# **PHARMACEUTICS**

# **Pharmaceutics - I**

#### (PRODUCT DEVELOPMENT AND FORMULATIONS)

#### 1. Preformulation Studies

Objective of preformulation and methodology, solid state properties partition coefficient, solubility, dissolution, crystal form and stability, compatibility studies, dissolution of drug substances and dosage form design.

# 2. Kinetic principles and stability testing

Order of reaction, influence of pH, temperature, acid-base catalysis, Effect of ionic strength on degradation, complex reactions, amide hydrolysis, ring alteration, oxidation-reduction, chemical and physical stability of dosage forms. Influence of packaging components on dosage form stability.

# 3. Optimization

Optimization Technique in Pharmaceutics, formulation and processing.

Optimization parameters, statistical design and application.

#### 4. Documentation

Relevance and importance of documentation, statuary requirements and procedure for documentation, critical examination of documents.

#### 5. Pharmaceutical Process Validation

Regulatory basis, Validation of sterile products; Solid dosage forms, Process Validation and non-sterile Analytical method validation.

# 6. Quality Control: Process of dosage forms Process control

Control of quality Validation, Control of manufacturing Process, Statistical quality control, Control charts, Sampling plans, Automated and process control, Doses form control, Testing programme and method, Product Identification systems, Adulteration, Misbranding, Maintenance of record, Manufacturer's reliability, Manufacturer/drug information profile.

# 7. Bioequivalence and its determination, study design for assessment of bioavailability and bioequivalence.

Correlation of in-vitro dissolution and in-vivo bioavailability,

Statistical concepts in estimation of bioavailability and bioequivalence.

#### 8. Pharmacokinetics

Consideration of one, two and multiple compartment models of intravenous administration, intravenous infusion and first order absorption of single dose regimens. Kinetics of multiple dosing dosage regimens, loading dose, maintenance doses, one and two compartment

models on intravenous administration and first order absorption of single dosing.

#### **Books Recommended**

- 1. Lachman, Leon and H.A. Lieberman. The theory and industrial pharmacy, 3<sup>rd</sup> edition. Varghese publishing Co.
- Gilbert S. Banker and C. T. Rhodes, Modern Pharmaceutics. Marcel Decker.
- 3. Barnard T.L. and Robert A. Narth, Pharmaceutical process validation volume 23, Marcel Decker.
- Norman A. Hodges and Stephen P. Denyer, hand book of Microbiology Quality Control Tayler and francies, London.
- Horth Tonneson, Photostability of Drugs and Drugs formulations,
   Taylor and Frances, London.

#### Pharmaceutics -I Practicals

To illustrate the topics included under theory.

# **Pharmaceutics – II (INDUSTRIAL PHARMACY)**

# 1. General Consideration, Preparation of Master Manufacturing

#### Procedure.

Material handling, Blending, Granulation, Drying, Slugging, Compression, Coating, Liquid Dosage forms, Contract manufacturing materials management, Sales forecasting, cost control.

# 2. Production and Planning Management -

Space allocation, Environmental factors, Manufacturing, materials management, sales forecasting, Cost control.

# 3. Drug Regulatory Methods

Definitions, Federal food, drug and cosmetic Act; Kafaurver Harre's Amendments, New Drug Application, Drug efficacy study implementations, Patents, Copy right, Trade Marks, Drug recalls, Product liability, Intellectual Property rights (IPR), Clinical trails.

# 4. Good Manufacturing Practices

GMP in manufacturing, Processing, Packing and holding of drug; control of components containers and closures, Production and process controls; packaging and labeling controls, Inspection for compliance with GMP, Potable water standards; Premises; design, construction, maintenance, equipment maintenance, warehousing, ISO 9000 series.

# 5. Polymers and their application

Nomenclature, Polymer classification, Physicochemical properties, Chemistry, Blends of polymer and properties of blends, Evaluation of polymer, Medical and surgical applications of polymer, polymerization mechanism, polymerization methods, Properties of polymers and characterization, Mechanism of drug release from polymers, Application of Polymers in controlled release of active agents and in other formulations.

