbasedondiagnosis;

CO5: 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);

CO6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO7: To summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO8: To discuss the controversies in drug therapy;

CO9: To discuss the preparation of individualized therapeutic plans based on diagnosis

CO10: Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

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

Reference Books

1. Pathologic basis of disease –Robins S L, 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, 4thEdn, 1997, Ad is International Limited.

6. Relevant review articles from recent medical and pharmaceutical literature.

PD – 402: PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical: 3 Hrs. /Week Practical:

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.

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

Course content

Unit 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.

Unit 2

Hematological system: Anemias, Venous thromboembolism, Drug induced blood disorders.

Unit 3

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

Unit 4

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

Unit 5

Pain management including Pain pathways, neuralgias, headaches.

Unit 6

Evidence Based Medicine

Assignments:

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

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year

4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8 + 2 Min.

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).

PD – 403: HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week

Scope:

In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counseling, and therapeutic drug monitoring for improved patient care.

Course outcomes (COs):-

CO1: Know various drug distribution methods;

CO2: Know the professional practice management skills in hospital pharmacies;

CO3: Provide unbiased drug information to the doctors;

CO4: Know the manufacturing practices of various formulations in hospital setup;

CO5: Appreciate the practice-based research methods; and

CO6: Appreciate the stores management and inventory control.

Text books: (latest editions)

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

References:

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

Course content

Unit 1

Hospital- its Organization and functions

Unit 2

Hospital pharmacy- Organization and management

- **a.** Organizational structure-Staff, Infrastructure & workload statistics
- **b.** Management of materials and finance
- **c.** Roles & responsibilities of hospital pharmacist

Unit 3

The Budget–Preparation and implementation

Unit 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

Unit 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

a. Drug distribution in the hospital

i. Individual prescription method

ii. Floor stock method

iii. Unit dose drug distribution method

b. Distribution of Narcotic and other controlled substances

c. Central sterile supply services– Role of pharmacist

Unit 6

Manufacture of Pharmaceutical preparations

a. Sterile formulations– large and small volume parenterals

b. Manufacture of Ointments, Liquids, and creams

c. Manufacturing of Tablets, granules, capsules, and powders

d. Total Parenteral nutrition

Unit 7

Continuing professional development programs

- Education and training

Unit 8

- Radio Pharmaceuticals–Handling and packaging

Unit 9

- Professional Relations and practices of hospital pharmacist

PD – 404: HOSPITAL PHARMACY (PRACTICAL)

Practical: 3 Hrs. /Week

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

List of Assignments:

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

PD – 405: CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

Course outcomes (COs):-

CO1: Monitor drug therapy of patient through medication chart review and clinical review;

CO2: Obtain medication history interview and counsel the patients;

CO3: Identify and resolve drug related problems;

CO4: Detect, assess and monitor adverse drug reaction;

CO5: Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and

CO6: Retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

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

References

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

Course content

Unit 1

Definitions, development and scope of clinical pharmacy

Unit 2

Introduction to daily activities of a clinical pharmacist

a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
b. Ward round participation

c. Adverse drug reaction management

d. Drug information and poisons information

e. Medication history

f. Patient counseling

g. Drug utilization evaluation (DUE) and review (DUR)

h. Quality assurance of clinical pharmacy services

Unit 3

Patient data analysis

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

Unit 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

Unit 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

Unit 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.

Unit 7

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

Unit 8

Pharmaceutical care concepts

Unit 9

Critical evaluation of biomedical literature

Unit 10

Medication errors

PD – 406: CLINICAL PHARMACY (PRACTICAL)

Practical: 3 Hrs. /Week

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

a. Answering drug information questions (4 Nos)

b. Patient medication counseling (4 Nos)

c. Case studies related to laboratory investigations (4 Nos)

d. Patient medication history interview (3 Nos)

Assignment:

- Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.
- Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.

