DAYANANDA SAGAR UNIVERSITY

Shavige Malleshwara Hills, Kumaraswamy Layout,

Bengaluru - 560078, Karnataka.

SCHOOL OF HEALTH SCIENCES

COLLEGE OF PHARMACEUTICAL SCIENCES

SCHEME & SYLLABUS
FOR
DOCTOR OF PHARMACY (PHARM D) – 2015

(With Effect from 2015-16)

SEMESTER / YEAR : **II YEAR**
COURSE CODE : **15PD202**
TITLE OF THE COURSE : **PHARMACEUTICAL MICROBIOLOGY (Theory)**
L:T:P :**3:1:3**

Course objectives

- Develop a thorough knowledge of application of microbiology with relevance to pharmaceutical industry which involves study of bacteria, fungi and virus.
- Provide conceptual understanding of the various aspects of aseptic techniques and production of sterile immunological products.
- Recent advances in Biotechnology.

Course Outcomes

- Students will be able to isolate and identify sources of microbial contamination in pharmaceutical products.
- Demonstrate a critical awareness of recent techniques applicable to research in pharmaceutical biotechnology and their roles in effective therapeutic treatment.

Unit -1 **15 hrs**

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

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

Unit – 2 **15hrs**

3 Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.

4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.

Unit -3 **15 hrs**

5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations . Brief information on Validation.

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

Unit – 4 **15 hrs**

7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive). Antigens, chemical nature of antigens structure and formation of Antibodies, AntigenAntibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.

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

Unit – 5 **15 hrs**

9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B_2 and B_{12}. Standardisation of vaccines and sera.

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

SEMESTER / YEAR : II YEAR
COURSE CODE : 15PD272
TITLE OF THE COURSE : PHARMACEUTICAL MICROBIOLOGY (Practical)
L:T:P :3:1:3

Title of the Experiment:

1 Study of apparatus used in experimental microbiology*.
2 Sterilisation of glass ware's. Preparation of media and sterilisation.* 3 Staining techniques – Simple staining Gram's staining ; Negative staining** 4 Study of motility characters*.
3 Enumeration of micro-organisms (Total and Viable)*
4 Study of the methods of isolation of pure culture.*
5 Bio chemical testing for the identification of micro*-organisms.
6 Cultural sensitivity testing for some micro-organisms.*
7 Sterility testing for powders and liquids.*
8 Determination of minimum inhibitory concentration.*
9 Microbiological assay of antibiotics by cup plate method.*
10 Microbiological assay of vitamins by Turbidometric method**
11 Determination of RWC.**
12 Diagnostic tests for some common diseases, Widal, malarial parasite.** * Indicate minor experiment & ** indicate major experiment

Text Books:

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

Reference Books:

a. Prescot L.M., Jarley G.P Klein D.A —Microbiology|| 2nd- edition Mc Graw Hill Company Inc
b. Rawlins E.A.||Bentley's Text Book of Pharmaceutics|| B ailliere Tindals 24-28 London 1988
c. Forbisher — Fundamentals of Microbiology|| Philidelphia W.B. Saunders.

d. Prescott L.M. Jarley G.P., Klein.D.A. — Microbiology.||2nd edition WMC Brown Publishers, Oxford. 1993
e. War Roitt, Jonathan Brostoff, David male, — Immunology||3rd edition 1996, Mosbyyear book Europe Ltd, London.
f. Pharmacopoeia of India, Govt of India, 1996.

SEMESTER / YEAR : II YEAR
COURSE CODE : 15PD203
TITLE OF THE COURSE : PHARMACOGNOSY & PHYTOPHARMACEUTICALS (Theory)
L:T:P :3:1:3

Course objectives

 Students will be aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

Course Outcomes understand the basic principles of cultivation, collection and storage of crude drugs;

- know the source, active constituents and uses of crude drugs; and
- appreciate the applications of primary and secondary metabolites of the plant.

Unit -1 **10 hrs**

1 Introduction.
2 Definition, history and scope of Pharmacognosy.
3 Classification of crude drugs.

Unit -2 **15 hrs**

4 Cultivation, collection, processing and storage of crude drugs.
5 Detailed method of cultivation of crude drugs.
6 Study of cell wall constituents and cell inclusions.

Unit -3 **20 hrs**

7 Microscopical and powder Microscopical study of crude drugs.
8 Study of natural pesticides.

Unit -4 **20 hrs**

9 Detailed study of various cell constituents.
10 Carbohydrates and related products.
11 Detailed study carbohydrates containing drugs.(11 drugs)

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

Unit -5 **10 hrs**

14 Definition, classification, chemistry and method of analysis of protein.
15 Study of plants fibers used in surgical dressings and related products.
16 Different methods of adulteration of crude drugs.

SEMESTER / YEAR : II YEAR
COURSE CODE : 15PD271
TITLE OF THE COURSE : PHARMACOGNOSY & PHYTOPHARMACEUTICALS (Practical)
L:T:P :3:1:3

List of experiments:

Introduction of Pharmacognosy laboratory and experiments.

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

Text Books:

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

Reference Books:

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

SEMESTER / YEAR : II YEAR
COURSE CODE : 15PD204
TITLE OF THE COURSE : COMMUNITY PHARMACY (Theory)
L:T:P :2:1:0

Course objectives

- Students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.

Course Outcomes

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

Unit -1 **7 hrs**

1. Definition, scope, of community pharmacy, Roles and responsibilities of Community pharmacist
2. Community Pharmacy Management
   a) Selection of site, Space layout, and design
   b) Staff, Materials- coding, stocking
   c) Legal requirements
   d) Maintenance of various registers
   e) Use of Computers: Business and health care soft wares

Unit – 2 **5 hrs**

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

4. Inventory control in community pharmacy Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock

Unit -3 **10 hrs**

5. Pharmaceutical care Definition and Principles of Pharmaceutical care.
6. Patient counselling Definition, outcomes, various stages, barriers, Strategies to overcome barriers Patient information leaflets- content, design, & layouts, advisory labels Patient medication adherence Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.
7. Health screening services Definition, importance, methods for screening Blood pressure/ blood sugar/ lung function and Cholesterol testing

Unit -4 **15 hrs**

8. OTC Medication- Definition, OTC medication list & Counselling
9. 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 –5 **13 hrs**

10. 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.
11. Essential Drugs concept and Rational Drug Therapy Role of community pharmacist
12. Code of ethics for community pharmacists

Text Books:

a. Health Education and Community Pharmacy by N.S.Parmar.
b. WHO consultative group report.
c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference Books:

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

SEMESTER / YEAR : II YEAR
COURSE CODE : 15PD205
TITLE OF THE COURSE : PATHOPHYSIOLOGY (Theory)
L:T:P :3:1:0

Course objectives

- To objective of this course is to provide graduate level instruction in pathophysiology: the study of biochemical and structural and functional changes in cells, tissues and organs which causes or caused by the diseases. The course is designed for graduate students training for a career in biomedical research.

Course Outcomes

- The outcome of the course will be expand and extend the students knowledge of normal structure and function, into the realm of diseases processes. The course also provides a foundation for understanding the medical science literature.

Unit – 1

Cell Injury, Inflammation & Shock **16 hrs**

A i.) Definition of pathology, health and disease. Terminologies used in pathology.
ii) Basic principles of cell injury and adaptation: Causes, pathogenesis and morphology of cell injury, Cellular adaptation's - physiologic and pathologic adaptations, Cellular ageing and death, Antioxidant enzymes-superoxide dismutase, catalase and glutathione peroxidase.

B **Inflammation:**

i) Definition, causes, signs ,types of inflammation and chemical-mediators.

ii) Pathogenesis of acute inflammation (vascular events, Cellular events, transdate, exudate, edema, phagocytosis). iii) Pathogenesis of chronic-inflammation and difference between acute and chronic inflammation.

iv) Tissue renewal and repair: regeneration healing and fibrosis

v) Wound healing: process of wound healing, types of cells, factors influencing healing of wounds. Mechanism of repair

C. **Shock:**

Types, mechanism, stages and Management

Unit -2

A. **Diseases of Immunity & Hypersensitivity** **12 hrs**

Components of the immune system:

i) Cells involved in immune response- T and B cells, Macrophages, dendritic cells and Natural killer cells. ii) MHC proteins or transplantation antigens. iii) Immune Tolerance

B. **Auto-immunity:**

i.) Mechanism of Autoimmunity. ii.) Classification of autoimmune diseases in man. iii.) Transplantation rejection (types and mechanisms).

C. Acquired Immune Deficiency Syndrome (AIDS)

D. Hypersensitivity:

i) Hypersensitivity type I, II, III, IV ii) Biological significance of hypersensitivity. iii) Allergy due to food, chemicals and drugs.

Unit – 3

A. Environmental Factors & Cancer: 15 hrs

i.) General aspects of neoplasia, Definition, terminology, Differences between benign and malignant tumors

ii.) Etiology and pathogenesis of cancer

iii.) General biology and classification of malignant tumors

iv.) Invasions and metastasis of cancer

B. Biological effects of radiation:

Introduction on radiation, strength of radiation, mechanism of action of ionizing and non-ionizing radiations and their toxic effects.

C. Environment and Nutritional diseases: i) Obesity

ii) Malnutrition iii) Pathogenesis of deficiency diseases with special reference to vitamins and minerals

iv) Air pollution and smoking — SO_2, NO and CO

Unit- 4

A. Pathophysiology of non-infectious diseases (etiology, pathogenesis, signs and symptoms) 16 hrs

i) Peptic ulcer and inflammatory bowel disease

ii) Gastritis iii) Hypertension

iv) Angina

v) Myocardial Infarction

vi) Congestive cardiac failure

vii) Atherosclerosis viii) Stroke (Ischemic and Hemorrhage)

ix) Diabetes Mellitus

x) Hypo and hyperthyroidism
xi) Cirrhosis and Alcoholic liver diseases
xii) Asthma and chronic obstructive airway diseases
xiii) Parkinsonism
xiv) Schizophrenia, Depression and Mania
xv) Alzheimer's disease
xvi) Acute and chronic renal failure

Unit - 5

Genetics & Infectious disorders **16 hrs**

A Pathophysiology (causative organisms, mode of transmission, pathogenesis, signs and symptoms)

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

B. Genetics and chromosomal disorders:

Mendelian disorders, Cytogenic disorders (Karyotypic abnormalities)

Text Books:

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

Reference Books:

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

SEMESTER / YEAR : **II YEAR**
COURSE CODE : **15PD206**
TITLE OF THE COURSE : **PHARMACOTHERAPEUTICS I (Theory)**
L:T:P :**3:1:3**

Course objectives

- to impart knowledge and skills necessary forcontribution to quality use of medicines.
- cover briefly pathophysiology and mostly therapeutics of various diseases.
- Students will be able to understand the pathophysiology of common diseases and their management.

Course Outcomes

- the pathophysiology of selected disease states and the rationale for drug therapy;
- the therapeutic approach to management of these diseases; &the controversies in drug therapy;
- the importance of preparation of individualised therapeutic plans based on diagnosis;
- summarise the therapeutic approach to management of these diseases including reference to the latest available evidence.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Unit-1 **30 hrs**

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

Unit – 2 **23 hrs**

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

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

Unit – 3 **I7 hrs**

3 **General prescribing guidelines for**

a. Paediatric patients
b. Geriatric patients

SEMESTER / YEAR : II YEAR
COURSE CODE : 15PD273
TITLE OF THE COURSE : PHARMACOTHERAPEUTICS I (Theory)
L:T:P :3:1:3

c. Pregnancy and breast feeding

Unit – 4 **6 hrs**

4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial

Unit -5 **9 hrs**

5 **Introduction to rational drug use** Definition, Role of pharmacist Essential drug concept Rational drug formulations

Practicals :

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

Text Books:

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

Reference Books:

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

SEMESTER / YEAR **: III YEAR**
COURSE CODE **: 15PD301**
TITLE OF THE COURSE **: PHARMACOLOGY II (Theory)**
L:T:P **:3:1:3**

Course Objectives This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of 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 Outcomes a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
b. carry out the animal experiments confidently,
c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
d. correlate and apply the knowledge therapeutically.

Unit - 1

Chemotherapy

a. Introduction
b. Sulphonamides and Co-trimoxazole
c. Penicillins and Cephalosporins
d. Tetracyclines and Chloramphenicol
e. Macrolides, Aminoglycosides, Plyenes and Polypeptides antibiotics
f. Quinolones and Fluroquinolones
g. Antifungal antibiotics
h. Antiviral agents
i. Chemotherapy of Malaria
j. Chemotherapy of Protozoal infections (Amoebiasis, Giardiasis)
k. Pharmacology of Anthelmintic drugs
l. Chemotherapy of Cancer

SEMESTER / YEAR
COURSE CODE
TITLE OF THE COURSE
L:T:P

UNIT - 2

Pharmacology of drugs acting on Blood and Blood forming agents

a. Anticogulants
b. Thrombolytics and antiplatelet agents

c. Haemopoietics and plasma expanders

Pharmacology of drugs acting on Renal system

a. Diuretics
b. Antidiuretics

Immunopharmacology

Pharmacology of Immunosuppressants and stimulants

UNIT -3

Principles of Animal toxicology: Acute, Subacute and Chronic toxicity.

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

a. **Cell and macromolecules**: Cellular classification, subcellular orgenelles, macromolecules, large macromolecular assemblies
b. **Chromosome structure:** Pro and eukaryotic chromosome stractures, chromatin structure, genome complexity, the flow of genetic information.
c. **DNA replication:** General, bacterial and eukoryotic 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 P13-kinase pathways, biosensors.

Unit - 4

The Gene: Genome structure and function:

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

Unit - 5

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanism of protein synthesis, intiation in eukaryotes, translation control and post- translation events.

Altered gene functions: Mutations, deletions, amplifications, LOH, translocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes. The gene sequencing, mapping and cloning of human disease genes. Introduction to gene therapy and targeting.

Recombinant DNA technology: Principles, processes (gene transfer technology) and applications.

SEMESTER / YEAR : III YEAR
COURSE CODE : 15PD371
TITLE OF THE COURSE : PHARMACOLOGY II (Practical)
L:T:P :3:1:3

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 guineapig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:

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

References Books:

Molecular biology of the Cell by B. Bray, D . Lewis and Watson, JD, 3rd Edition.

Molecular biology by Lodish et al., 5th edition.
Molecular biology by Turner., 2nd edition.
Genes VIII by Lewin, B (2004)
Pharmaceutical Biotechnology, by Crommelin (1997)
Recombinant DNA by Watoson et al., (1996)
Biopharmaceutical : Biochemistry and Biotechnology by Walsh G., (1998).

SEMESTER / YEAR : III YEAR
COURSE CODE : 15PD302
TITLE OF THE COURSE : PHARMACEUTICAL ANALYSIS (Theory)
L:T:P :3:1:3

Course objectives This subject is designed to impart fundamental knowledge on the testing of drugs by various instrumental methods of analysis. This course is to give thorough understanding of the spectroscopy and chromatographic techniques.

Course Outcomes To understand the component and working of various analytical instruments. Shall be able to analyze the drugs by using above instruments.

Unit-1
1.Spectroscopy:

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

a. **Absorption Spectroscopy:**

Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, BeerLambert'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 detectorsPhotocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

b. **Infrared Spectroscopy**:

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

Unit - 2

2.Chromatography:

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

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

b. **TLC**: Introduction, principle, techniques, Rf value and applications.

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

d. **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.

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

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

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

Unit - 3

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

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

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

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

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

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

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

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

Unit - 4

4. Electrometric Methods:

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

a. **Potentiometry**: Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.

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

c. **Polarography**: Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.

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

Unit - 5

5. i **Quality Assurance:**

Introduction, sources of quality variation, control of quality variation.

a. Concept of statistical quality control.

b. **Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration**.

c. GLP, ISO 9000.

d. Total quality management, quality review and documentation.

e. ICH- international conference for harmonization-guidelines.

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

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

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

SEMESTER / YEAR : III YEAR
COURSE CODE : 15PD372
TITLE OF THE COURSE : PHARMACEUTICAL ANALYSIS (Practicals)
L:T:P :3:1:3

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

Reference Books:

1. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
2. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
3. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
4. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
5. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
6. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.

7. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
8. TLC by Stahl, Spring Verlay.
9. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
10. I.P.-1996, The Controller of Publications, New Delhi.
11. BPC- Dept. of Health, U.K. for HMSO.
12. USP - Mack Publishing Co., Easton, PA.

SEMESTER / YEAR : III YEAR
COURSE CODE : 15PD303
TITLE OF THE COURSE : PHARMACOTHERAPEUTICS II (Theory)
L:T:P :3:1:3

Course Objectives This course is designed to impart knowledge and skills necessary for contribution to rational use of medicines. This will enable the student to understand the pathophysiology of common diseases and their management.

Course Outcomes

- know the various therapeutic approach to management of these diseases
- know the importance of preparation of individualised therapeutic plans based on diagnosis; and monitoring the therapy(side effects, ADR, drug interactions)

Unit – 1 (17hrs)

Bacterial Infectious disease: Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections

Unit – 2 (15hrs)

Protozoal infectious disease - Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis

Unit -3 (9+6hrs)

Musculoskeletal disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematous

Dermatological disorders: Psoriasis, Scabies, Eczema, Impetigo.

Unit – 4 (13hrs)

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

UNIT – 5 (15hrs)

Oncology: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis

SEMESTER / YEAR : III YEAR
COURSE CODE : 15PD373
TITLE OF THE COURSE : PHARMACOTHERAPEUTICS II (Practical)
L:T:P :3:1:3

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.

l Infectious disease: Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections

Unit – 2

Protozoal infectious disease - Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis

Unit -3

Musculoskeletal disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematous

Dermatological disorders: Psoriasis, Scabies, Eczema, Impetigo.

Unit – 4

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

UNIT – 5

Oncology: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis

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.