2. Reference(s) shall be included at the end.

3. Assignment can be a combined presentation at the end of the academic year.

4. It shall be computer draft copy.

5. Name and signature of the student.

6. Time allocated for presentation may be 8 + 2 Min.

PD – 407 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory: 2 Hrs. /Week

Unit 1 Research Methodology

a. Types of clinical study designs: Case studies, observational studies, interventional studies,

b. Designing the methodology

c. Sample size determination and Power of a study

Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study

d. Report writing and presentation of data

Unit 2 Biostatistics

2.1

a. Introduction

b. Types of data distribution

c. Measures describing the central tendency distributions- average, median, mode

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

2.2 Data graphics

Construction and labeling of graphs, histogram, pie charts, scatterplots, semi logarthimic plots

2.3 Basics of testing hypothesis

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

b. Level of significance (Parametric data)- students t test (paired and unpaired), chi-Square-test, Analysis of Variance (one-way and two-way)

c. Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one-way ANOVA)

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

e. Introduction to statistical software: SPSS, EpiInfo, SAS.

2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

Unit 3 Computer applications in pharmacy

- Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.
- Computer In Community Pharmacy Computerizing the Prescription Dispensing process
- Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system
- Drug Information Retrieval & Storage:
- Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval

Reference books:

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rdedition, publisher Marcel Dekker Inc. New York.

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

PD – 408: BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

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 arises therein.

Course outcomes (COs):-

CO 1: Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.

CO 2: Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

CO 3: To understand the concepts of bioavailability and bioequivalence of drug products and their significance.

CO4: Understand various pharmacokinetic parameters, their significance & applications.

Course content

Unit 1

Biopharmaceutics

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

Unit 2

Pharmacokinetics

1. Introduction to Pharmacokinetics.
   a. Mathematical model
   b. Drug levels in blood.
   c. Pharmacokinetic model
   d. Compartment models
   e. Pharmacokinetic study.
2. One compartment open model.
   a. Intravenous Injection(Bolus)

b. Intravenous infusion.

3. Multi compartment models.

a. Two compartment open model.

b. IV bolus, IV infusion and oral administration

4. Multiple – Dosage Regimens.

a. Repititive Intravenous injections–One Compartment Open Model

b. Repititive Extra vascular dosing – One Compartment Open model

c. Multiple Dose Regimen–Two Compartment Open Model

5. Nonlinear Pharmacokinetics.

a. Introduction

b. Factors causing Non-linearity.

c. Michaelis- menton method of estimating parameters.

6. Non-compartmental Pharmacokinetics.

a. Statistical Moment Theory.

b. MRT for various compartment models.

c. Physiological Pharmacokinetic model.

7. Bioavailability and Bioequivalence.

a. Introduction.

b. Bioavailability study protocol.

c. Methods of Assessment of Bioavailability

PD – 409: BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical: 3 Hrs. /Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.

2. Comparison of dissolution studies of two different marketed products of same drug.

3. Influence of polymorphism on solubility and dissolution.

4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.

5. Extent of plasma- protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.

6. Bioavailability studies of some commonly used drugs on animal/ human model.

7. Calculation of Ka, Ke, $t_1/2$, Cmax, AUC, AUMC, MRT etc. from blood profile data.

8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. *In vitro* absorption studies.
11. Bioequivalency studies on the different drugs marketed. (eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

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 Swar brick
7. Biopharmaceutics 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, Pennsylvania1989.
10. Biopharmaceutics and Clinical Pharmacokinetics- Anintroduction4thedition Revised
11. and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swar brick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

PD – 410: CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

Course outcomes (COs):-

CO1: After the course the students shall have the necessary knowledge and understanding of basic toxicology (including toxicokinetics) relevant for drugs, and the principles for toxicological testing of new drugs and toxicological follow-up of drugs already on the marked.

CO2: In addition, the students shall know the most usual acute-toxic drugs and chemicals, poisoning symptoms, treatments and antidotes

Course content

Unit1 General Principles involved in the management of poisoning

Unit 2 Antidotes and the clinical applications.

Unit 3 Supportive care in clinical Toxicology.

Unit 4 Gut Decontamination.

Unit 5 Elimination Enhancement.

Unit 6 Toxicokinetics.

Unit 7 Clinical symptoms and management of acute poisoning with the following agents

a. Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
b. Opiates overdose.
c. Antidepressants
d. Barbiturates and benzodiazepines.
e. Alcohol: ethanol, methanol.
f. Paracetamol and salicylates.
g. Non-steroidal anti-inflammatory drugs.
h. Hydrocarbons: Petroleum products and PEG.
i. Caustics: inorganic acids and alkali.
j. Radiation poisoning

Unit 8

Clinical symptoms and management of chronic poisoning with the following

Agents–Heavy metals: Arsenic, lead, mercury, iron, copper

Unit 9

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

Unit 10 Plants poisoning. Mushrooms, Mycotoxins.