Text books (Theory)

SEMESTER / YEAR : III YEAR
COURSE CODE
TITLE OF THE COURSE
L:T:P

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

Reference books (Theory)

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

b. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and KodaKimble MA]

: 15PD304
: PHARMACEUTICAL JURISPRUDENCE (Theory)
:2:1:0

Course Objectives

a. practice the Professional ethics;
b. understand the various concepts of the pharmaceutical legislation in India;
c. know the various parameters in the Drug and Cosmetic Act and rules;
d. know the Drug policy, DPCO, Patent and design act;
e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Course Outcomes

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

Unit- 1 **10 hrs**

1. **Pharmaceutical Legislations** – A brief review. **2 hrs**
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI. **3 hrs**
3. **Pharmacy Act –1948.**
   Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER. **5 hrs**

Unit- 2 **15 hrs**

4. **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- 3 **8 hrs**

5. Medicinal and Toilet Preparation Act –1955. Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations. **3 hrs**
6. Prevention Of Cruelty to animals Act-1960. **3 hrs**
7. Patents & design Act-1970. **2 hrs**

UNIT- 4 **9 hrs**

8. 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. **6 hrs**
9. Brief study of prescription and Non-prescription Products. **3 hrs**

UNIT- 5 **8 hrs**

10. Study of Salient Features of Drugs and magic remedies Act and its rules. **3 hrs**
11. Study of essential Commodities Act Relevant to drugs price control Order. **3 hrs**
12. Drug Price control Order & National Drug Policy (Current). **2 hrs**

Text books (Theory)

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

Reference books (Theory)

SEMESTER / YEAR : III YEAR
COURSE CODE
TITLE OF THE COURSE
L:T:P

a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.

b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.

c. Reports of the Pharmaceutical enquiry Committee

d. I.D.M.A., Mumbai. DPCO 1995

e. Various reports of Amendments.

f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.

g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

: 15PD305

: MEDICINAL CHEMISTRY (Theory)

L:T:P : 3:1:3

Course objectives

- The subject deals with the understanding of use of chemical compounds as medicinal agents.
- It includes study of history, development fundamental principles of drug therapy and use of chemotherapeutic agents.

Course Outcomes

- The student will be able to understand the use of chemical agents as drugs to treat various diseases and understand their action in the physiological system.

Unit -1

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure ActivityRelationaship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules. **6hrs**

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

2. Anti-infective agents
   a) Local anti-infective agents
   b) Preservatives
   c) Antifungal agents
   d) Urinary tract anti-infectives
   e) Antitubercular agents
   f) Antiviral agents and Anti AIDS agents
   g) Antiprotozoal agents
   h) Anthelmentics
   i) Antiscabies and Antipedicular agents **10 hrs**

Unit - 2

3. Sulphonamides and sulphones
4. Antimalarials
5. Antineoplastic agents

15hrs

Unit - 3

6. Antibiotics **14hrs**

SEMESTER / YEAR : III YEAR
COURSE CODE
TITLE OF THE COURSE

Unit - 4

7. Cardiovascular agents
    a) Antihypertensive agents
    b) Antianginal agents and vasodilators
    c) Antiarrhythmic agents
    d) Antihyperlipidemic agents
    e) Coagulants and Anticoagulants
    f) Endocrine **16 hrs**

Unit - 5

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

14hrs : 15PD374

: MEDICINAL CHEMISTRY (Practical)

L:T:P : 3:1:3

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

Reference Books:

a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
c. Burgers, Medicinal Chemistry, M.E.,WellyMed.Chemistry M.E. WalffedJohnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
d. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
e. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
f. Organic Drug Synthesis-LedniserMitzsher Vol. I and II.
g. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

: III YEAR

: 15PD306

: PHARMACEUTICAL FORMULATIONS (Theory)

L:T:P : 2:1:3

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

Unit – 1 **12hrs**

1.Pharmaceutical dosage form- concept and classification

2.**Tablets**: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.

Unit – 2 **8hrs**

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

UNIT -3 **14hrs**

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

2.**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 – 4 **8hrs**

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

SEMESTER / YEAR
COURSE CODE
TITLE OF THE COURSE

Unit – 5 **8hrs**

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

: III YEAR
: 15PD375
: PHARMACEUTICAL FORMULATIONS (Practical)

L:T:P :2:1:3

List of Experiments :

1. **Manufacture of Tablets**
   - **a.** Ordinary compressed tablet-wet granulation
   - **b.** Tablets prepared by direct compression.
   - **c.** Soluble tablet.
   - **d.** Chewable tablet.

2. **Formulation and filling of hard gelatin capsules**

3. **Manufacture of parenterals**
   - **a.** Ascorbic acid injection
   - **b.** Calcium gluconate injection
   - **c.** Sodium chloride infusion.
   - **d.** Dextrose and Sodium chloride injection/ infusion.

4. **Evaluation of Pharmaceutical formulations (QC tests)**
   - **a.** Tablets
   - **b.** Capsules
   - **c.** Injections

5. **Formulation of two liquid oral preparations and evaluation by assay**
   - **a.** Solution: Paracetamol Syrup
   - **b.** Antacid suspensions- Aluminum hydroxide gel

6. **Formulation of semisolids and evaluation by assay**
   - **a.** Salicyclic acid and benzoic acid ointment
   - **b.** Gel formulation Diclofenac gel

7. **Cosmetic preparations**
   - **a.** Lipsticks
   - **b.** Cold cream and vanishing cream
   - **c.** Clear liquid shampoo

d. Tooth paste and tooth powders.

8.Tablet coating (demonstration)

Text books (Theory)

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

Reference books (Theory)

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

: IV YEAR
: 15PD401
: PHARMACOTHERAPEUTICS III (Theory)

L:T:P : 3:1:3

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

2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
   a. the pathophysiology of selected disease states and the rationale for drug therapy;
   b. the therapeutic approach to management of these diseases;
   c. the controversies in drug therapy;
   d. the importance of preparation of individualised therapeutic plans based on diagnosis;
   e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
   g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
   h. to discuss the controversies in drug therapy;
   i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
   j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

SEMESTER / YEAR
COURSE CODE
TITLE OF THE COURSE

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

Title of the topic

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

SEMESTER / YEAR **: IV YEAR**
COURSE CODE **: 15PD471**
TITLE OF THE COURSE : PHARMACOTHERAPEUTICS III (Practical)
L:T:P : 3:1:3

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

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

Title of the topic

7 **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.

8 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.

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

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

11 Pain management including Pain pathways, neuralgias, headaches.

12 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.

Text Books

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

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

Lange

Reference Books

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

SEMESTER / YEAR **: IV YEAR**
COURSE CODE **: 15PD402**
TITLE OF THE COURSE : HOSPITAL PHARMACY (Theory)
L:T:P : 2:1:3

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

Objectives: Upon completion of the course, the student shall be able to – a. know various drug distribution methods;

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

Unit – 1

1 Hospital - its Organisation and functions

2 Hospital pharmacy-Organisation and management

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

3 The Budget – Preparation and implementation

Unit -2

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 -3

5. Hospital pharmacy services

a) Procurement & warehousing of drugs and Pharmaceuticals

b) Inventory control

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

c) Drug distribution in the hospital

i) Individual prescription method

ii) Floor stock method

iii) Unit dose drug distribution method

d) Distribution of Narcotic and other controlled substances

e) Central sterile supply services – Role of pharmacist

Unit -4

6. Manufacture of Pharmaceutical preparations

i Sterile formulations – large and small volume parenterals
ii Manufacture of Ointments, Liquids, and creams iii Manufacturing of Tablets, granules, capsules, and powders iv Total parenteral nutrition

Unit -5

7. Continuing professional development programs

Education and training

8. Radio Pharmaceuticals – Handling and packaging

9. Professional Relations and practices of hospital pharmacist

SEMESTER / YEAR : **IV YEAR**
COURSE CODE : **15PD472**
TITLE OF THE COURSE : **HOSPITAL PHARMACY (Practical)**
L:T:P : **2:1:3**

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

List of Assignments:

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

Text books: (latest editions)

a. Hospital pharmacy by William .E. Hassan

b. A text book of Hospital Pharmacyby S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

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

SEMESTER / YEAR : IV YEAR
COURSE CODE : 15PD403
TITLE OF THE COURSE : CLINICAL PHARMACY (Theory)
L:T:P : 3:1:3

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

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

Unit – 1 **38 hrs**

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

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

Unit -2 **6 hrs**

3. **Patient data analysis**

SEMESTER / YEAR
COURSE CODE

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

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

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

Unit – 3 **8 hrs**

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 -4 **8 hrs**

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 -5 **15 hrs**

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

8. Pharmaceutical care concepts

9. Critical evaluation of bio medical literature

10. Medication errors

SEMESTER / YEAR : IV YEAR
COURSE CODE

SEMESTER / YEAR : IV YEAR
COURSE CODE : 15PD473
TITLE OF THE COURSE : CLINICAL PHARMACY (Practical)
L:T:P : 3:1:3

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

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

Text books (Theory)

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.

d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

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

: 15PD405

TITLE OF THE COURSE : BIOPHARMACEUTICS & PHARMACOKINETICS(Theory)

L:T:P : 3:1:3

Unit - 1

1. Biopharmaceutics

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

Unit -2

2. **Pharmacokinetics**

2. Introduction to Pharmacokinetics.

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

Unit - 3

3. One compartment open model.
   a. Intravenous Injection (Bolus)
   b. Intravenous infusion.

4. Multicompartment models.
   a. Two compartment open model.
   b. IV bolus, IV infusion and oral administration

Unit -4

5. Multiple – Dosage Regimens.
   a. Repititive Intravenous injections – One Compartment Open Model
   b. Repititive Extravascular dosing – One Compartment Open model

SEMESTER / YEAR : IV YEAR
COURSE CODE

c. Multiple Dose Regimen – Two Compartment Open Model

6. Nonlinear Pharmacokinetics.

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

Unit - 5

7. Noncompartmental Pharmacokinetics.

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

8. Bioavailability and Bioequivalence.

a. Introduction.
b. Bioavailability study protocol.
c. Methods of Assessment of Bioavailability

TITLE OF THE COURSE : BIOPHARMACEUTICS & PHARMACOKINETICS (Practical)
L:T:P : 3:1:3

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:

a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
c. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
f. Biopharmaceutics; By Swarbrick
g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.

SEMESTER / YEAR : IV YEAR
COURSE CODE

k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

SEMESTER / YEAR : IV YEAR
COURSE CODE : 15PD406
TITLE OF THE COURSE : CLINICAL TOXICOLOGY (Theory)
L:T:P : 2:1:0

Unit -1 **13 hrs**

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.

Unit -2 **14 hrs**

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 -3 **10 hrs**

8. Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.

Unit – 4 **7 hrs**

10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Unit

– 5 **6 hrs**

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

a) CNS stimulants :amphetamine

b) Opioids
c) CNS depressants
d) Hallucinogens: LSD
e) Cannabis group
f) Tobacco

References:

a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

SEMESTER / YEAR : V YEAR
COURSE CODE : 15PD501
TITLE OF THE COURSE : CLINICAL RESEARCH (Theory)
L:T:P : 3:1:0

Unit -1 — 15 hrs

1. Drug development process:

Introduction

Various Approaches to drug discovery

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

Unit -2 — 16 hrs

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

Unit -3 — 14 hrs

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.

Unit -4 — 13 hrs

10. Role and responsibilities of clinical trial personnel as per ICH GCP a. Sponsor
    b. Investigators
    c. Clinical research associate
    d. Auditors
    e. Contract research coordinators

Unit

f. Regulatory authority

-5 **17 hrs**

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 :

a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

SEMESTER / YEAR : **V YEAR**

COURSE CODE : **15PD502**

TITLE OF THE COURSE : **PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Theory)**

L:T:P : **3:1:0**

Unit – 1 **14 hrs**

1. Pharmacoepidemiology :

Definition and scope:

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

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

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

Unit -2 **26 hrs**

Concept of risk in pharmacoepidemiology

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

Pharmacoepidemiological methods

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

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

Unit -3 **12 hrs**

Sources of data for pharmacoepidemiological studies Ad

Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

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

Unit

Unit -4 **19 hrs**

2. Pharmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility.

-5 **4 hrs**

3. Applications of Pharmacoeconomics

Software and case studies

SEMESTER / YEAR : V YEAR
COURSE CODE : 15PD503
TITLE OF THE COURSE : CLINICAL PHARMACOKINETICS & PHARMACO-THERAPEUTICS DRUG MONITORING (Theory)
L:T:P : 2:1:0

Unit -1

1. **Introduction to Clinical pharmacokinetics.**

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

3. **Pharmacokinetics of Drug Interaction:**
   a. Pharmacokinetic drug interactions
   b. Inhibition and Induction of Drug metabolism
   c. Inhibition of Biliary Excretion.

Unit -2

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

Unit -3

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 -4

6. **Population Pharmacokinetics.**
   a. Introduction to Bayesian Theory.
   b. Adaptive method or Dosing with feed back.
   c. Analysis of Population pharmacokinetic Data. **Unit -5**

7. **Pharmacogenetics**

Unit

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

VI PHARM.D
INTERNSHIP

1) **SPECIFIC OBJECTIVES :**

i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.

ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.

iii) to promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.

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

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

vi) to communicate effectively with patients and the community.

2) **OTHER DETAILS :**

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

ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such

trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

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

3. ASSESSMENT OF INTERNSHIP :

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

ii) Satisfactory completion of internship shall be determined on the basis of the following:-

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

(2) The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5

(3) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5

(4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0 -5

(5) Initiative, participation in discussions, research aptitude. SCORE 0-5

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

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

DAYANANDA SAGAR UNIVERSITY

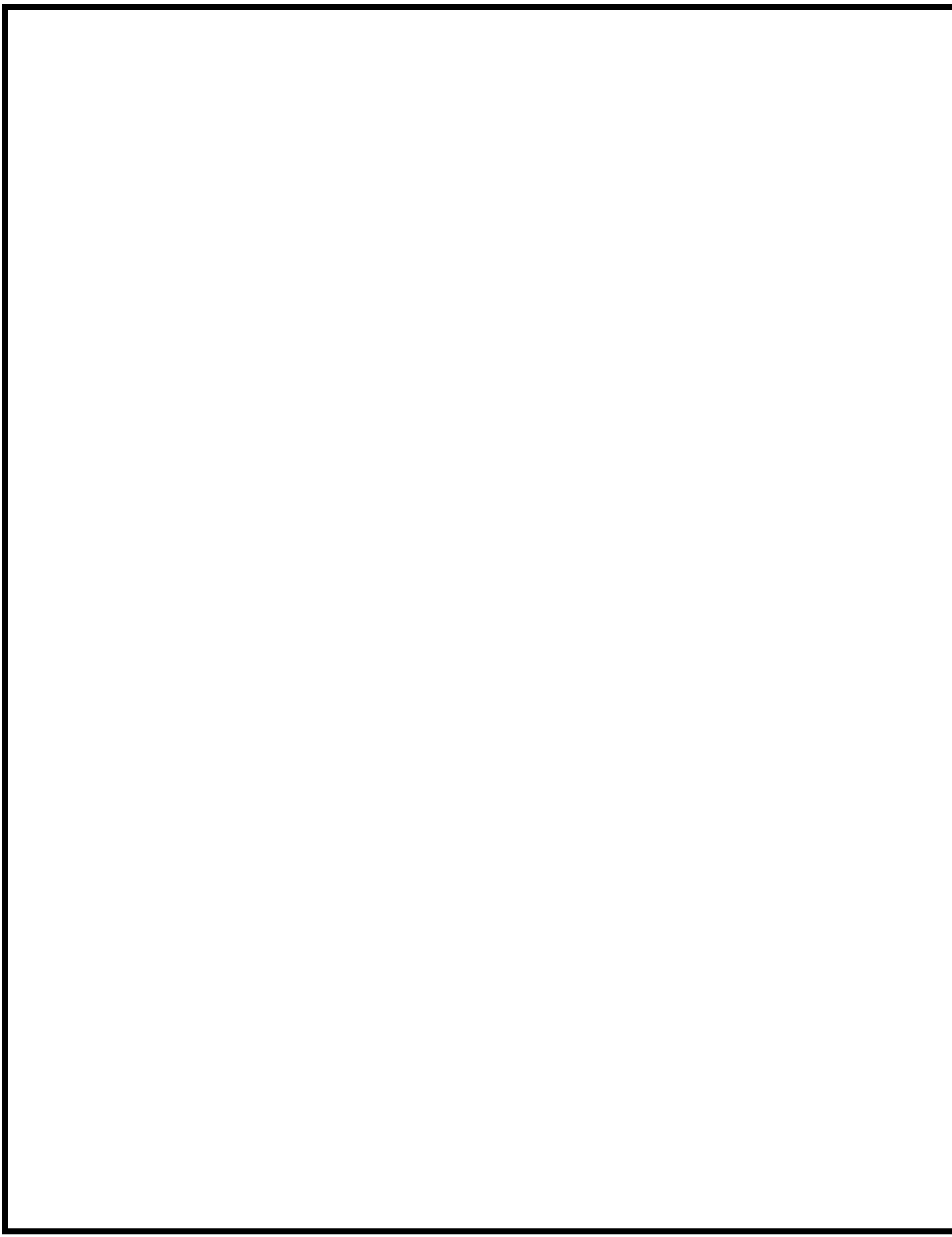
Shavige Malleshwara Hills, Kumaraswamy Layout, Bengaluru - 560078, Karnataka.

SCHOOL OF HEALTH SCIENCES

COLLEGE OF PHARMACEUTICAL SCIENCES

SCHEME & SYLLABUS
FOR
BACHELOR OF PHARMACY (B.PHARM) – 2015
(ANNUAL SCHEME)

(With Effect from 2015-16)



Unit

SEMESTER/YEAR : II YEAR
COURSE CODE : 15BP271
TITLE OF THE COURSE : PHYSICAL PHARMACEUTICS – PRACTICAL
L: T/A: P: C : 0 : 0 : 3 : 1.5

1. Determination of viscosity of liquids using Ostwald's viscometer.*
2. Determination of surface tension of liquid by drop weight method.*
3. Study of flow properties of granules viz., rate of flow, angle of repose, bulk density.*
4. Preparation, stabilization and evaluation of hydrophobic colloids.**
5. Determination of partition coefficient of benzoic acid between benzene and water.**
6. Determination of CST of phenol-water system.*
7. Determination of HLB number of surfactants by Griffin's method.**
8. Preparation of buffers and measurement of pH.*
9. Determination of dissociation constant and pKa value. *
10. Determination of rate constant for first order reactions**
11. Determination of rate constant for second order reactions.**
12. Study of particle size distribution by optical microscopy.*
13. Determination of constants of Freundlich and Langmuir adsorption for adsorptions of acetic acid on activated charcoal.**
14. Preparation of various types of suspensions and determination of their sedimentation parameters.*
15. Construction of rheograms and study of rheological behaviour of biphasic systems employing multipoint viscometers. (For demonstration)

**** Major experiments * Minor experiments**

TEXT BOOKS:

1. Patrick JS. Martin's Physical Pharmacy and Pharmaceutical Sciences. 5th ed. New York: Lippincott Williams and Wilkins; 2006.
2. Rawlins EA. Bentley's Textbook of Pharmaceutics. 8th ed. New Delhi: All India Traveller Book Seller; 2002.
3. Carter SJ. Cooper and Gunn's Tutorial Pharmacy. 6th ed. New Delhi: CBS Publishers; 2000.
4. Subrahmanyam CVS. The Text Book of Physical Pharmaceutics. 2nd ed. VallabhPrakashan; 2000.

REFERENCE BOOKS:

1. Alfonso R Gennaro. Remington: The Science and Practice of Pharmacy, 20th ed.

Vol l and ll, Philadelphia, USA: Lippincott Williams and Wikkins; 2000.
2. Indian Pharmacopoeia 2010
3. Lachman L, Liberman HA. The Theory and Practice of Industrial Pharmacy. Special Indian ed. CBS Publishers; 2009.

SEMESTER/YEAR : II YEAR
COURSE CODE : 15BP202
TITLE OF THE COURSE : PHARMACEUTICAL MICROBIOLOGY & BIOTECHNOLOGY – THEORY
L: T/A: P: C : 3 : 1 : 0 : 3

COURSE OBJECTIVES:

(i) Develop a thorough knowledge of application of microbiology with relevance to pharmaceutical industry which involves study of bacteria, fungi and virus.
(ii) Provide conceptual understanding of the various aspects of aseptic techniques and production of sterile immunological products.
(iii) Recent advances in Biotechnology.

COURSE OUTCOMES:

(i) Students will be able to isolate and identify sources of microbial contamination in pharmaceutical products.
(ii) Demonstrate a critical awareness of recent techniques applicable to research in pharmaceutical biotechnology and their roles in effective therapeutic treatment.

UNIT - I

1. Introduction, history and scope of Microbiology **3 hrs**

2. Study of Bacteria, Virus & Fungi **12 hrs**

Classification, Morphology and fine structure, Growth and cultivation – factors affecting growth, Culture media and its classification, Culture techniques – Aerobes and Anaerobes, Growth Curve, Synchronous growth, batch & continuous culture, Isolation and identification of bacteria: Identification by Staining techniques and biochemical tests, Measurement of growth - Total & viable counting techniques of bacteria. Study of

Fungi, Virus & other infectious agents, Morphology, Classification & cultivation

Unit

UNIT-II

3. Sterilization: **10 hrs**

Methods of sterilization and classification, kinetics of inactivation, sensitivity of microorganisms – dynamics, survival curve, D-value, Z-value, Bioburden determination and environmental control, validation of sterilization methods, sterility testing of pharmaceuticals, Sterile pharmaceutical products – sterilization methods and tests for sterility

4. Disinfection: **5 hrs**

Types and Classification, Factors affecting disinfection, Evaluation of disinfectants and preservatives, Evaluation of preservatives in pharmaceutical preparations.

UNIT - III

5. Immunology and Immunological Preparations: **10 hrs**

Introduction, types of immunity antigens and antibodies, Antigen-antibody reactions and their applications, Vaccines- classification, preparation, standardisation and storage of various vaccines like BCG, Cholera, DPT, Polio, Rabies and production of sera diphtheria, Immunization programme, Diagnostic tests like Schick's test, Widal, Mantoux and VDRL, Immunoblotting Techniques: ELISA, Western blot, Southern blot and Northern blot.

6. Infectious diseases: **5 hrs**

Study of mode of transmission, causative agents, diagnosis, prevention, treatment and control of the following: Cholera, Tetanus, Syphilis, Typhoid, Malaria, AIDS, Hepatitis.

UNIT-IV

7. Microbial Genetics: Genetic organization of Prokaryotes. Phenotypic and Genotypic changes in bacteria, mutations, genetic exchange in bacteria-transformation, transduction, conjugation. plasmids and transposons.

5 hrs

8. Genetic Engineering: **10 hrs**

Steps involved in genetic engineering, Study of cloning vectors, restriction endonucleases and DNA ligase, Applications in the production of recombinant products like Insulin & Hepatitis-B vaccine

UNIT-V

9. Fermentation technology: Introduction to fermentation technology, study, design and operation of fermenter. Production of Penicillin, Streptomycin & Vitamin B12.

5 hrs

10. Microbiological assays: Principles and methods of microbiological assays, antibiotic sensitivity tests. Method of assay of streptomycin. **5 hrs**

11. Animal tissue culture: techniques, nutritional requirements and application - Hybridoma technology: production and application of monoclonal antibodies.

3 hrs

12. Bioinformatics: **2 hrs**

Introduction, Alignment tools, Data mining

TEXT BOOKS:

1. Pelczar MJ, Chan ECS, Krieg NR (1986) Microbiology. 5thEdition. New Delhi: McGraw-Hill
2. AnathNaryan and Pannicker, Text book of microbiology, 6thed, Orient longman, Chennai, 1995.
3. S.P. Vyas and Dixit, pharmaceutical biotechnology, 1sted, CBS publishers and distributors, New Delhi 1998.
4. Rawlins EA (1977) Bentley's Textbook of Pharmaceutics. 8thEdition. London: Bailliere Tindall.
5. S.S.Kori, Pharmaceutical biotechnology, Fundamentals and applications, 1st ed, VallabhPrakashan, New Delhi.
6. Hugo W.B. and Russell A.D. (1998) Pharmaceutical Microbiology. 6th Edition. Blackwell Science.

REFERENCE BOOKS:

1. Carter S.J. (2005) Cooper and Gunn's Tutorial Pharmacy. 6th Edition. New Delhi: CBS Publishers.
2. Prescott LM, Harley JP, Klein DA. (1990) Microbiology. 5th Edition. USA: Wm. C. Brown Publishers.
3. Tortora, G.J., Funke, B.R. & Case C.L. (2010) Microbiology: An Introduction. 10th Edition. New York: Benjamin Cummings.
4. Frobishers, Fundamentals of microbiology, 9th ed, Toppan company ltd, Tokyo. Japan.
5. Watson J.D Recombinant DNA technology, 2nd, Scientific American books ltd 1992.

Unit

SEMESTER/YEAR	**: II YEAR**
COURSE CODE	**: 15BP272**
TITLE OF THE COURSE	**: PHARMACEUTICAL MICROBIOLOGY & BIOTECHNOLOGY – PRACTICAL**
L: T/A: P: C	**: 0 : 0 : 3 : 1.5**

1. Study of apparatus used in experimental microbiology.
2. Sterilization techniques – Glasswares, Media.
3. Preparation and sterilization of Media, subculture, maintanence of culture and aseptic techniques.
4. Isolation techniques– Streak plate, Pour plate, spread plate techniques 5. Staining techniques- Simple staining Gram's staining, negative staining.
6. Total and viable count of Microorganisms.
7. Motility of the microorganism by Hanging drop method.
8. Isolation of Plasmid DNA.
9. Gel electrophoresis of plasmid DNA.
10. Bacteriological analysis of water by MPN techniques.
11. Sterility testing for Pharmaceutical products.
12. Microbiological assay of antibiotics.
13. Antibiotic sensitivity test
14. Determination of MIC
15. Biochemical tests like carbohydrate, starch hydrolysis, gelatin liquefaction.

TEXT BOOKS:

1. Pelczar MJ, Chan ECS, Krieg NR (1986) Microbiology. 5thEdition. New Delhi: McGraw-Hill
2. AnathNaryan and Pannicker, Text book of microbiology, 6thed, Orient longman, Chennai, 1995.
3. S.P. Vyas and Dixit, pharmaceutical biotechnology, 1sted, CBS publishers and distributors, New Delhi 1998.
4. Rawlins EA (1977) Bentley's Textbook of Pharmaceutics. 8thEdition. London: Bailliere Tindall.
5. S.S.Kori, Pharmaceutical biotechnology, Fundamentals and applications, 1st ed, VallabhPrakashan, New Delhi.

6. Hugo W.B. and Russell A.D. (1998) Pharmaceutical Microbiology. 6th Edition. Blackwell Science.

REFERENCE BOOKS:

1. Carter S.J. (2005) Cooper and Gunn's Tutorial Pharmacy. 6th Edition. New Delhi: CBS Publishers.
2. Prescott LM, Harley JP, Klein DA. (1990) Microbiology. 5th Edition. USA: Wm. C. Brown Publishers.
3. Tortora, G.J., Funke, B.R. & Case C.L. (2010) Microbiology: An Introduction. 10th Edition. New York: Benjamin Cummings.
4. Frobishers, Fundamentals of microbiology, 9th ed, Toppan company ltd, Tokyo. Japan.
5. Watson J.D Recombinant DNA technology, 2nd, Sceintific American books ltd 1992.

SEMESTER/YEAR : II YEAR
COURSE CODE : 15BP203
TITLE OF THE COURSE : APPLIED BIOCHEMISTRY – THEORY
L: T/A: P: C : 3 : 1 : 0 : 3

COURSE OBJECTIVES: Deals with understanding of molecular level of chemical process of living cells and application of chemical lab methods to diagnosis and prevention of disease.

COURSE OUTCOMES: The students will be able to understand the importance of metabolic process of biomolecules in health and illness.

UNIT – I

1. Bio energetics **3 hrs**

a) Concept of free energy and its determination; redox potential
b) Energy rich compounds; ATP; Cyclic AMP; their biological significance

2. Biological Oxidation **5 hrs**

a) Electron transport chain : Mechanism and role, inhibitors and uncouplers
b) Oxidative phosphorylation

3. Vitamins - water soluble, fat soluble **2 hrs**

4. Enzymes and Coenzymes **13 hrs**

a) Definition ; Nomenclature, classification
b) Properties of enzymes;
c) Factors effecting enzyme activity;

Unit

d) Enzyme kinetics (Michaels plot ; Line Weaver Burke plot)
e) Enzyme Inhibition (with examples)
f) Enzyme Induction; repression
g) Applications of enzymes
h) Coenzymes: structure of NAD, FAD, ubiquinone and their biochemical role

UNIT - II

5. Carbohydrate metabolism **13 hrs**

a) Introduction: Definition, classification and biological significance
b) Glycolysis along with significance and energetic
c) Glycogenesis, glycogenolysis,
d) TCA cycle; (Amphiboles nature of TCA cycle) along with significance and energetic
e) Gluconeogenisis and its significance
f) Various shuttle systems (glycerol phosphate; Malate aspartate)
g) HMP Shunt Pathway and its significance
h) Disorders of carbohydrate metabolism: glycogen storage diseases, Diabetes mellitus i) Blood glucose regulation

UNIT - III

6. Lipid metabolism **10 hrs**

a) Introduction: Definition, classification, essential fatty acids
b) Oxidation of saturated (palmitic acid) fatty acids
c) Oxidation of unsaturated fatty acids (-linolenic acid)
d) Oxidation of odd numbered fatty acids
e) Formation and fate of ketone bodies
f) Cholesterol biosynthesis & metabolism
g) Biosynthesis of fatty acids (de novo)

UNIT- IV

7. Amino acid metabolism **12 hrs**

a) Amino acids definition, classification and significance
b) General reactions of amino acids: Transamination, deamination and decarboxylations of
Amino acids
c) Urea cycle, deficiency symptoms of urea cycle enzymes
d) Metabolism of sulphur containing amino acids
e) Catabolism of tyrosine, tryptophan, phenylalanine, phenyl ketonurea

f) Synthesis & significance of biologically important substances: creatine, histamine, 5-HT, dopamine, noradrenaline, adrenaline.

g) Bile Pigments; Hyperbilirubinemia

8. Principles and significance for following Biochemical tests 5 hrs

a) Kidney function tests

b) Liver function tests

c) Lipid profile

d) Glucose tolerance test

UNIT- V

9. Nucleotides and Nucleic acids 12 hrs

a) Introduction: Structure and numbering of purine and pyrimidine nucleus

b) Biosynthesis of Purine & Pyrimidines

c) Catabolism of purines and pyrimidines

d) DNA structure, significance as genetic material

e) RNA types, structure and significance

f) DNA replication

g) Mutation and repair of DNA

h) Transcription or RNA synthesis

i) Genetic code

j) Translation or protein synthesis and its Inhibition

TEXT BOOKS:

1. Harper's review of biochemistry –Martin
2. Text book of Biochemistry, A.C.Deb
3. Text book of Biochemistry- Varunkumar Malhotra
4. Text book of Biochemistry – Sathyanarayana

REFERENCE BOOKS:

1. Text book of Biochemistry – Lehninger
2. Outlines of Biochemistry-Conn & Stump

Unit

SEMESTER/YEAR : II YEAR
COURSE CODE : 15BP273
TITLE OF THE COURSE : APPLIED BIOCHEMISTRY – PRACTICAL
L: T/A: P: C : 0 : 0 : 3 : 1.5

1. Identification of carbohydrates (Scheme and identification)
(glucose, fructose, lactose, maltose, sucrose)
2 Identification of proteins (Scheme and identification)
(casein, albumin, gelatin, peptone)
3. Quantitative estimation of carbohydrates (any one method)
DNS reagent Anthrone Reagent
4. Quantitative estimation of proteins (any one method): Biuret Reagent, Lowry's Reagent
5. Qualitative analysis of Urine
a) For Normal constituents
b) Abnormal constituents **6. Quantitative Urine analysis**
a. Titrable acidity and ammonia
b. Estimation of reducing sugars in urine (Benedict's method)

c. Estimation of chlorides in urine
d. Estimation of Creatinine in urine
e. Estimation of calcium in urine

7. Quantitative analysis of blood

a. Estimation of glucose in blood (Folin-Wu method)
b. Estimation of creatinine in blood
c. Estimation of cholesterol in blood

8. Enzyme

Salivary amylase activity

a. Effect of temperature on enzyme (amylase) activity
b. Effect of pH on enzyme (amylase) activity

TEXT BOOKS:

1. Harper's review of biochemistry –Martin
2. Text book of Biochemistry, A.C.Deb
3. Text book of Biochemistry- Varunkumar Malhotra
4. Text book of Biochemistry – Sathyanarayana

REFERENCE BOOKS:

1. Text book of Biochemistry – Lehninger
2. Outlines of Biochemistry-Conn & Stump

SEMESTER/YEAR : II YEAR
COURSE CODE : 15BP274
TITLE OF THE COURSE: PHARMACEUTICAL ORGANIC CHEMISTRY II – PRACTICAL L: T/A: P: C : 0 : 0 : 3 : 1.5

(Following experiments to be in 25 different classes)

I. Quantitative determination of organic compounds via functional groups **

1. Phenolic group by bromination method.
2. Alcoholic group by acetylation method.
3. Carbonyl group by hydroxylamine hydrochloride-pyridine method.
4. Aldehyde group by sodium sulphite-sulphuric acid procedure.
5. Carboxyl group by acid-base method.

Unit

6. Determination of acetone by sodium hypoiodide method
7. Amino group by bromination method.
8. Amino acid Formal titration method.

II. Analysis of oils and fats: (I.P. Method).

1. Acid value.
2. Saponification value.
3. Iodine value.

III. Synthesis/ preparation involving more than one step* 1. *p*-bromoanaline from acetanilide.
2. *p*-Nitroaniline from acetanilide.
3. *p*-Nitrophenylhydrazine from p-nitroaniline.
4. 3-methyl-1-phenyl-5-pyrazole from ethyl acetoacetate.
5. Benzilic acid from benzoin.
6. Pthalimide from benzophenone.
7. Pthalimide from pthalic acid.
8. Synthesis of 2, 3-Diphenyl quinoxaline.
9. Benzimidazolefrom Orthophenylene Diamine.
10.Benzoic acid from benzaldehyde.(Cannizaro's method) 0

REFERENCE BOOKS :

1. E. L. Eliel, John Wiley and Son, Stereochemistry of Organic Compounds. New York, 1993.
2. I. L. Finar, Organic Chemistry Vol. I and II, Sixth Edition, 2003, ELBS.
3. T. W. G. Solomans, Organic Chemistry, Sixth Edition, John Wiley and Son, NewYork, 1996.
4. Advanced Organic Chemistry- Reactions, Mechanism and Structure - Jerry March Wiley Interscience Publication, New York.
5. Reaction and reagents O P Agrawal, Goel Publishing House, Subhash Bazar, Meerut (U.P) India.

TEXT BOOKS:

1. R. J. Morrison and R. N. Boyd Organic Chemistry, Fifth Edition, Prentice Hall of India Pvt. Ltd., New Delhi.
2. B. S. Bhal and ArunBhal, S. Chand, Advanced Organic Chemistry and Company, New Delhi, 2001.
3. Raj K. Bansal, Heterocyclic Chemistry, New age international Ltd., New Delhi, Third Edition, 2001.
4. A. I. Vogel, Elementary Organic Chemistry, Part-3, Quantitative Organic Analysis, second edition,CBS Publishers and Distributors, New Delhi, 2000.

5. Mann and Sounders, Practical Organic Chemistry-ELBS and Longman group Ltd.
6. Lab Experiments in Organic Chemistry by ArunSethi.
7. R.M. Acheson. An Introduction to Chemistry of Heterocyclic Compounds, Wiley Interscience Publication, New York.

Unit

SEMESTER/YEAR : II YEAR
COURSE CODE : 15BP205
TITLE OF THE COURSE : PATHOPHYSIOLOGY
L: T/A: P: C : 3 : 1 : 0 : 3

COURSE OBJECTIVES: The objective of this course is to provide graduate level instruction in pathophysiology: the study of biochemical and structural and functional changes in cells, tissues and organs which causes or caused by the diseases. The course is designed for graduate students training for a career in biomedical research.

COURSE OUTCOMES: The outcome of the course will be expand and extend the students knowledge of normal structure and function, into the realm of diseases processes. The course also provides a foundation for understanding the medical science literature.

UNIT – I

Cell Injury, Inflammation & Shock 16 hrs

A i) Definition of pathology, health and disease. Terminologies used in pathology. ii) Basic principles of cell injury and adaptation:

Causes, pathogenesis and morphology of cell injury, Cellular Adaptations - physiologic and pathologic adaptations, Cellular ageing and death, Antioxidant enzymes- superoxide dismutase, catalase and glutathione peroxidase.

B Inflammation:

i) Definition, causes, signs ,types of inflammation and chemical-mediators.
ii) Pathogenesis of acute inflammation (vascular events, Cellular events, transdate, exudate, edema, phagocytosis).
iii) Pathogenesis of chronic-inflammation and difference between acute and chronic inflammation.
iv) Tissue renewal and repair: regeneration healing and fibrosis
v) Wound healing: process of wound healing, types of cells, factors influencing healing of wounds. Mechanism of repair **C Shock:**
Types, mechanism, stages and Management

UNIT -II 12 hrs

A. Diseases of Immunity & Hypersensitivity Components of the immune system:

i) Cells involved in immune response- T and B cells, Macrophages, Dendritic cells and Natural killer cells.
ii) MHC proteins or transplantation antigens.
iii) Immune Tolerance

B. Auto-immunity:

i.) Mechanism of Autoimmunity.
ii.) Classification of autoimmune diseases in man.
iii.) Transplantation and rejection (types and mechanisms).

C. Acquired Immune Deficiency Syndrome (AIDS)

D. Hypersensitivity:

i) Hypersensitivity type I, II, III, IV ii) Biological significance of hypersensitivity. iii)Allergy due to food, chemicals and drugs.