Unit 11 Food poisonings

Unit 12 Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

a. CNS stimulants: amphetamine
b. Opioids
c. CNS depressants
d. Hallucinogens: LSD
e. Cannabis group
f. Tobacco

References:

1. Matthew J Ellenhorn. Ellenhorns medical toxicology – diagnosis and treatment of poisoning. Second edition. Williams and Willkins publication, London
2. V V Pillay Handbook of forensic medicine and toxicology. Thirteenth edition 2003 Paras Publication, Hyderabad

Fifth year

PD – 501: CLINICAL RESEARCH (THEORY)

Theory: 3 Hrs. /Week

Course outcomes (COs):-

CO1: Demonstrate competency in biopharmaceutical clinical trial research designs and regulatory affairs management to meet the health and medical needs of current and future biopharmaceutical product consumers

CO2: Evaluate critical domestic and global regulatory and health care issues that challenge and influence biopharmaceutical product development

CO3: Effectively assess and manage ethical clinical trial programs and biopharmaceutical development projects

CO4: Forecast the resources necessary for developing and managing biopharmaceutical clinical research grants and trials as required and regulated by global regulatory agencies

Course content

Unit 1 Drug development process:

Introduction Various Approaches to drug discovery

a. Pharmacological
b. Toxicological
c. IND Application
d. Drug characterization
e. Dosage form

Unit 2 Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO)guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB/IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICHGCP
    a. Sponsor
    b. Investigators
    c. Clinical research associate

d. Auditors

e. Contract research coordinators

f. Regulatory authority

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

12. Informed consent Process

13. Data management and its components

14. Safety monitoring in clinical trials.

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; May1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects2000. 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, Jan2000, Wiley Publications.

7. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. Mc Graw Hill Publications,2001

PD – 502: PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory: 3 Hrs. /Week

Course Outcomes (COs):-

CO1: Identify the applications of pharmaco epidemiology and pharmaco economics in clinical settings

CO2: Discuss the various pharmaco epidemiological outcome measures

CO3: Describe the concept of risk in pharmaco epidemiology and different methods of measuring risk

CO4: Explain the various pharmaco epidemiological methods

CO5: Explain the sources of data for pharmaco epidemiological studies

CO6: Explain the various systems for studying drug effects in populations

CO7: Discuss the methods to measure outcomes in pharmaco ecnomic studies

CO8: Describe the current pharmaco economic evaluation methods

Course content

Unit 1

Pharmaco epidemiology

Definition and scope:

Origin and evaluation of pharmaco epidemiology need for pharmaco epidemiology, aims and applications.

Measurement of outcomes in pharmaco epidemiology

Outcome measure and drug use measures

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

Concept of risk in pharmaco epidemiology

Measurement of risk, attribute able risk and relative risk, time-risk relationship and odds ratio

Pharmaco epidemiological methods

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

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

Sources of data for pharmaco epidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmaco epidemiology

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

Unit 2

Phrmaco economics:

Definition, history, needs of pharmaco economic evaluations

Role in formulary management decisions

Pharmaco economic evaluation

Outcome assessment and types of evaluation

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

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

Unit 3

Applications of Pharmaco economics

Software and case studies

PD – 503: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs. /Week

Course outcomes (COs):-

CO1: Formulate and design a dosage regimen for individual patients

CO2: Interpret and correlate the plasma drug concentration with patient's therapeutic outcomes

CO3: Recommend dosage adjustment in renal and hepatic disease

CO4: Recommend dosage adjustment for paediatrics, geriatrics and obese patients

CO5: Analyze and resolve pharmaco kintetic drug interactions

CO6: Illustrate and apply pharmacokinetic parameters in clinical settings

CO7: Interpret the impact of genetic poylmorphisms of individuals on pharmacokinetics and pharmaco dynamics of drugs

CO8: Employ pharmacokinetic modeling for the given data using the principles of pharmaco metrics

Course content

Unit 1 Introduction to Clinical pharmacokinetics.

Unit 2 Design of dosage regimens:

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

Unit 3 Pharmacokinetics of Drug Interaction:

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

Unit 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/ Pharmaco dynamic Correlation in drug therapy.
e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

Unit 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.

Unit 6 Population Pharmacokinetics.

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

Unit 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