UNIT – III **15 hrs**

A. Environmental Factors & Cancer:

i.) General aspects of neoplasia, Definition, terminology, Differences between benign and malignant tumors
ii.) Etiology and pathogenesis of cancer iii.)
General biology and classification of malignant tumors
Invasions and metastasis of cancer

B. Biological effects of radiation:

Introduction on radiation, strength of radiation, mechanism of action of ionizing and non-ionizing radiations and their toxic effects.

C. Environment and Nutritional diseases:

i
)
Obesity
ii)
Malnut
rition

iii)Pathogenesis of deficiency diseases with special reference to vitamins and minerals iv) Air pollution and smoking — SO_2, NO and CO

Unit

UNIT- IV **16 hrs**

A. Pathophysiology of non-infectious diseases (etiology, pathogenesis, signs and symptoms)

i) Peptic ulcer and inflammatory bowel disease

ii) Gastritis

iii)Hypertension iv) Angina v) Myocardial Infarction

vi)Congestive cardiac failure

vii) Atherosclerosis

viii)Stroke (Ischemic and Hemorrhage)

ix) Diabetes Mellitus

x) Hypo and hyperthyroidism xi) Cirrhosis and Alcoholic liver diseases

xii) Asthma and chronic obstructive airway diseases

xiii) Parkinsonism

xiv) Schizophrenia, Depression and Mania xv) Alzheimer's disease

xvi) Acute and chronic renal failure

UNIT – V **16 hrs**

A Genetics & Infectious disorders

Pathophysiology (causative organisms, mode of transmission, pathogenesis, signs and symptoms)

Hepatitis - infective hepatitis,

Sexually transmitted diseases (Syphilis, Gonorrhea), Pneumonia, Typhoid, Urinary tract infections, Tuberculosis, Leprosy, Malaria, Dysentery (Bacterial and amoebic), Dengue and Chikungunya.

B. Genetics and chromosomal disorders:

Mendelian disorders, Cytogenic disorders (Karyotypic abnormalities)

TEXT BOOKS:

1. Kumar V., Abbas A.K. and Aster J., Robbins Basic Pathology, 9th Edition, Elsevier, 2012.
2. Mohan H., Textbook of Pathology, 6thEdition ,Jaypee Brothers, Medical Publishers, 2010.

REFERENCE BOOKS:

1. Kumar V, Abbas A.K., Fausto N. and Aster J., Robbins and Cotran Pathologic Basis of Disease, 8th Edition , Saunders, 2009.
2. Mitchell R, Kumar V., Fausto N., Abbas A.K. and Aster J.,Pocket comparisons to Robbins Pathologic Basis of Disease,8th Edition, Saunders,2011.

SEMESTER/YEAR : III YEAR
COURSE CODE : 15BP371
TITLE OF THE COURSE : MEDICINAL CHEMISTRY I – PRACTICAL
L: T/A: P: C : 0 : 0 : 3 : 1.5

I Identification test and test for purity of*

1 Acetazolamide
2 Ascorbic acid
3 Aspirin
4 Aminophylline
5 Atropine sulphate
6 Caffeine
7 Paracetamol
8 INH
9 Sulphanilamide

II Assay of medicinally useful compounds (in solid dosage form)**

Unit

1 Ibuprofen by alkalimetry
2 Analgin by iodimetry
3 Ephedrine HCl/Phenobarbitone by non-aqueous titration
4 Procaine/Benzocaine by diazotisation
5 Chlorpromazine by cerrimetry

III Preparation of medicinally useful compounds*

1 Phenytoin from benzoin
2 Paracetamol from p-nitrophenol
3 Benzocaine from p-aminobenzoic acid
4 4-hydroxycoumarin from resorcinol
5 Mefenamic acid from anthranilic acid
6 Phenothiazine from diphenylamine

IV 1. Degradation of caffeine*
2. Degradation of ephedrine*

TEXT BOOKS:

1. Text book of Organic Medicinal & Pharmaceutical Chemistry, Wilson and Giswold
2. Medicinal Chemistry by Kadam, Vol I and II
3. Ashutoshkar's, Medicinal Chemistry.
4. Medicinal Chemistry by K. Ilango

REFERENCE BOOKS:

1. Burger's Medicinal Chemistry, Vol I to IV.
2. Medicinal Chemistry, W.A. Foye.
3. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
4. Medicinal and Pharmaceutical Chemistry by Harkishan Singh, V.K.Kapoor by Vallabh Prakashan New Delhi.
5. Vogel`s Text Book of Practical Organic Chemistry, ELBS / Longman , London.
6. Practical Organic Chemistry BY Mann and Saunder. Orient Longman, UK.
7. An Introduction to The Chemistry of heterocyclic Compounds by R.M. Acheson Wiley Eastern Ltd. New Delhi.
8. Indian Pharmacopoeia, 1985, 1996 and 2007

SEMESTER/YEAR : III YEAR
COURSE CODE : 15BP372
TITLE OF THE COURSE : PHYTOPHARMACOGNOSY – PRACTICAL
L: T/A: P: C : 0 : 0 : 3 : 1.5

Unit

1. **Quantitative Microscopy**
   a) Leaf Constants: Stomatal Number & Stomatal Index
      Vein Islet Number & Vein termination Number
   b) Determination of dimension of starch grains using eye piece micrometer, lycopodium spore method
   c) Determination of length and width of fibre using eye piece micrometer and camera lucida methods.
2. **Study of Morphology of drugs**.

Strophanthus, Squill, Rhubarb, Cascara, Ginseng, Liquorice, Senna, Digitalis, Rauwolfia, Wild Cherry bark, Nuxvomica, Vinca, Kurchi, Ephedra, Colchicum, Fennel, Cinnamon, Coriander, Eucalyptus, Ginger.

3. **Study of Powder microscopy (including mixture powder microscopy)**

Senna, Digitalis, Squill, Rhubarb, Cascara, Liquorice, Cinchona, Ipecac, Rauwolfia, Ephedra, Kurchi, Clove, Cinnamon, Fennel, Coriander, Ginger.

4. Determination of Ash Value
5. Determination of Extractive value 6. Determination of Moisture content
7. Production of Volatile oil.
8. Estimation of tannins.

REFERENCE BOOKS;

1. Kokate C.K. Purohit A.P. and Gokhale S.B., Text book of Pharmacognosy, 14th Ed, Nirali Prakashan, Pune, 1996.
2. Kokate C.K. Purohit A.P. and Gokhale S.B., Pharmacognosy, 22nd Ed, Nirali Prakashan, Pune, 2003.
3. Trease G.E and Evans, W.C., Pharmacognosy, 15th Ed, Bailliere Tindall, Eastbourne, U.K., 2002.
4. Wallis T.E., Text book of Pharmacognosy, 5th Ed, J.A., Churchill Limited, London., 1985.
5. Iyengar M.A. and Nayak SGK., Anatomy of crude Drugs, 8th Ed, Manipal Power Press, Manipal., 2001.
6. Kokate C.K., Practical Pharmacognosy, 3rd Ed., Vallabh Prakahan, Delhi, 1991.
7. Iyengar M.A., Study of Crude drugs, Manipal Power Press Manipal., 14th Ed, 2001.
8. Iyengar M.A., Pharmacognosy of powdered crude drugs, Manipal Power Press Manipal., 6th Ed, 2001.
9. Brain, K.R., Turner, T.D., The Practical Evaluation of Phytopharmaceuticals, wright- Scietechnica, Bristol
10. Herbal Pharmacopoeia of India, Government of India, Ministry of Health, Vol I & Vol II. (1998 & 2001), Lavoisier Publishing House, 1995.

11. Jean Bruneton, Pharmacognosy & Phytochemistry, Medicinal Plants , 2nd Ed 12. Wagner H and Bladt S, Plant Drug Analysis, TLC Atlas, 2nd Ed, Springer-verlag 1984.
13. Biren Shah, Seth, A.K., Textbook of Pharmacognosy & Phytochemistry, 2nd Ed., ELSEVIER, A division of Reed Elsevier India Private Limited, 2014.

Unit

SEMESTER/YEAR : III YEAR
COURSE CODE : 15BP373
TITLE OF THE COURSE : PHARMACOLOGY – PRACTTICAL
L: T/A: P: C : 0: 0 : 3 : 1.5

1. Regulatory perspectives of animal experiments with special reference to CPCSEA, IAEC, 5R's in experimental pharmacology guidelines.
2. Study of laboratory animals and their handling.
3. Study of physiological salt solutions used in experimental pharmacology.
4. Study of laboratory appliances used in experimental pharmacology.
5. Study of use of general anesthetics in lab animals.
6. Study of various routes of administration of drugs & withdrawal of blood in experimental animals.
7. To record the dose response curve of acetylcholine using isolated chick/goat ileum preparation
8. Study of potentiating effects of cholinergic drugs using isolated chick/goat ileum preparation.
9. Study of anticholinergic drugs using isolated chick/goat ileum preparation.
10. Simulated experiment to record the dose response curve of histamine using isolated guinea pig ileum preparation.
11. Study of agonistic effects of histaminergic drugs using suitable animal isolated tissue preparation.
12. Simulated study of antihistaminic drugs using suitable animal isolated tissue preparation.
13. Simulated experiments on effects of drugs on isolated heart of frog.
14. Simulated experiments on effects of various drugs on rabbit's eye.
15. Simulated experiments on effects of drugs on ciliary motility of frog's esophagus.

TEXT BOOKS:

1. Himanshu Joshi. An alternative approach to experimental pharmacology. 1st Ed, Himdeep Publication, 2015.
2. Kulkarni S.K., Hand book of Experimental Pharmacology, 3rd Ed, Vallabh Prakashan, 2005.
3. Goyal, R.K. Practicals in Pharmacology, 2nd Ed, Ahmedabad: BS Shah Prakashan, 2000.

REFERENCE BOOKS:

1. Ghosh M.N., Fundamentals of Experimental Pharmacology, 5th Ed, Hilton & Company, 2011.

2. Medhi B. and Prakash A., Practical manual of experimental and clinical pharmacology, 1st Ed, Jaypee Brothers, Medical Publishers, 2010.
3. Vogel H. Drug Discovery and Evaluation: pharmacological assay. Springer-Verlag Berlin Heidelberg, 3rd Ed, 2007.
4. Parmer, N.S. and Prakash, S. Screening Methods in Pharmacology, New Delhi: Narosa Publishing House, 2006.

SEMESTER/YEAR : III YEAR
COURSE CODE : 15BP304
TITLE OF THE COURSE : PHARMACEUTICAL ENGINEERING – THEORY
L: T/A: P: C : 3 : 1 : 0 : 3

COURSE OBJECTIVES:

(i) This course is planned to impart a fundamental knowledge on art and science of various equipment's used in pharma industries.
(ii) This subject mainly focuses on unit operations, material handling, pharma plant construction, corrosion, industrial pollution and its control.

COURSE OUTCOMES: The prime outcome is to know the operation of various equipments used in pharma industry; also know the corrosion, industrial hazards and its control, layout of pharma industry.

UNIT I

1. **Stoichiometry**
   2Hrs
   Unit processes, material and energy balances, units and their conversions, dimensional formulae, dimensionless equations.

2. **Heat transfer** **5 Hrs**
   Concept of heat flow by conduction, convection and radiation. Fourier's law and its application, Forced and natural convection, surface co-efficient, study of single, multi pass heat exchangers and liquid-liquid heat interchangers, radiations, black body, Stefan-Boltzmann equation.

3. **Evaporation** **5 Hrs**
   Classification of evaporators, factor affecting evaporation, evaporators–film evaporators, single effect and multiple effect

Unit

evaporators, forced circulation evaporation, material and energy balance, economy of multiple effect evaporator.

UNIT II

4. **Drying** **5 Hrs**

Theory of drying, Classification and types of dryers - Principle construction and working of tray dryer, fluidized bed dryer, drum dryer, freeze dryer, and spray dryer.

5. **Distillation** **5 Hrs**

Raoult's law, Dalton's law, volatility, Rayleigh's equation, real and ideal solutions, boiling point curves, simple, steam, molecular and flash distillations. Rectification and fractional columns, brief study on principle of azeotropic, molecular and extractive distillation.

6. **Size reduction** **6 Hrs**

Definition, objectives, factors affecting size reduction, laws governing energy and power requirement of a mill, stress strain relationship of deformation in solids. Types of mills, construction and working of ball mill, hammer mill, fluid energy mill, cutter mill, roller mill, edge runner and end runner mill.

UNIT III

7. **Size separation** **4 Hrs**

Definition and objectives of size separation, particle size distribution, standard sieves as per IP. Mechanical sieve shakers, sedimentation tanks, cyclone separators, air separators, bag filter.

8. **Mixing** **7 Hrs**

Theory of mixing, solid-solid, solid-liquid and liquid-liquid mixing. Equipments- V-cone, double cone and ribbon blenders, sigma blade and planetary mixer. Liquid Mixing devices: propellers, turbines, paddles, and baffles. Vortex formation and prevention. Homogenization and study on Silverson, Rapisonic and colloid mill.

9. **Material handling systems** **5 Hrs**

Transportation of solids-construction and working of belt conveyor, screw, pneumatic conveyors, pharmaceutical applications.

UNIT IV

10. Flow of fluids **5 Hrs**

Reynolds experiment and its significance, Bernoulis Theorem. Flow metersventuri meter, orifice meter and pitot tube.

11. Filtration and centrifugation **7 Hrs**

Study of Poiseuille's, Darcy's and Kozeny - Carman equation and study of filter aids and filter medium. Construction and working of filter press, filter leaf, meta filter and candle filter. Theory and principle of centrifugation, industrial centrifuges- basket, tubular bowl, conical disk centrifuges.

12. Crystallization **5 Hrs**

Definition and applications, characteristics- crystal forms, crystal habits. Mechanism of crystallization – super saturation, nucleation, crystal growth. Solubility curves, Mier's super-saturation theory, construction and working of agitated batch crystallizer, Swenson Walker crystallizer, Krystal crystallizer and vacuum crystallizers. Caking of crystals and its prevention.

UNIT V

13. Humidification and air conditioning **5 Hrs**

Definition of humidity, humid heat, humid volume. Study of psychrometric charts, wet bulb theory. Applications of humidity. Theory of airconditioning, Refrigeration - coefficient of performance.

14. Materials of construction **6 Hrs**

Factors affecting material selection, classification, chemical and mechanical properties of important materials such as steel, plastic, rubber and glass, their uses, advantages and disadvantages.

15. Corrosion **3 Hrs**

Definition, types, theories, prevention and control of corrosion.

TEXT BOOKS:

1. Carter SJ. Cooper and Gunn's Tutorial Pharmacy. 6th ed. New Delhi: CBS Publishers; 2000.

Unit

2. Walter L Badger , Julius T Banchero. Introduction to Chemical Engineering. 3rd ed. New York: McGraw Hill publication; 1955.
3. Rawlins EA. Bentley's Textbook of Pharmaceutics. 8th ed. New Delhi: All India Traveller Book Seller; 2002.
4. Paradkar AR. Introduction to Pharmaceutical Engineering. 6th ed. Pune: Nirali Prakashan; 2004.
5. Sambamurthy K. Pharmaceutical Engineering. ed. New Delhi: CBS publishers; 1998.
6. Subramanyam CVS, Timma Shetty J. Pharmaceutical Engineering Principles and Practices. 1st ed. New Delhi: Vallabh Prakashan; 2002.

REFERENCE BOOKS:

1. Max Peter. Elementary Chemical Engineering. 2nd ed. McGraw Hill international Book Company; 1984.
2. Don. WG, James. OM. Perry's Chemical Engineers Handbook. 6th ed. McGraw Hill Book Company; 1984.
3. Coulson JM, Richardson JF. Chemical Engineering. 2nd ed. ELBS Pergemom Press; 1977.
4. Alfonso R Gennaro. Remington: The Science and Practice of Pharmacy, 20th ed.

   Vol l and ll, Philadelphia, USA: Lippincott Williams and Wikkins;

2000. 5. Indian Pharmacopoeia 2010

6. www.ispe.org.
7. www.who.int.

SEMESTER/YEAR : III YEAR

COURSE CODE : 15BP374
TITLE OF THE COURSE : PHARMACEUTICAL ENGINEERING – PRACTICAL
L: T/A: P: C : 0 : 0 : 3 : 1.5

1. Drying of wet granules and to plot rate of drying curves.**
2. Operation of Ball mill and to calculate Rittinger's and Kick's co-efficient.**
3. Operation of sieve shaker and sieve analysis and deriving various statistical parameters.**
4. Determination of mixing efficiency when the propeller blade is introduced in different positions during liquid-liquid mixing. **
5. Determination of mixing index of blenders for a solid mixture using salicylic acid.*
6. Factors effecting rate of filtration on i) surface area ii) viscosity iii) concentration iv) thickness v) filter aids.**
7. Determination of water vapor permeability across the packing material.*
8. Experiment to determine the leaching of contents from packing material: Ampoules and Vials.**
9. Evaluation of pharmaceutical packing materials – corrugated box.*
10. Preparation of crystals of Potassium nitrate by shock cooling technique and study of its crystal habit. *
11. Measurement of humidity using psychrometric charts (Demonstration).
12. Evaporation: factors affecting the rate of evaporation.**

i) Surface area. ii) Concentration. iii) Viscosity.

**** Major experiments** **** Minor experiments**

TEXT BOOKS:

1 . Carter SJ. Cooper and Gunn's Tutorial Pharmacy. 6th ed. New Delhi: CBS Publishers; 2000.
2. Walter L Badger , Julius T Banchero. Introduction to Chemical Engineering. 3rd ed. New York: McGraw Hill publication; 1955.
3. Rawlins EA. Bentley's Textbook of Pharmaceutics. 8th ed. New Delhi: All India Traveller Book Seller; 2002.
4. Paradkar AR. Introduction to Pharmaceutical Engineering. 6th ed. Pune: Nirali Prakashan; 2004.
5. Sambamurthy K. Pharmaceutical Engineering. ed. New Delhi: CBS publishers; 1998.

Unit

6. Subramanyam CVS, Timma Shetty J. Pharmaceutical Engineering Principles and Practices. 1st ed. New Delhi: Vallabh Prakashan; 2002.

REFERENCE BOOKS:

1. Max Peter. Elementary Chemical Engineering. 2nd ed. McGraw Hill international Book Company; 1984.
2. Don. WG, James. OM. Perry's Chemical Engineers Handbook. 6th ed. McGraw Hill Book Company; 1984.
3. Coulson JM, Richardson JF. Chemical Engineering. 2nd ed. ELBS Pergemom Press; 1977.
4. Alfonso R Gennaro. Remington: The Science and Practice of Pharmacy, 20th ed.
Vol l and ll, Philadelphia, USA: Lippincott Williams and Wikkins;
2000. 5. Indian Pharmacopoeia 2010
6. www.ispe.org.
7. www.who.int.

SEMESTER/YEAR : III YEAR
COURSE CODE : 15BP305
TITLE OF THE COURSE : PHARMACEUTICAL JURISPRUDENCE
L: T/A: P: C : 2 : 1 : 0 : 2

COURSE OBJECTIVES:

(i) To understand the legal and ethical aspects of drugs.
(ii) The course exposes the student to several important legislations to the profession of pharmacy in India

COURSE OUTCOMES:

(i) Upon completion of the course, student will be able to understand the significance and relevance of pharmaceutical laws in India and role of ethics in Pharmacy profession.
(ii) The student will be able to understand the significance of various schedules of D & C Act.
(iii) The student will possesses the knowledge about Patents & IPR.

UNIT-I **10 Hours**

1. **Introduction to Pharmaceutical Jurisprudence**
    a. Definitions of Rules, Acts, & Guidelines
    b. Introduction to National and International drug regulatory law like D & C Act, US FDA, EMA, TGA
2. **Pharmaceutical Legislations –**
    a. Brief Introduction,

Unit

b. Study of drugs enquiry committee,
c. Health survey and development committee,
d. Hathi committee and Mudaliar committee

3. Code of Pharmaceutical ethics:

a. Definition,
b. Pharmacist in relation to his job, trade, medical profession and his profession,
c. Pharmacist's oath

4. Pharmacy Act –1948:

a. Objectives, Definitions,
b. Pharmacy Council of India; its constitution and functions,
c. Education Regulations,
d. State and Joint state pharmacy councils; its constitution and functions,
e. Registration of Pharmacists,
f. Offences and Penalties

UNIT-II **10 Hours**

5. DGHS- CDSCO & State drug control, structure role and responsibilities.

6. Drugs and Cosmetics Act, 1940 and its rules 1945:

a. Objectives, Definitions, Legal definitions of schedules to the act and rules
b. Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.
c. Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,
d. Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.
e. Introduction of export of Drugs.

UNIT-III **10 Hours**

7. **Drugs and Cosmetics Act, 1940 and its rules 1945.**

a. Detailed study of Schedule L1, N, H, M, Y, P, U, V, X & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties
b. Labelling & Packing of drugs- General labelling requirements and specimen labels for drugs and cosmetics, List of permitted colours. Offences and penalties.
c. Administration of the act and rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee,

Government analysts, Licensing authorities, controlling authorities, Drug Inspectors

d. Introduction to non-clinical Studies

8. **Medicinal and Toilet Preparation Act –1955:**

a. Objectives, Definitions, Licensing,
b. Manufacture In-bond and Outside bond,
c. Export of alcoholic preparations,
d. Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.
e. Offences and Penalties.

UNIT-IV **10 Hours**

9. **Drugs and magic remedies Act and its rules:**

a. Objectives, Definitions,
b. Prohibition of certain advertisements,
c. Classes of Exempted advertisements,
d. Offences and Penalties

10. **Prevention of Cruelty to animals Act-1960:**

a. Objectives, Definitions,
b. Institutional Animal Ethics Committee,
c. Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records,
d. Power to suspend or revoke registration,
e. Offences and Penalties

11. **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013.

a. Objectives, Definitions,
b. Sale prices of bulk drugs,
c. Retail price of formulations,
d. Retail price and ceiling price of scheduled formulations,
e. National List of Essential Medicines (NLEM)

UNIT-V **10 Hours**

12. **Narcotic Drugs and Psychotropic Substances Act-1985 and Rules:**

a. Objectives, Definitions,
b. Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee,
c. National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation,
d. opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium,

Unit

e. Offences and Penalties

13. **Medical Termination of pregnancy act**
14. **Right to information Act**
15. **Introduction to Intellectual Property Rights(IPR)**
    a. Trade Mark, Copyright, Trade Secrets
    b. Difference between a patent and generic drug.
    c. The Patent Act,
    d. Special reference to pharmaceuticals-process patent & product patent.
    e. General procedure for obtaining a pharmaceutical patent
16. **New Drug Application, Abbreviated new drug application (ANDA)**
17. **Introduction to regulatory requirements for**
    Medical Devices and diagnostics, Biologicals, Clinical Trials, BA/BE, Pharmacovigilance programme.

(NOTE: All the above topics to be discussed with latest amendments)

RECOMMENDED BOOKS: (LATEST EDITION):

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain **REFERENCE BOOKS:**

1. Drugs and Cosmetics Act/Rules by Govt. of India publications.
2. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
3. Narcotic drugs and psychotropic substances act by Govt. of India publications
4. Drugs and Magic Remedies act by Govt. of India publication
5. Bare Acts of the said laws published by Government. Reference books (Theory)
6. CDSCO guidelines
7. ICMR guidelines

WEB REFERENCES:

1. http://www.ipindia.nic.in/
2. http://www.pci.nic.in
3. http://www.cdsco.nic.in/
4. http://www.rti.gov.in/
5. http://narcoticsindia.nic.in/
6. http://www.mohfw.nic.in/
7. http://www.cdsco.nic.in

SEMESTER/YEAR : III YEAR
COURSE CODE : 15BP306
TITLE OF THE COURSE : PHARMACEUTICAL MANAGEMENT & MARKETING L: T/A: P: C : 2 : 1 : 0 : 2

COURSE OBJECTIVES: To understand the general management and marketing principles in pharmaceutical marketing, the types of markets, competitive practices in pharmaceutical industries, pharmaceutical product and regulatory requirements.

COURSE OUTCOMES: Upon completion of the course the student shall be able to (i) Know pharmaceutical market.
(ii) Understand various product strategies
(iii) Understand the basic principles of management sciences.
(iv) Appreciate the importance of marketing in product promotion.
(v) Basic knowledge of regulatory requirements for marketing pharmaceuticals

UNIT I **12 HOURS**

1.Marketing

a) Definition and scope of marketing.
b) Distinction between Marketing and Selling.
c) The pharmaceutical market-
   a. Quantitative and qualitative aspects,
   b. Size and composition of the market,
   c. Demographic descriptions and
   d. Socio-psychological characteristics of the consumer,
   e. Market segmentation.
d) Analysing the market- role of market research.
e) Consumer profile-
   a. Motivation and prescribing habits of the physician,
   b. Patients' choice of physician and Retail pharmacist.

Unit

f) Emerging Concepts and Trends of Marketing: Vertical and Horizontal Marketing, Rural Marketing, Consumerism, Industrial Marketing, Global Marketing.

2.The Organization

Manufacturer-

a. Company objectives,
b. Influence of internal controls such as company policy on the company's operation,
c. Effects of government regulations and controls on marketing practices.

UNIT II **12 HOURS**

3.The Pharmaceutical Product

a) Market consideration in product development,
   a. Marketing mix, product life cycle(PLC), effects of different elements of marketing mix at different stages of PLC,
   b. Product classification,
   c. Product planning,
   d. Product differentiation,
   e. Me- too products,
   f. Modification of existing product.

b) New product development-
   a. All stages from the new product idea to the stage of marketing in developed product (Bulk drugs and formulations).

c) Branding-
   a. Concept of brand,
   b. Different types of brand,
   c. Importance and reasons for branding,
   d. Packaging.

4.Competitive Practices in Pharmaceutical Industries

a) Price competition-
   a. Pricing,
   b. Objectives,
   c. Basis and strategies.
   d. Rate contracts.

b) Non-price competition: all types of non-price competition with special emphasis on

   a. Competition through research and development,

b. Competition through quality.

UNIT III **10 HOURS**

5.Promotions

a) Communication and its importance
b) Different ways of promotion-

Advertising, direct mail, professionals, journals, sampling, retailing, medical exhibition, public relations, Online Promotional Techniques for OTC Products.

c) Professional sales representative-
   a. Duties of PSR,
   b. Purpose of detailing,
   c. Selection and training,
   d. Compensation and future prospects of the PSR.

6.Distribution

a) The wholesale-
   a. His role in distribution of pharmaceutical services offered to the manufacturer and the retailer,
   b. Advantages and disadvantages of distribution through wholesaler. c) The retailer-

a. Classification of retail institution, advantages and disadvantages of retail institution, the hospital as retail outlet.

UNIT IV **10 HOURS**

7.Management

a) Concepts of management, Nature of management, principles of management.
b) Primary functions of management- planning, organizing, staffing, directing and controlling, motivation, and entrepreneurship development.
c) Secondary functions of management: Decision- making, Leadership, innovation, delegation of authority/ responsibility.

8.Entrepreneurship

Meaning, Entrepreneurship: Concept, knowledge and skills requirement; characteristic of successful entrepreneurs; role of entrepreneurship in economic development; entrepreneurship process; factors impacting emergence of entrepreneurship; managerial vs. entrepreneurial approach and emergence of entrepreneurship.

Unit

UNIT V **6 HOURS**

9.Quality Management

a) Introduction to Statistical Methods,
b) Statistical Quality Control Tools,
c) Statistical Tools for Decision Making,
d) Total Quality Management/Kaizen: Six Sigma,
e) Quality Circle and CPM (Critical Path Method)

10.Regulatory Authorities and their Guidelines

ICH, USFDA, TGA, MHRA, WHO, IPC, Worldwide pharmaceutical Regulatory Agencies

RECOMMENDED BOOKS:

1. Philip Kotler, Amstrong: Principles of Marketing, Prentice Hall Pvt Ltd.,13th edition
2. Heinz Weihrich, Harold Koontz: Management: A global Perspective, McGraw Hill International Edition, Tenth edition.
3. S.V.R. Subba Rao, Pharmaceutical Marketing in India, Asian Institute of Pharmaceutical Marketing, Hyderabad, 1998 edition.
4. Arun Kumar and N. Meenakshi: Marketing Management, Vikas Publishing, India.
5. Mickey C. Smith, Principles of Pharmaceutical Marketing, CBS publishers and distributors, New Delhi, 3rd edition.
6. C.V.S. Subrahmanyam. Pharmaceutical production and management, Vallabh Prakashan publisher, New Delhi, 2005.
7. Peter F. Drucker, Management-tasks, responsibilities, practices. Allied Publishers Pvt Ltd., Mumbai, 2003.
8. Mickey C. Smith, Pharmaceutical Marketing in the 21st Century, pharmaceutical product press, New York, USA, 1996
9. Sachin Itkar, Pharmaceutical Management, Nirali Prakashan Publishers, Pune, 2007.

WEBSITE REFERENCES:

1. www.ich.org,
2. http://www.fda.gov/,
3. https://www.gov.uk,
4. https://www.tga.gov.au/quality-guidelines

SEMESTER/YEAR : IV YEAR
COURSE CODE : 15BP401
TITLE OF THE COURSE : PHARMACEUTICAL TECHNOLOGY AND BIOPHARMACEUTICS - THEORY

L: T/A: P: C
: 3 : 0 : 0 : 3

COURSE OBJECTIVES: To study the technologies involved in the manufacturing of various dosage forms and also the biopharmaceutical aspects of drugs.

COURSE OUTCOMES: The students will be able to understand the various techniques of manufacturing of dosage forms and also have a knowledge about pharmacokinetic parameters of drugs.

UNIT I

1. **Preformulation studies:** Study of physicochemical properties of drug substances and their effect on formulation, stability and bioavailability. **05 hrs**

2. **Tablets:** Definition, advantages and disadvantages, classification of different types of tablets, excipients used for tablet preparation, granulation methods, tablet compression machines, processing problem of tablets, in process quality control and evaluation of tablets. Tablet coating: Definition, objectives of coating, types of coating, sugar coating, film coating, coating equipments, film defects and
   evaluation of coated tablets. **13 hrs**

UNIT II

3. **Capsules:** Hard gelatin capsules: Definition of capsule, advantages and disadvantages of capsules, materials used for preparing hard gelatin capsule, production, filling and finishing of hard gelatin capsule, and quality control test. Soft gelatin capsules: Capsule shell and content, base adsorption and its importance, production, quality control, stability and storage. **8 hrs**

4. **Liquid orals:** Formulation and manufacturing, filling and packaging of liquid orals.
   4 **hrs**

UNIT III

Unit

5. **Parenteral preparation:** Definition, advantages and disadvantages, parenteral routes of administration, official types of injections, formulations, types, production of parenterals including facilities, filling, sealing of ampoules and vials, containers and closures, and quality control test.

Ophthalmic formulations: Definition, types of ophthalmic formulations, requirements, formulation of ophthalmic products such as eye drops, eye ointment and occuserts, containers, and evaluation. **15 hrs**

UNIT IV

6. **Pharmaceutical aerosols:** Definition, advantages, disadvantages, propellants, containers, valves, types of aerosol systems, manufacture of aerosols, stability testing, evaluation and application of aerosols. **8 hrs**

7. **Cosmetics:** Formulation and preparation of cosmetic preparations such as cold cream, vanishing cream, face and talcum powder, shampoos, lipsticks, nail
   lacquers, hair dyes, and tooth pastes. 8 **hrs**

UNIT V

8. Pharmaceutical Packaging: Materials used for packaging of pharmaceutical products, advantages, and disadvantages.
   4 hrs

9. **Biopharmaceutics:** Definition, applications of biopharmaceutics, drug absorption, different types of drug transport across GIT.Factors influencing drug absorption such as biological, physico-chemical and pharmaceutical factors. Pharmacokinetics basic concepts, blood level curves for oral, intra muscular, intravenous, constant rate infusion and sustained release dosage forms. Definition for bioavailability and bioequivalence, importance of bioavailability,
   and bioavailability measurement. **10 hrs**

TEXT BOOKS:

1. Theory and Practice of Industrial Pharmacy – Leon Lachmann, Herbert A. Libermann and J. L. Kanig, Lea & Febiger, Philadelphia.
2. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia.
3. Biopharmaceutics and Pharmacokinetics, A Treatise, D.M.Brahmankar and Sunil B. Jaiswal.

REFERENCE BOOKS:

1. Pharmaceutics – The Science of Dosage Form Design by M. E. Aulton, Churchill Livingstone.
2. Remington's Pharmaceutical Sciences, Mack Publishing Co. Easton.
3. Cosmetics – Formulation, manufacturing and quality control – P. P. Sharma.
4. Bentley's Textbook of Pharmaceutics By Rawlins CBS Publishers New Delhi.
5. Harry's Textbook of Cosmetology.
6. Pharmacopoeias: I.P., B.P., U.S.P.
7. Dispensing for Pharmaceutical Students by Cooper and Gunn, 12th Edition.
8. Modern Text Book of Pharmaceutics by Gilbert Banker and Christopher Rhodes, Informa Press.
9. Lachmann and Libermann, Pharmaceutical Dosage Form-Parenteral Medication Edited by Avis,Informa Press (Latest Edition).
10. Lachmann and Libermann, Pharmaceutical Dosage Form- Tablets Vol I, II, III (Latest Edition), Informa Press.

Unit

SEMESTER/YEAR : IV YEAR
COURSE CODE : 15BP471
TITLE OF THE COURSE : PHARMACEUTICAL TECHNOLOGY AND BIOPHARMACEUTICS - PRACTICAL
L: T/A: P: C : 0 : 0 : 3 : 1.5

1. Manufacture of tablets
    a. Tablets prepared by wet granulation.
    b. Preformulation studies on granules
    b. Tablets prepared by direct compression.
    c. Mouth dissolving tablet.
    d. Chewable tablet
2. Evaluation of tablets
3. Manufacture of parenteral
    a. Ascorbic acid injection
    b. Calcium gluconate injection
    c. Sodium chloride injection
    d. Dextrose injection
4. Cosmetic preparations
    a. Lipsticks
    b. Cold cream and vanishing cream
    c. Clear liquid shampoo
    d. Tooth paste and tooth powders
    e. Sunscreens
5. Formulation of liquid orals
    a. Paracetamol syrup
    b. Antacid suspensions- magnesium hydroxide and aluminum hydroxide gel
6. Demonstration of tablet coating
7. Demonstration of microencapsulation technique and matrix tablets.

TEXT BOOKS:

1.Theory and Practice of Industrial Pharmacy – Leon Lachmann, Herbert A. Libermann and J. L. Kanig, Lea & Febiger, Philadelphia.

2. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia.
3. Biopharmaceutics and Pharmacokinetics, A Treatise, D.M.Brahmankar and Sunil B. Jaiswal.

REFERENCE BOOKS:

1. Pharmaceutics – The Science of Dosage Form Design by M. E. Aulton, Churchill Livingstone.
2. Remington's Pharmaceutical Sciences, Mack Publishing Co. Easton.
3. Cosmetics – Formulation, manufacturing and quality control – P. P. Sharma.
4. Bentley's Textbook of Pharmaceutics By Rawlins CBS Publishers New Delhi.
5. Harry's Textbook of Cosmetology.
6. Pharmacopoeias: I.P., B.P., U.S.P.
7. Dispensing for Pharmaceutical Students by Cooper and Gunn, 12th Edition.
8. Modern Text Book of Pharmaceutics by Gilbert Banker and Christopher Rhodes, Informa Press.
9. Lachmann and Libermann, Pharmaceutical Dosage Form-Parenteral Medication Edited by Avis,Informa Press (Latest Edition).
10. Lachmann and Libermann, Pharmaceutical Dosage Form- Tablets Vol I, II, III (Latest Edition), Informa Press.

Unit

SEMESTER/YEAR : IV YEAR
COURSE CODE : 15BP402
TITLE OF THE COURSE : INSTRUMENTAL & BIOMEDICAL ANALYSIS - THEORY

L: T/A: P: C
: 3 : 0 : 0 : 3

COURSE OBJECTIVES: To give basic knowledge on Instrumental methods of Chemical & Pharmaceutical Analysis and train students to perform practical work on real samples to get acquainted with instrumentation and equipment.

COURSE OUTCOMES:

(i) The student shall be able to know the principle, instrumentation and application by using the above instruments.

(ii) Shall be able to use modern instruments in the quality control and research of pharmaceuticals.

This subject is designed to impart a fundamental knowledge on the testing of drugs by various instrumental methods of analysis. This course also gives idea about modern instruments that are used for drug testing like UV, IR, HPLC, HPTLC etc,

UNIT-1

Spectroscopy:

a. UV –Visible Spectroscopy:

Electromagnetic spectrum, Wave parameters, Electronic Transitions, Chromophores, Auxochromes, Bathochromic shift, hypsochromic shift, Hyperchromic and hypochromic effects. Beer and Lambert's law, Derivation and Deviations, Effect of solvent and pH on absorption spectra. **6 hours**

Instrumentation - Sources of radiation, collimating system, sample cells, monochromators Detectors- Barrier layer cell, photo tube, photomultiplier tube, diode array.

Applications- Spectrophotometric titrations, single component & multi component analysis. **7 hours**

b. Fluorimetric analysis: Theory, concept of singlet and triplet electronic states, Internal and external conversions, intersystem crossing, factors affecting fluorescence, Quenching.

Instrumentation and applications **4 hours**

UNIT-II

a. IR Spectroscopy*:* Theory, Hooke's law, vibration modes of molecules, Instrumentation- Sources of radiation, Monochromators, Sample handling methods, detectors and applications. **6 hours**

b. Flame emission and atomic absorption spectrometry: Principle, Interferences,

Instrumentation and applications. **4 hours**

c. Nephelometry and Turbidimetric Analysis: Principle, Instrumentation and applications. **2 hours**

d. NMR: Theory, Instrumentation of H^1NMR and applications. **2 hours**

UNIT-III

Chromatography: Introduction and classification 2 hours

a. Column chromatography: Adsorption column chromatography, development Techniques Factors affecting column efficiency, recovery and applications.

Partition Chromatography – Principle, Development techniques and applications.

3 hours

b. Paper Chromatography: Introduction, Principle, Development Techniques,

Detection methods and applications. **2 hours c. Thin layer chromatography:** Introduction, principle, techniques, detection methods and applications. **2 hours**

Unit

d. **Ion exchange chromatography**: Principle, classification of ion exchange resins, Properties of ion exchangers, mechanism of ion exchange process, factors affecting ion exchange and applications. **3 hours**

e. **Size exclusion chromatography:** Theory, Instrumentation and applications **2 hours**

UNIT-IV

a. **Gas chromatography**: Introduction, types of Gas chromatography, theory, instrumentation of GLC, Derivatisation techniques, Programmed temperature gas chromatography and applications. **5 hours**

b. **HPLC:** Introduction, theory, instrumentation and applications. **4 hours**

c. **HPTLC:** Basic concepts, Instrumentation, Difference between TLC and HPTLC, applications. **2 hours**

d. **Electrophoresis:** Principles of separation, Factors affecting separation, equipment for paper and gel electrophoresis, Moving boundary electrophoresis, isoelectric focusing electrophoresis and Applications **3 hours**

e. **Mass Spectroscopy:** Basic concepts, Instrumentation and applications. **2 hours**

UNIT-V

Electrometric methods:

a. **Potentiometry:** Electrochemical cell, construction and working of reference electrode, Normal hydrogen electrode, calomel electrode, silver-silver chloride electrode, Indicator electrodes- Glass electrode, Antimony electrode, Quinhydrone electrode, Potentiometric titrations, methods of detecting end point and applications. **6 hours**

b. **Conductometry:** Introduction, conductivity cell, cell constant, conductometric titrations and applications **2 hours**

c. **Quality assurance:** Introduction, Sources of quality variation, control of quality variation, Validation methods. **4 hours**

d. **X-ray Diffraction:** Theory of X-ray diffraction and applications**.** **2 hours**

TEXT BOOKS:

1. Instrumental methods of analysis by Hobarth Willard, Lynne L Merritt and John A Dean,6th edition, 1986, CBC publishers, New Delhi.
2. Instrumental methods of chemical analysis by B. K. Sharma, 10th edition, GOEL publishing house, 2002.

3. Practical pharmaceutical chemistry by Beckett A. H. and Stenlake J. B., 4th edition, CBS publishers, New Delhi, 1997.
4. Spectrometric identification of organic compounds by Robert M Silverstein, G.
   Clayton and Terence C. Morill, 6th edition, John Wiley and Sons, 2004.
5. Organic Spectroscopy by William Kemp.
6. Quantitative analysis of drugs by D.C.Garrett.
7. Text Book of Pharmaceutical Analysis by K.A.Connors.

REFERENCE BOOKS:

1. Indian Pharmacopoeia'96 Vol I & II
2. Principles of instrumental analysis by Doglas A Skoog, F. James Holler, 5th edition, eastern press, Bangalore, 1998
3. Quantitative analysis of drugs in Pharmaceutical formulation . P. D. Sethi, 3rd edition, CBS Publishers, New Delhi, 1997.
4. TLC by Stahl, Spring Verlay, 2nd edition, 1969.
5. Applications of Absorption Spectroscopy of Organic Compounds by John R Dyer.
6. Analytical Chemistry by Garry Christian.

Unit

SEMESTER/YEAR : IV YEAR
COURSE CODE : 15BP472
TITLE OF THE COURSE :INSTRUMENTAL & BIOMEDICAL ANALYSIS-PRACTICAL
L: T/A: P: C : 0 : 0 : 3 : 1.5

Note: At least 15 experiments to be covered from the following list

1. Separation & identification of amino acids by Ascending paper chromatography*.
2. Separation & identification of amino acids by Radial paper chromatography*.
3. Separation & identification of alkaloids by TLC*.

4. Determination of absorption maxima for a given solution of the drug*.
5. Colorimetric estimation of Sulphanilamide using BM Reagent**.
6. Colorimetric estimation of Ferrous ions using 1,10 Phenanthroline**.
7. Colorimetric estimation of Paracetamol*.

8. UV spectrophotometric determination of Paracetamol tablets*.
9. UV spectrophotometric determination of Ibuprofen tablets*.
10. Determination of Ibuprofen and Paracetamol by simultaneous equation method**.
11. Determination of pKa using pH meter*.
12. Conductometric titration of mixture of stong acids with a strong base**.
13. Potentiometric titration of stong acid with a strong base**.
14. Estimation of Quinine sulphate by Spectrofluorimetry**.
15. Study of quenching effect in Spectrofluorimetry*.
16. Determination of Sodium/Potassium by flame photometry*.
17. Determination of chloride and sulphates by Nepheloturbidimetric method**.
18. IR interpretation of samples with different functional groups*.

19. Demonstration of HPLC*.
20. IR interpretation of any two organic compounds**.

Major experiment (Experiment indicated by **)
Minor experiment (Experiment indicated by *)

TEXT BOOKS:

1. Instrumental methods of analysis by Hobarth Willard, Lynne L Merritt and John A Dean,6th edition, 1986, CBC publishers, New Delhi.
2. Instrumental methods of chemical analysis by B. K. Sharma, 10th edition, GOEL publishing house, 2002.
3. Practical pharmaceutical chemistry by Beckett A. H. and Stenlake J. B., 4th edition, CBS publishers, New Delhi, 1997.
4. Spectrometric identification of organic compounds by Robert M Silverstein, G.
   Clayton and Terence C. Morill, 6th edition, John Wiley and Sons, 2004.
5. Organic Spectroscopy by William Kemp.
6. Quantitative analysis of drugs by D.C.Garrett.
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1. Indian Pharmacopoeia'96 Vol I & II
2. Principles of instrumental analysis by Doglas A Skoog, F. James Holler, 5th edition, eastern press, Bangalore, 1998
3. Quantitative analysis of drugs in Pharmaceutical formulation . P. D. Sethi, 3rd edition, CBS Publishers, New Delhi, 1997.
4. TLC by Stahl, Spring Verlay, 2nd edition, 1969.
5. Applications of Absorption Spectroscopy of Organic Compounds by John R Dyer.
6. Analytical Chemistry by Garry Christian.

Unit

SEMESTER/YEAR : IV YEAR
COURSE CODE : 15BP403
TITLE OF THE COURSE : PHARMACOLOGY & TOXICOLOGY - THEORY
L: T/A: P: C
: 3 : 0 : 0 : 3

COURSE OBJECTIVES: It deals with the effects of drugs in man and how drugs are used most effectively to treat diseases. The overall objectives of this course are to provide the students with scientific and practical basis of successful drug therapy.

COURSE OUTCOMES:

(i) After completion of the course, the student come to know the site of drug action, changes caused by drugs in the normal function of tissues and organs.
(ii) Relationship between the doses of drugs and its effects.
(iii) How drug reduce their effects?
(iv) What happens the drugs once they enter the body?

UNIT 1

1. **Bio Assays:** Scope, General Principles and Methods
   2hours

2. **Drug discovery and development:** a. Preclinical evaluation (Regulatory Toxicity Studies as per OECD guidelines- Genotoxicity, Mutagenicity, carcinogenicity, Reproductive and developmental toxicity) b. Clinical evaluation including pharmacovigilance, GPP, ICH & OECD guidelines with respect to toxicology.

3 hours

UNIT 2

Pharmacology of Drugs Acting on Central Nervous System : General consideration

(Introduction), Alcohol, General anesthetics, Sedatives and hypnotics, AntiEpileptics, Psychopharmacological agents, Classification and mechanism of action of drugs used in psychosis, Pharmacology of Chlorpromazine (a prototype drug), Salient features of Antipsychotics including atypical Antipsychotics. Drugs used in Parkinsonism and Alzheimer's disease. Antidepressants: Classification and mechanism of action of drugs used in Depression, Pharmacology of imipramine (a prototype TCA), Salient features of other Antidepressants, including SSRIs and atypical antidepressants, Pharmacology of Lithium and other agents used in bipolar disorder. Anxiolytics, Drug dependence and drug abuse. Brief introduction on the recent development in the CNS drugs **19 hours**

UNIT 3

4. **Analgesics and anti-inflammatory agents:** Pain pathway, classification and mechanism of action of centrally acting analgesics, Pharmacology of Morphine (a prototype Opioid), Salient features of other opioids including antagonists, Classification and mechanism of action of NSAIDs, Pharmacology of Aspirin (a prototype NSAID), Salient features of other NSAIDs including COX-2 inhibitors. Brief introduction on the recent development in Analgesics and anti-inflammatory drugs. **8 hours**

5. **Pharmacology of Drugs Acting on Gastro Intestinal Tract:** Antiulcer drugs, Antacids, Laxatives and Purgatives, Emetics and Antiemetics, Appetizers, Digestants, Carminatives. Brief introduction to the role of micro-biomes in gut health. **4 hours**

UNIT 4

Unit

6. **Chemotherapy:** Introduction and principles of chemotherapy including general mechanisms of antimicrobials, mechanism of resistance, super infections, antimicrobial combinations. Classification, mechanism of action, spectrum of activity, resistance development, adverse drug reactions and therapeutic use of the following: 1. Sulfonamides and Co-trimoxazole, 2. Penicillins and Cephalosporins, 3. Tetracyclines and Chloramphenicol, 4. Macrolides, 5. Aminoglycosides, 6. Polyene & Polypeptide antibiotics, 7. Quinolones and Fluoroquinolones, 8 Lincosamides, Glycopeptides, urinary antiseptics, 9. Antifungal agents, 10. Antiviral agents including anti-HIV, 11. Chemotherapy of Tuberculosis and Leprosy, 12. Chemotherapy of Malaria, 13. Chemotherapy of Protozoal infections (amoebiasis, Giardiasis), 14. Pharmacology of Anthelmintic drugs, 15. Chemotherapy of Cancer. Brief introduction on: (Immune oncology Eg.
   CTLA-4, Monoclonal antibodies in cancer therapy, Antibody drug conjugates, CAR-T.) **31 hours**

UNIT 5

7. **Immunopharmacology** Pharmacology of immunosuppressants (Calcineurin inhibitors, cytotoxic agents, Glucocorticoids, Interleukin inhibitors, mTOR inhibitors, *TNF* – α inhibitors, cytokine inhibitors) and stimulants (Thymosin, Colony-
   Stimulating Factors) **2 hours**

8. **Principles of Toxicology:** General principles of treatment of acute toxicity and acute poisoning Signs, Symptoms and treatment of acute and chronic poisoning due to i) Barbiturates ii) Alcohols iii) Benzodiazapines iv) Antidepressants, v) Neuroleptics vi) Insecticides vii) Snake bite viii) Heavy metals (iron, lead,
   mercury, arsenic). **4 hours**

9. **Pharmacology of Local anesthetics** **2 hours**

PHARMACOLOGY & TOXICOLOGY TEXT BOOKS:

1. Tripathi KD, Essentials of Medical Pharmacology, 7th Edition, Jaypee Brothers, 2010.
2. Satoskar R.S., Bhandarkar S.D. and Rege N.N., Pharmacology and
   Pharmacotherapeutics, 21st Edition, Popular Prakashan Pvt Ltd, 2010.
3. Chaudhary S.K., Quintessence of Medical Pharmacology, 3rd Revised Edition, Central Book Agency Pvt. Ltd., 2010.

4. Sharma H.L. and Sharma K.K., 2nd Edition, Principles of Pharmacology, Paras Medical, 2011.
5. Ghosh M.N., Fundamentals of Experimental Pharmacology, 5th Edition, Hilton & Company, 2011.
6. Kulkarni S.K., Hand book of Experimental Pharmacology, 3rd Edition ,Vallabh Prakashan, 2005.
7. Medhi B. and Prakash A., Practical manual of experimental and clinical pharmacology, 1st Edition, Jaypee Brothers, Medical Publishers, 2010.

PHARMACOLOGY & TOXICOLOGY REFERENCE BOOKS:

1. Brunton L.L., Chanbner B.A., and Knollmann B.C., Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Edition, McGraw-Hill Professional, 2010.
2. Katzung B.G., Masters S.B. and Trevor A.J., Basic and Clinical Pharmacology, 12th Edition, McGraw-Hill, 2011.
3. Rang H.P., M.M. Dale, J.M. Ritter., Flower R.J. and Henderson G., Pharmacology, 7th illustrated Edition, Elsevier Science Health Science Division, 2011.
4. Craig C.R. and Stitzel R.E., Modern Pharmacology with Clinical Applications, 6th Edition, Lippincott Williams and Wilkins, 2003.
5. Harvey R.A., Clark M.A., Finkel R, Jose A.R. and Whalen K, 5th Edition, Lipponcott's Illustrated Reviews: Pharmacology, Lippincott Williams and Wilkins, 2011.
6. Barar F.S.K., Essentials of Pharmacotherapeutics, 6th Revised Edition, S.Chand & Co. Ltd, 2011.
7. DiPiro J, Talbert R.L., Yee G., Matzke G., Wells B. and Posey L.M., Pharmacotherapy: A Pathophysiologic Approach, 8th Edition, McGraw-Hill Medical, 2011.

SEMESTER/YEAR : IV YEAR
COURSE CODE : 15BP473
TITLE OF THE COURSE : PHARMACOLOGY & TOXICOLOGY - PRACTICAL L: T/A: P: C : 0 : 0 : 4 : 2

1. To record the dose response curve of Histamine using isolated chick/rat/guinea pig ileum preparation.**
2. To carry out bioassay of Histamine using isolated chick/rat/guinea pig ileum preparation by matching method.**

Unit

3. To carry out bioassay of Histamine using isolated chick/rat/guinea pig ileum preparation by interpolation method.**
4. To carry out bioassay of Histamine using isolated chick/rat/guinea pig ileum preparation by three point method.**
5. To record the dose response curve of Acetylcholine using isolated ileum preparation.**
6. To carry out bioassay of Ach using isolated chick/rat/guinea pig ileum preparation by interpolation method.**
7. To carry out bioassay of Acetylcholine using isolated ileum preparation by matching method.**
8. To carry out bioassay of Acetylcholine using isolated ileum preparation by threepoint method.**
9. To carry out MAO inhibitory activity using chick/rat liver homogenate.*
10. To carry out amylase/α-glucosidase inhibitory activity using *in vitro* technique.*
11. Study of principle, procedure involved and interpretation of given results for analgesic property of drug using analgesiometer*
12. Study of principle, procedure involved and interpretation of given results for Anti inflammatory effect of drugs using rat-paw edema method.*
13. Study of principle, procedure involved and interpretation of given results for Anti convulsant activity of drugs using MES method.*
14. Study of principle, procedure involved and interpretation of given results for Anti convulsant activity of drugs using pentylenetetrazole method.*
15. Study of principle, procedure involved and interpretation of given results for antidepressant activity of drugs using pole climbing apparatus.*
16. Study of principle, procedure involved and interpretation of given results for hypnotic and sedative property using Pentobarbitone induced sleeping time method.*
17. Study of principle, procedure involved and interpretation of given results for locomotor activity evaluation of drugs using Actophotometer.*
18. Study of principle, procedure involved and interpretation of given results for evaluation of muscle grip strength/relaxant effect of drugs using rotarod.*
19. Study of principle, procedure involved and evaluation of anthelmintic activity of drugs using earthworm as a model.*
20. To determine the clastogenic potential of test compound by assessing i*n-vito* micronuclease formation.

Note: ** Denotes major experiments * Denotes minor experiments

PHARMACOLOGY & TOXICOLOGY TEXT BOOKS:

1. Tripathi KD, Essentials of Medical Pharmacology, 7th Edition, Jaypee Brothers, 2010.
2. Satoskar R.S., Bhandarkar S.D. and Rege N.N., Pharmacology and Pharmacotherapeutics, 21st Edition, Popular Prakashan Pvt Ltd, 2010.
3. Chaudhary S.K., Quintessence of Medical Pharmacology, 3rd Revised Edition, Central Book Agency Pvt. Ltd., 2010.
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5. Ghosh M.N., Fundamentals of Experimental Pharmacology, 5th Edition, Hilton & Company, 2011.
6. Kulkarni S.K., Hand book of Experimental Pharmacology, 3rd Edition ,Vallabh Prakashan, 2005.
7. Medhi B. and Prakash A., Practical manual of experimental and clinical pharmacology, 1st Edition, Jaypee Brothers, Medical Publishers, 2010.

PHARMACOLOGY & TOXICOLOGY REFERENCE BOOKS:

1. Brunton L.L., Chanbner B.A., and Knollmann B.C., Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Edition, McGraw-Hill Professional, 2010.
2. Katzung B.G., Masters S.B. and Trevor A.J., Basic and Clinical Pharmacology, 12th Edition, McGraw-Hill, 2011.
3. Rang H.P., M.M. Dale, J.M. Ritter., Flower R.J. and Henderson G., Pharmacology, 7th illustrated Edition, Elsevier Science Health Science Division, 2011.
4. Craig C.R. and Stitzel R.E., Modern Pharmacology with Clinical Applications, 6th Edition, Lippincott Williams and Wilkins, 2003.
5. Harvey R.A., Clark M.A., Finkel R, Jose A.R. and Whalen K, 5th Edition, Lipponcott's Illustrated Reviews: Pharmacology, Lippincott Williams and Wilkins, 2011.
6. Barar F.S.K., Essentials of Pharmacotherapeutics, 6th Revised Edition, S.Chand & Co. Ltd, 2011.
7. DiPiro J, Talbert R.L., Yee G., Matzke G., Wells B. and Posey L.M., Pharmacotherapy: A Pathophysiologic Approach, 8th Edition, McGraw-Hill Medical, 2011.

Unit

SEMESTER/YEAR : IV YEAR
COURSE CODE : 15BP404
TITLE OF THE COURSE : MEDICINAL CHEMISTRY II - THEORY
L: T/A: P: C
: 3 : 0 : 0 : 3

COURSE OBJECTIVES: The subject deals with understanding of chemistry, properties and action of medicinal agents for treating various disorders, basic concepts involved in drug design.

COURSE OUTCOMES: The student will be able to understand the action of drugs in different disease condition and apply basic principles in designing of new drug molecules.

UNIT I

A. Introduction to QSAR: Study of hydrophobic, Electronic & Steric parameters **2 hours**

B. Prodrugs: Definition and examples **1 hour**

C. Introduction to drug discovery- Definition of lead molecule and its identification methods viz, high throughput screening, large scale screening, and fragment based lead generation, fast followers **2 hours**

D. History and development of chemotherapeutic agents: Structure, uses and synthesis of only those compounds that are superscripted by's'.

1.Antifungal agents:

a) Antifungal antibiotics- Nystatin, Griseofulvin, Ampoterecin-B Synthetic anti fungal agents
b) Substituted imidazoles: Clotrimazole, Miconazole[s], Ketoconazole, oxyconazole, Intraconazole.
c) Miscellaneous–Zinc propionate, Sodium caprylate, Tolnaftate[s]. **4 hours**

3. Antiviral Agents

a) Amantidine hydrochloride, Iodoxuridine, Acyclovir, Zidovidine.
b) Anti-AIDS: Aza thymidine, Suramin **2 hours**

3. Antiprotozoal agents: Emetine hydrochloride, Metronidazole[s], tinidazole, arnidazole, secnidazole, Diloxanide furoate, 8-hydroxy quinoline derivatives (clioquinal, iodoquinal) Carbarsone

2 hours 4. Anthelmintics: Piperazine, Diethyl carbamazine, Pyrantelpamoate, Thiabendazoles
Albendazoles, Mebendazole **2 hours**

UNIT II

E. Sulfonamides, Sulfones as antibacterial agents :

1. SAR and mode of Sulfonamides.
2. Classification of sulfonamides based on duration of action and site of action with examples. Sulfamethiazole, Sulfisoxazoles, Sulfapyridine, Sulfamethoxazoles , Sulfadiazine, Sulfacetamide, sulfasalazine, Phthalyl sulfathiazole.
3. Folatereductase inhibitors: Trimethoprim, Synergistic action of the combination of sulfamethoxazole and Trimethoprims.
4. Sulfone: Dapsones **4 hours**
5. Antitubercular drugs:

a) Synthetic antitubercular agents: p-Aminosalysilic acid , Isoniazids , Ethambutols , Pyrazinamide, Ethionamide, Clofazamine,Bedaquiline

b) Antitubercular Antibiotics: Cycloserine, Viomycin sulfate, Capreomycin sulfate, Rifampicin.

c) Combination therapy for TB, DOTS **4 hours**

Urinary tract anti-infectives:

Quinolones: Nalidixic acid, Cinoxacin, Norfloxacin, Ciprofloxacins, Pefloxacin, d) Ofloxacin, Sparfloxacin

e) Miscellaneous: Nitrofurantoins . **3 hours**

F. Antimalarials: Etiology of malaria, History, Mechanism and SAR

1. Quinolines and analogues: 7-chloro-4-amino quinolines :Chloroquine phosphates , HydroxyChloroquinesulphate, Amodiaquine, 8-amino quinolines: Pamaquine, Primaquines , 9-amino acridines: Quinacrine.
2. Artimicin and its derivatives: Artiether, Artimether, Artisunate 3. Biguanides and Dihydrothiazines: Chloroguanides, Cycloguanil.
4. Miscellaneous: Mefloquine, Pyrimethamine , Trimethoprim. **6 hours**

UNIT III

G. Antibiotics: Classification and Mechanism of action

1. Beta lactam antibiotics: Pencillins – structures, chemical degradation, bacterial resistance. Penicillin G, Penicillin V, Cloxacillin sodium, Naficillin sodium, Ampicillin, Amoxycillin.
2. Cephalosporins: Structure and uses of Cephalexin, Cephradine, Cefadroxil, Cefixime,

Unit

Cefapyridine, Cefutroxime

3. Monolactams: Sulfazecin, Aztreonam, Tigmonam.
4. Beta lactamase inhibitors: Clavulanic acid and its salts, Thienamycin.
5. Aminoglycosides: Structural features and Mechanism of action, Streptomycin, Amikacin, Neomycin, Kanamycin, Gentamycin, Netilmycin
6. Tetracyclines: Chemistry and SAR, tetracycline, Chlortetracycline, Methacycline, Demeclocycline, Oxytetracycline, Meclocycline, Doxycycline, Minocycline.
7. Macrolide: Structure and specific uses of Erythromycin, Azithromycin, oleandomycin.
8. Lincomycins: Lincomycin, Clindamycin.
9. Polypeptides: Gramicidin, Bacitracin, Polymyxin B, Colistin.
10. Miscellaneous: Chlormphenicol[s] ,Vancomycin, Novobiocin. **12 hours**

UNIT IV

H. Antineoplastic agents: Introduction, mechanism of action and classification with examples.

1. Alkylating agents: Mechlorethamine, Cyclophosphomide, Melphalan, Chlorambucil[s] , Busulfan, Lomustine,
2. Antimetabolites: Mercaptopurine, Thioguanine, 5-Flurouracil, Methotrexate[s], 3. Antibiotics: Dactinomycin, Bleomycin, Mitomycin, Streptozocin.
4. Plant products: Etopside, Taxol, Camphothesin, Vincristine, Vinblastin.
5. Harmones: Dromostanalone, Megestrol,
6. Kinase inhibitors: Imatinibmesylate
7. Miscellaneous: Asparginase, Cisplatin, Hydroxy urea.
8. Immunotherapy: Interferon alpha 2a and 2b. **6 hours**

I. Cardiovascular agents:

1. Antianginal agents and vasodilators: Chemical structure and specific uses of Amyl nitrite, Nitroglycerine, Isosorbide dinitrate.
2. Calcium antagonists: Brief introduction of calcium channels and their blockers. Chemical Structures and uses of Verapamil, Diltiazem, Nifedepine, Nimodepine,

   Felodepine, Dipyridamole, Cyclandelate.
3. Antiarrhythmic drugs: Structure, chemical name, and classification of antiarrythmics with examples

   Class I- Membrane depressant drugs: Quinidine Procainamide, Phenytoin[s].

   Class II-Beta adrenergic blocking agents.Tocainide, propranolol[s]

   Class III-Repolarization prolongators. Bretylium, Amiodarone

   Class IV-Calcium channel blocker. Diltiazem, Verapamil
4. Antihypertensive agents:

Beta-blockers: Propranolol. Timolol
ACE Inhibitors: Captopril, Enalapril
Diuretics: Hydrochlorthiazide, Spiranolactone
Calcium channel blockers: Nifedipine, Felodipine, Amlodipine α_1 -Antagonist: Prazocin
α_2 -agonist: Clonidines, Guanithedine
Angiotensin –II receptor antagonist: Losartan, Valsartan
Miscellaneous: Resperpine, Hydralazines, Minoxidil **11 hours**

UNIT V

1.Antihyperlipidemic agents: Structure and specific uses.Clofibrate, Lovastatin,
Cholesteramine, Colestipol, Atorvastatin **3 hours**

2.Anticoagulants: Dicumorol, Warfarins ,Phenindione **1**

3. Hypoglycemic agents: Insulin and its preparations. **hour**
Sulfonylureas–Chlorpropamides , Acetohexamide, Glipizide,
Biguanides-Phenformin, Metformin
Substituted benzoic acid derivatives – Meglitinides, Nateglinide
Thiazolidinediones –Glitazones, Pioglitazone, Ciglitazone, Rosiglitazone
Glipitines – Sitagliptin, Anagliptin **3 hours**

4.Thyroid harmones : L-thyroxine, L-thyronine, **1 hour**

5. Antithyroid drugs: Propylthiouracil, Methimazole. **1 hour**

J. Diuretics: Introduction

1. Carbonic anhydrase inhibitors: Acetazolamides, Methazolamide.
2. Thiazide and Thiazide like diuretics: Chlorthiazides, Benzthiazides, Xipamide, Chlorthalidone.
3. High-ceiling or loop diuretics: Furosemides, Ethacrynic acids .
4. Potassium sparing diuretics: Spironolactone, Triampterene, Amiloride.
5. Miscellaneous: Mannitol. **5 hours**

MEDICINAL CHEMISTRY II TEXT BOOKS (THEORY):

Latest editions and all volumes of

1. Foye's principles of Medicinal chemistry
2. Wilson and Griswold's Text book of Organic and Pharmaceutical chemistry 13th Edition.
3. K.Ilango, Medicinal Chemistry

Unit

MEDICINAL CHEMISTRY II REFERENCE BOOKS (THEORY):

Latest editions and all volumes of

1. Burger's medicinal chemistry
2. The Martindale's Extra Pharmacopoeia
3. A.I.Vogel, Text Book of practical organic chemistry including the qualitative analysis
4. A.H.Becket and J.B.Stanlake, Practical Pharmaceutical chemistry
5. LedniserMitzsher, Organic drug synthesis, Vol.1 and 2
6. I.L. Finar, Text Book organic chemistry
7. T. Robinson, Organic constituents of higher plants
8. Feiser and Feiser Steroids
9. Drug design by Ariens
10. Smith and Williams, Introduction to principles of drug design
11. Purcell, Strategy of drug design
12. CIMS

SEMESTER/YEAR : IV YEAR
COURSE CODE : 15BP474
TITLE OF THE COURSE : MEDICINAL CHEMISTRY II - PRACTICAL
L: T/A: P: C : 0 : 0 : 3 : 1.5

Assay of

1. Sulphadiazine by diazotization
2. Piperazine Citrate by non aqueous titration
3. Ascorbic acid by Iodimetry/Cerrimetry
4. Isonicotinic acid by $KBrO_3$ (Bromimetry)

5. Benzyl penicillin by Iodometry
6. Metronidazole/Mepacrine by non aqueous titration
7. Furosemide by neutralization titration
8. Diethyl carbamazine by neutralization titration

Preparation of medicinally important compounds or intermediates required for synthesis of drugs

1. PAS from p-nitro salicylic acid
2. Dichloramine T from toluene p-sulphonamide
3. Chloramine T from Dichloramine T
4. Fluorescein from pthalic anhydride
5. Eosin from Fluorescin
6. Sulphacetamide from sulphanilamide
7. Sulphanilamide from Acetanilide
8. INH from γ Picoline
9. Chlorobutanol
10. Benzotriazole
11. 2,3-Diphenyl quinoxaline
12. 2,4,5Triphenyl imidazole from Benzoin

Green Chemistry Synthesis

1. Microwave assisted synthesis of 1.4-dihydropyridine/pyrimidine
2. Synthesis of p-bromoacetanilide from aniline using KBr

Estimation of the functional groups in medicinally important compound

1. Hydroxyl group in cholesterol
2. Ketone in camphor
3. Hydroxyl group in menthol
4. Amide in nicotinamide

MEDICINAL CHEMISTRY II REFERENCE BOOKS (PRACTICALS):

1. A.I.Vogel, Text Book of practical organic chemistry
2. A.H. Beckett and Stanlake, Practical pharmaceutical chemistry
3. J.G.Mann and Saunders, Practical organic chemistry 4. Jayaveera KN, Practical medicinal chemistry 5. All editions of IP.

SEMESTER/YEAR : IV YEAR
COURSE CODE : 15BP405
TITLE OF THE COURSE : INDUSTRIAL PHARMACOGNOSY - THEORY

Unit

L: T/A: P: C
: 2 : 0 : 0 : 2

COURSE OBJECTIVES: To learn about the various standardization procedures, extraction methods of various plant drugs along with cosmetic preparations and alternative system of medicine – also about plant and enzyme biotechnology

COURSE OUTCOMES:

Students will be aware of

(i) Transgenic plants, tissue culture, enzyme technology.
(ii) Extraction techniques, identification and characterization of herbal drugs.
(iii) Herbal formulations and alternative system of medicine.

UNIT I

Secondary Metabolites: 10hrs

- Biosources, methods of isolation, identification, estimation, therapeutic uses, commercial applications of the following secondary metabolites: Gymnemic acid, Asiaticoside, Diosgenin, Quinine, Ephedrine, Digitoxin, Ca-sennosides, Glycyrrhizin , Andrographolides, Phyllanthin, caffeine.

UNIT II

A) Herbal formulation and nutraceuticals
7 hrs

a. Importance of herbal cosmetics. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.
b. Preparation of herbal extracts, stability testing and formulations.
c. Role of Herbs in Cosmetics
   Hair care preparation – Soapnut, Henna, Amla, Hibiscus
   Skin Care preparation – Aloevera, Turmeric, Sandalwood
d. Nutraceuticals – Antioxidants, Spirulina, Garlic, Ginseng, Honey

B) Traditional drugs and its marketed Products:
3 hrs

Study of common and vernacular names, source active constituents and uses of: Shatavari, Bilva, Lehsun, Kantakari, Rasna, Punarnava, Shankapushpi, Guduchi, Chirata, Shilajit, Arjuna, Gokhru and Gymnema.

UNIT III

A) Alternative system of medicine: 4 hrs

a) Basic principles involved in traditional systems of medicine like Ayurveda, Siddha, Chinese, Homeopathy and Unani.

b) Method of preparation of Ayurvedic preparations like Arishtas, Asavas, Gutikas, Tailas, Churnas, Leha and Bhasmas along with a few marketed products.

B) Standardization of Natural Products: 6 hrs

- Evaluation, quality control and standardization.
- WHO Guidelines – for assessment of Herbal Medicine and Cosmetics. Standardization of following drugs:
  Gymnema, Gokhru, Vasaka, Curcuma, Glycyrrhiza, Kalmegh, Brahmi, Ashwagandha, Tinospora and Phyllanthus.
- Determination of alcoholic content in ayurvedic formulations like Aristas and Asavas.

UNIT IV

Plant tissue culture 10 hrs

- Historical development, nutritional requirement, growth and maintenance of tissue culture. Applications of plant tissue culture, detailed study of various types of cultures related to cell suspension culture, callus culture, hairy root culture and protoplast culture.
- Applications of Transgenic plants.
- Gene transfer using vectors and physical delivery methods in plants.

UNIT V

Biological preparations from Natural Products 10 hrs

- Definition, isolation and purification of enzymes and enzyme reactors.
- Immobilization of cell & enzymes and their applications.
- Biological source, preparation and uses of the following enzymes - Papain, Bromelain, Streptokinase and Urokinase.

Unit

- Allergenic extracts.
- Vaccines

TEXT BOOKS:

1. Kokate C.K., Purohit A.P and Gokhale S.B. Pharmacognosy, 45th ed., Nirali Prakashan, Pune, 2010.
2. Trease G.E. and Evans W.C., Pharmacognosy, 15th ed, Bailliere Tindall, Eastbourne, U.K., 2002.
3. Vinod D. Rangari. Pharmacognosy and Phytochemistry, 1st ed. Career publications, Nashik, 2003.
4. Ashutosh Kar. Pharmacognosy and Pharmacobiotechnology, 1st ed. New Age International Publishers, New Delhi, 2003.
5. Vyas S.P & Dixit. Pharmaceutical Biotechnology, 1st ed. CBS Publishers & distributors, New Delhi, 1998.

REFERENCES:

1. Pulok Mukherjee. Quality control of herbal drugs, 1st ed. Business horizons, New Delhi, 2002.
2. Peach K., and Tracey M.V, Modern Methods of Plant Analysis, 1-4, Narosa publishing house, New Delhi.
3. Rajpal V. Standardisation of Botanicals, 1st ed. Eastern publishers, New Delhi, 2002.
4. Indian Herbal Pharmacopoeia, Vol I & Vol II. Government of India, Ministry of Health. A Joint Publication of RRL, Jammu and IDMA, Mumbai, 1998 & 1999.

SEMESTER/YEAR : IV YEAR
COURSE CODE : 15BP475
TITLE OF THE COURSE : INDUSTRIAL PHARMACOGNOSY - PRACTICAL
L: T/A: P: C : 0 : 0 : 3 : 1.5

1. Isolation of some selected phytoconstituents studied in theory and their chromatographic profiles.** Glycyrrhizin from *Liquorice*

   Hesperidin from *Orange peel*

   Quinine from *Cinchona*

   Caffeine from *Tea leaves*

   Andrographolide from *Kalmegh*

2. Studies of traditional drugs, common vernacular names, botanical sources, morphology, chemical nature of chief constituents, pharmacological and common uses of the drugs studied in theory.*

Unit

3. Estimation of some of the isolated phytoconstituents :** Caffeine, Curcumin and Quinine
4. Chromatography*

   Thin layer chromatography of alkaloids

   Paper chromatography of amino acids
5. Estimation of bitters in Kalmegh*
6. Determination of swelling index in mucilage containing drugs*
7. Determination of alcoholic content in Aristas and Asavas.*
8. Immobilization of enzymes like amylase and yeast cells and determination of their activity.*
9. Tissue culture: Initiation of callus culture.*

** Major experiment: - Isolation of phytoconstituents from plant source.

Estimation of phytoconstituents

* Minor experiment: - Morphology

Powder microscopy

Chromatography

Immobilization

Alcohol content determination

Tissue culture

TEXT BOOKS:

1. Kokate C.K., Purohit A.P and Gokhale S.B. Pharmacognosy, 45th ed., Nirali Prakashan, Pune, 2010.
2. Trease G.E. and Evans W.C., Pharmacognosy, 15th ed, Bailliere Tindall, Eastbourne, U.K., 2002.
3. Vinod D. Rangari. Pharmacognosy and Phytochemistry, 1st ed. Career publications, Nashik, 2003.
4. Ashutosh Kar. Pharmacognosy and Pharmacobiotechnology, 1st ed. New Age International Publishers, New Delhi, 2003.

5. Vyas S.P & Dixit. Pharmaceutical Biotechnology, 1st ed. CBS Publishers & distributors, New Delhi, 1998.

REFERENCES:

1. Pulok Mukherjee. Quality control of herbal drugs, 1st ed. Business horizons, New Delhi, 2002.
2. Peach K., and Tracey M.V, Modern Methods of Plant Analysis, 1-4, Narosa publishing house, New Delhi.
3. Rajpal V. Standardisation of Botanicals, 1st ed. Eastern publishers, New Delhi, 2002.
4. Indian Herbal Pharmacopoeia, Vol I & Vol II. Government of India, Ministry of Health. A Joint Publication of RRL, Jammu and IDMA, Mumbai, 1998 & 1999.

SEMESTER/YEAR : IV YEAR
COURSE CODE : 15BP406
TITLE OF THE COURSE : ADVANCED INDUSTRIAL PHARMACY

Unit

L: T/A: P: C
: 2 : 0 : 0 : 2

COURSE OBJECTIVES: To study the development of various sustained and controlled release formulations as well as pilot plant scale up and validation.

COURSE OUTCOMES: The student will be able to understand the formulation aspects of sustained and controlled release dosage forms and also have a knowledge about pilot plant set up and validation aspects of various processes.

UNIT I

1. Controlled release drug delivery systems: Principle, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on dissolution, diffusion and ion exchange principles. Microencapsulation: Definition, applications, air suspension, coacervation and phase separation techniques. **10 hrs**

UNIT II

2. Novel drug delivery systems: Concepts, advantages and disadvantages, types of drug delivery systems such as transdermal, nasal, ocular and buccal with suitable examples. Targeted drug delivery systems: Concepts and approaches, advantages and disadvantages. Preparation and applications of microspheres, liposomes, niosomes, and nanoparticles. **12 hrs**

UNIT III

3. Biopharmaceutical classification, systems and methods to improve the bioavailability of poorly soluble drugs - solid dispersion and complexation techniques. **04 hrs**

4. Pilot Plant scale up: General considerations - including significance of personnel requirements, space requirements, raw materials and development of Master Formula Records and Batch Manufacturing Records. Pilot plant scale up considerations for tablets. **06hrs**

UNIT IV

5. Current Good Manufacturing Practices (cGMP): As per D&C Act, USFDA, MHRA and

TGA guidelines. **04 hrs**

6. ICH guidelines: Quality, efficacy and safety and stability of drugs.
   05 hrs UNIT V
7. Nutraceuticals: Introduction, history, classification. Probiotics and their role in prevention of diseases. **03 hrs**
8. Validation: Definition, types of validation, methods for process validation of pharmaceutical operations – Mixing and compression. **06 hrs**

TEXT BOOKS:

1. Controlled and Novel Drug Delivery by NK Jain, CBS Publishers.
2. Novel Drug Delivery Systems by Y.W. Chien, Marcel Dekker Inc., NY.
3. Regulatory Affairs by CVS Subrahmanyam, Vallabh Prakashan, New Delhi.

REFERENCE BOOKS:

1. Pharmaceutical Regulatory Affairs by CVS Subrahmanyam, Vallabh Prakashan, New Delhi.
2. Novel Drug Delivery Systems and Regulatory Affairs by Yajamanv Sudhakar, S Chand Publishing, New Delhi.
3. Controlled Drug Delivery Systems by Joseph R. Robinson and Vincent H.L. Lee. Marcel Dekker Inc., NY.
4. Controlled Drug Delivery by SP Vyas and Roop C Khar Vallabh Prakashan, New Delhi.
5. Pharmaceutical Process Validation by Robert A Nash, Marcel Dekker Inc., NY.
6. Validation in Pharmaceutical Industry, PP Sharma, Vandana Publications, Delhi.

Unit

DAYANANDA SAGAR UNIVERSITY

Shavige Malleshwara Hills, Kumaraswamy Layout, Bengaluru - 560078, Karnataka.

SCHOOL OF HEALTH SCIENCES

COLLEGE OF PHARMACEUTICAL SCIENCES

SCHEME & SYLLABUS
FOR
MASTER OF PHARMACY (M. PHARM) – 2017
(Semester Scheme)

(With Effect from 2017-18)

Unit

SEMESTER/YEAR : I SEM
COURSE CODE : 17MPH101
TITLE OF THE COURSE : MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

COURSE OBJECTIVES

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

UNIT – I **11 hrs**

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

c. Spectro flourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT – II **11 hrs**

NMR spectroscopy: Quantum numbers and their role in NMR, Principle , Instrumentation , Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

UNIT – III **11 hrs**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT – IV **11 hrs**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

UNIT – V **11 hrs**

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis
   d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.

UNIT – VI **5 hrs**

6 Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.

REFERENCES:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

17MPH102 DRUG DELIVERY SYSTEMS

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

COURSE OBJECTIVES

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

- The various approaches for development of novel drug delivery systems.

Unit

- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems..

10 hrs

1. Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation.
   Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

10 **hrs**

2. Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

10 **hrs**

3 Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

6 hrs

4 Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

10 hrs

5 Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

8 hrs 6. Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

6 **hrs**

7. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

REFERENCES:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

Unit

17MPH103
MODERN PHARMACEUTICS

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

COURSE OBJECTIVES

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

The elements of preformulation studies.

- The Active Pharmaceutical Ingredients and Generic drug Product development - Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

10 hrs 1. a.

Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

10 hrs

b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation

10 hrs

2 Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.

10 hrs

3 cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

10 hrs

4 Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.

10 hrs

5 Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

17MPH104

REGULATORY AFFAIRS

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

COURSE OBJECTIVES

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance - To learn the documentation requirements for - To learn the importance and Objectives:

Unit

COURSE OUTCOMES

Upon completion of the course, it is expected that the students will be able to Understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products - Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials - Pharmacovigilence and process of monitoring in clinical trials.

12 hrs

1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

12 hrs

2 CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

12 hrs 3 Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

12 hrs

4 Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143

2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

Unit

I SEM
17MPH105 PHARMACEUTICS
PRACTICALS - I

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Mucoadhesive tablets.
12. Formulation and evaluation of transdermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

II SEM
17MPH201
MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

COURSE OBJECTIVES

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems. - The criteria for selection of drugs and polymers for the development of NTDS - The formulation and evaluation of novel drug delivery systems.

12 hrs

1. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

12 hrs

2 Targeting Methods: introduction preparation and evaluation. Nanoparticles & Liposomes: Types, preparation and evaluation.

12 hrs

3 Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

12 hrs

4 Pulmonary Drug Delivery Systems : Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

12 hrs

5 Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

II SEM

17MPH202

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Unit

COURSE OBJECTIVES

Upon completion of this course it is expected that students will be able understand, -

The basic concepts in biopharmaceutics and pharmacokinetics.

- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- the design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

12 hrs

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), Ph Microclimate Intracellular pH Environment, Tight-Junction Complex.

12 hrs

2 Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

12 hrs 3

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

12 hrs 4

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

12 hrs

5 Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.

Unit

10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

17MPH203

TITLE OF THE COURSE COMPUTER AIDED DRUG DEVELOPMENT

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

COURSE OBJECTIVES

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

12 hrs

1. a. Computers in Pharmaceutical Research and Development:

A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

b. Quality-by-Design In Pharmaceutical Development:

Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

2 Computational Modeling Of Drug Disposition: **12 hrs**

Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

3 Computer-aided formulation development: **12 hrs**

Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

Unit

4 a. Computer-aided biopharmaceutical characterization: **12 hrs**
Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitroin vivo correlation, Biowaiver considerations

b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

12 hrs

5 Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

REFERENCES:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

17MPH204 TITLE OF THE COURSE

COSMETICS AND COSMECEUTICALS

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

COURSE OBJECTIVES

Upon completion of the course, the students shall be able to understand -

Key ingredients used in cosmetics and cosmeceuticals.

- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

12 hrs

1. Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

12 hrs

2 Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

12 **hrs**

3 Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals.

Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

12 **hrs**

Unit

4 Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

12 **hrs**

5 Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition 4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

17MPH205 TITLE OF THE COURSE PHARMACEUTICS PRACTICALS - II

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and Dandruff

SEMESTER/YEAR : I SEM
COURSE CODE : 17MPC101
TITLE OF THE COURSE : MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

COURSE OBJECTIVES

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

10 hrs

Unit

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

10 hrs

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

10 hrs

3.Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

10 hrs 4

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography
b) High Performance Thin Layer Chromatography
c) Ion exchange chromatography

d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography
g) Ultra High Performance Liquid chromatography
h) Affinity chromatography
i) Gel Chromatography

10 hrs

5 a.Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

10 hrs

6 a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.
b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.
Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

Unit

SEMESTER/YEAR : I SEM
COURSE CODE : 17MPC102
TITLE OF THE COURSE : ADVANCED ORGANIC CHEMISTRY - I

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

COURSE OBJECTIVES

Upon completion of course, the student shall be to understand

- The principles and applications of reterosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

12 hrs

1. Basic Aspects of Organic Chemistry:

1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
2. Types of reaction mechanisms and methods of determining them
3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations. Addition reactions

a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
c) Rearrangement reaction

12 hrs 2

Study of mechanism and synthetic applications of following named Reactions:

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, BaeyerVilliger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

12 hrs

3 Synthetic Reagents & Applications:

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP). Protecting groups

a. Role of protection in organic synthesis

b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates,
cyclic acetals & ketals

c. Protection for the Carbonyl Group: Acetals and Ketals

d. Protection for the Carboxyl Group: amides and hydrazides, esters

e. Protection for the Amino Group and Amino acids: carbamates and amides

12 hrs 4 Heterocyclic Chemistry:

Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as DebusRadziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.

12 hrs

5 Synthon approach and retrosynthesis applications

i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA) ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-,
1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds iii. Strategies for synthesis of three, four, five and six-membered ring.

REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press
   2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.

Unit

7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

COURSE CODE **17MPC103**
TITLE OF THE COURSE **ADVANCED MEDICINAL CHEMISTRY**

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

COURSE OBJECTIVES

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

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

12 hrs

1. Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets.
Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

12 hrs 2 Prodrug Design and Analog design:

a) Prodrug design: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.

c) Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

12 hrs

3 Medicinal chemistry aspects of different class of drugs Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:

a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

Unit

b) Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

4 Rational Design of Enzyme Inhibitors **12 hrs**

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

5 Peptidomimetics **12 hrs**

Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh..
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

COURSE CODE **17MPC104**
TITLE OF THE COURSE **CHEMISTRY OF NATURAL PRODUCTS**

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such

compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

COURSE OBJECTIVES

At completion of this course it is expected that students will be able to understand-

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

12 hrs

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs

a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
d) Neuromuscular Blocking Drugs: Curare alkaloids
e) Anti-malarial drugs and Analogues
f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)

2 a) Alkaloids **12 hrs**

General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

b) Flavonoids

Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

c) Steroids

General introduction, chemistry of sterols, sapogenin and cardiac glycosides.
Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones
(Testosterone, Estradiol, Proge sterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).

3 a) Terpenoids **12hrs**

Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol,

Unit

camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene).
b) Vitamins - Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

12 hrs

4 a). Recombinant DNA technology and drug discovery rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

b). Active constituent of certain crude drugs used in Indigenous system Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.

12 hrs 5

Structural Characterization of natural compounds Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

COURSE CODE **17MPC105**
TITLE OF THE COURSE **PHARMACEUTICAL CHEMISTRY PRACTICAL - I**

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

To perform the organic reactions of synthetic importance 1.
Purification of organic solvents, column chromatography
2. Claisen-schimidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant Constituents

Unit

17MPC201
ADVANCED SPECTRAL ANALYSIS

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LCMS, GC-MS, ATR-IR, DSC etc.

Course Objectives

At completion of this course it is expected that students will be able to understand- -
Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

1. UV and IR spectroscopy: **12 hrs**

Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

2 NMR spectroscopy: **12 hrs**

1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.

3 Mass Spectroscopy **12 hrs**

Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

4 Chromatography: **12 hrs**

Principle, Instrumentation and Applications of the following : a) GC-MS b) GC-AAS c) LCMS d) LC-FTIR e) LC-NMR f) CEMS g) High Performance Thin Layer chromatography h)
Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion- Exclusion Chromatography) k) Flash chromatography

5 a). Thermalmethods of analysis **12 hrs**

Introduction, principle, instrumentation and application of DSC, DTA and TGA.

b). Raman Spectroscopy

Introduction, Principle, Instrumentation and Applications.

c). Radio immuno assay

Biological standardization , bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Unit

17MPC202
ADVANCED ORGANIC CHEMISTRY - II

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Course Objectives

Upon completion of course, the student shall able to understand

- The principles and applications of Green chemistry -
  The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis. -

1. Green Chemistry: **12 hrs**

a. Introduction, principles of green chemistry

b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis

c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications

d. Continuous flow reactors: Working principle, advantages and synthetic applications.

2 Chemistry of peptides **12 hrs**

a. Coupling reactions in peptide synthesis

b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides

c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies

d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, overactivation and side reactions of individual amino acids.

3 Photochemical Reactions **12 hrs** Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation. Pericyclic reactions Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples

4 Catalysis: **12 hrs**

a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
f. Phase transfer catalysis - theory and applications

5 Stereochemistry & Asymmetric Synthesis **12 hrs**

a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.

b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston,NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

Unit

17MPC203
COMPUTER AIDED DRUG DESIGN

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

Course Objectives

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

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

12 hrs

1. Introduction to Computer Aided Drug Design (CADD) History, different techniques and applications.
Quantitative Structure Activity Relationships: Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett
equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

12 hrs

2 Quantitative Structure Activity Relationships: Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters.

3 Molecular Modeling and Docking **12 hrs**

a) Molecular and Quantum Mechanics in drug design.
b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation
c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

4 Molecular Properties and Drug Design **12 hrs**

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.
b) De novo drug design: Receptor/enzyme-interaction and its analysis,

Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design. c) Homology modeling and generation of 3D-structure of protein.

5 Pharmacophore Mapping and Virtual Screening **12 hrs**

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

Unit

17MPC204
PHARMACEUTICAL PROCESS CHEMISTRY

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Course Objectives

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

- The strategies of scale up process of apis and intermediates
- The various unit operations and various reactions in process chemistry

1. Process chemistry **12 hrs**

Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities

2 Unit operations **12 hrs**

a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.

b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,

c) Distillation: azeotropic and steam distillation

d) Evaporation: Types of evaporators, factors affecting evaporation.

e) Crystallization: Crystallization from aqueous, nonaqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

3 Unit Processes – I **12 hrs**

a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration

b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.

c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.

4 Unit Processes – II **12 hrs**

a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.

b) Fermentation: Aerobic and anaerobic fermentation. Production of

i. Antibiotics; Penicillin and Streptomycin,

ii. Vitamins: B2 and B12 iii. Statins:

Lovastatin, Simvastatin

c) Reaction progress kinetic analysis

i. Streamlining reaction steps, route selection, ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

5 Industrial Safety **12 hrs**

a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)

b) Fire hazards, types of fire & fire extinguishers

c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO14001(Environmental Management System), Effluents and its management

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever- Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis 7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, Mc Grawhill.
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House

Unit

17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

17MPC205

PHARMACEUTICAL CHEMISTRY PRACTICALS – II

1. Synthesis of organic compounds by adapting different approaches involving
(3 experiments) a) Oxidation
b) Reduction/hydrogenation
c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotolene from p-toluidine.
13. NaBH4 reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two) 17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment

Unit

COURSE CODE **17MPL101**
TITLE OF THE COURSE **MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Course Objectives

After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

10 hrs

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

10 hrs

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

10 **hrs**

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

10 **hrs**

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of

drug from excipients, data interpretation and applications of the following: j) Thin Layer chromatography

k) High Performance Thin Layer Chromatography
l) Ion exchange chromatography
m) Column chromatography
n) Gas chromatography
o) High Performance Liquid chromatography
p) Ultra High Performance Liquid chromatography
q) Affinity chromatography
r) Gel Chromatography

10 hrs

5 Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

10 hrs

6 Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.
Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons,

Unit

1982.

COURSE CODE **17MPL102**
TITLE OF THE COURSE **ADVANCED PHARMACOLOGY - I**

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved.

Course Objectives

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

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

1. General Pharmacology **12 hrs**

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

2 Neurotransmission **12 hrs**

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine]. d. Non adrenergic non cholinergic transmission (NANC). Cotransmission

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems Autonomic Pharmacology Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

12 hrs

3 Central nervous system Pharmacology General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.

12 hrs

4 Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and antiplatelet drugs

12 hrs

5 Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, KluwerLippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

COURSE CODE **17MPL103**

TITLE OF THE COURSE **PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I**

Scope

Unit

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Course Objectives

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

1. Laboratory Animals Common **12 hrs**

laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice.

Bioassay-Principle, scope and limitations and methods

12 hrs

2 Preclinical screening of new substances for pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

12 **hrs**

3 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: antiasthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, antidiarrheal and laxatives.

12 **hrs**

4 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents

and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

12 **hrs**

5 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. immunomodulators, Immunosuppressants and immunostimulants. General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A 3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

Unit

17MPL104
CELLULAR AND MOLECULAR PHARMACOLOGY

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Course Objectives:

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

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

1. Cell biology **12 hrs**

Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.

2 Cell signaling **12 hrs**

Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogenactivated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

12 **hrs**

3 Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

12 **hrs**

4 Pharmacogenomics Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics,

functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

5 a. Cell culture techniques **12 hrs**

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

Unit

17MPL105
PHARMACOLOGICAL PRACTICAL - I

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

- Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples. 12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines, 2.
Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash

Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

Unit

17MPL201 ADVANCED PHARMACOLOGY - II

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

Course Objectives

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

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases
-

1. Endocrine Pharmacology **12 hrs**

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation

2 Chemotherapy **12 hrs**

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

3 Chemotherapy **12 hrs**

Drugs used in Protozoal Infections
Drugs used in the treatment of Helminthiasis
Chemotherapy of cancer
Immunopharmacology
Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.
Immunosuppressants and Immunostimulants

4 GIT Pharmacology **12 hrs**

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.
Chronopharmacology
Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

5 Free radicals Pharmacology **12 hrs**

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant

Recent Advances in Treatment:

Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, KluwerLippincott Williams & Wilkins Publishers

17MPL202

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Course Objectives:

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

Explain the various types of toxicity studies.

- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

12 hrs

Unit

1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)
Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development

12 hrs

2 Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
Test item characterization- importance and methods in regulatory toxicology studies

12 hrs 3

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies

12 hrs

4 IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.
Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

12 hrs

5 Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glphandbook. pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi 3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals

(http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ ucm073246.pdf)

COURSE CODE **17MPL203**
TITLE OF THE COURSE **PRINCIPLES OF DRUG DISCOVERY**

Scope:
The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

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

Explain the various stages of drug discovery.

- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery
-

12 hrs

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

12 hrs

2 Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

3 Rational Drug Design **12 hrs**

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches
Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

12 hrs

4 Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

12 hrs

5 QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

COURSE CODE **17MPL204**
TITLE OF THE COURSE **CLINICAL RESEARCH AND PHARMACOVIGILANCE**

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Preclinical, Clinical phases of Drug development and post market surveillance.

Course Objectives:

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

- Explain the regulatory requirements for conducting clinical trial - Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

12 hrs

1. Regulatory Perspectives of Clinical Trials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines

Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

2 Clinical Trials: Types and Design **12 hrs**

Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

12 hrs

3 Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

4 Basic aspects, terminologies and establishment of pharmacovigilance **12 hrs**

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring

programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

5 Methods, ADR reporting and tools used in Pharmacovigilance **12 hrs**

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

6 Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

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 Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

COURSE CODE **17MPL205**
TITLE OF THE COURSE **PHARMACOLOGICAL PRACTICAL - II**
L: T/A:P: C **: 3 :1 : 0 : 3**

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.

7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations 9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test. 16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.) 19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

SEMESTER / YEAR : III SEMESTER
COURSE CODE : 17MPR301
TITLE OF THE COURSE : RESEARCH METHODOLOGY & BIOSTATISTICS

UNIT – 1

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – 2

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-

parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – 3

Medical Research: History, values in medical ethics, autonomy, beneficence, nonmaleficence, double effect, conflicts between autonomy and beneficence/nonmaleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – 4

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – 5

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.