## 6. Packaging Materials Science

Packaging design and specifications, packaging validation trial, material of construction, component product validation regulatory requirements, Quality control testing and standards, GMP requirement and its deficiencies; In process control during component manufacture, documentation, sterilization of packaging components; packaging and filling equipment; Pharmaceutical packaging including sterile filling area; customer complaints.

#### 7. Pilot plant Scale up Technologies

Signification of pilot plant scale up phase to affect an orderly step up from Laboratory procedures and formulations to routing production procedures. Pilot study of some important dosage forms such as tablets capsules & Liquid orals & Discussion on important parameters such as formula &

equipment, Product Uniformity and stability. Raw material and process, Physical Layout, Personal requirements & Reporting responsibilities.

## 8. Industrial Safety

Industrial Results due to Fire, Accidents, Medical & electrical Equipments, Chemicals & Pharmaceuticals. Monitoring and prevention system of Industrial effluents, testing & treatment.

## **Books Recommended**

- Lachman, leon and H.A. Lieberman, The theory and practices of industrial pharmacy, 3<sup>rd</sup> edition, Varghese publishing Co.
- Gilberts S. Banker and C.T. Rhodes, Modern Pharmaceutics Marcel Decker.
- 3. Kennerth Harburn, Quality control of packaging material in the Pharmaceutical Industry.
- Sidney H. Willing, Good Manufacturing Practice for Pharmaceuticals Marcel Decker Inc.
- Kinam Park, Shalaby. S.W. and Haesun park, Biodegradable
   Hydrogel of drug delivery, Technomic basel.
- 6. Armstrong, N.A. and James K.C., Pharmaceutical experimental design and interpretation, Tayler and Francies London.

7. Brody, A.L. and Marsh, K.S., Encyclopedia of packaging Technology, John Wiley and sons, New York.

#### **Pharmaceutics – II Practical**

To illustrate the topic included under theory.

# **Pharmaceutics – III**

# (Advance Drug Delivery systems)

# 1. Fundamentals of Controlled release Drug Delivery systems

Fundamentals and rational of sustained / controlled delivery, factors influencing the design and performance of sustained / controlled release products, Drug targeting, Use of polymers in controlled release of active agents, Pharmacokinetics / Pharmacodynamic basis of controlled drug delivery systems, Regulatory requirements. Application of Pharmacokinetics in the design & development of drug delivery systems.

# 2. Design and Fabrication of Controlled Drug Delivery systems

Novel chemical approaches for sustained drug delivery systems, Parenteral products, implantable systems, transdermal systems, ocular, intra-vaginal intra-uterine systems.

# 3. Biochemical and Molecular Biology : Approaches for Controlled Drug delivery

Microparticulate drug carriers; Liposomes, Microspheres and cells, selective endocytosis of macromolecular drug carriers, Antibodies for drug delivery, Research erythrocytes, Niosomes.

4. Advances in the monitoring of pharmacotherapeutics and in drug delivery system design.

## **Books Recommended:**

- Robenson and Lee, Controlled drug Delivery Fundamentals and Application, Volume 29, 2<sup>nd</sup> edition, Marcel Dekker Inc.
- 2. James Swabrick, Novel Drug Delivery Systems.
- Gillbert S. Banker and C.T. Rhodes, Modern Pharmaceutics 2<sup>nd</sup> edn.,
   Marcel Decker
- Robinson J.R. and Vincet H.L. Lee, Controlled Drug Delivery, Fundamental and Applications, Volume-29, 2<sup>nd</sup> edition, Marcel Dekker Inc.
- 5. Avis, K.E., Leon Lachman, and H. Lieberman, Pharmaceutical Dosage forms: Parenteral Medications, Volume –2.
- Scher H.B., Controlled Release delivery Systems of Pesticides, Marcel Dekker.
- Lieberman, H.A. and Leon Lachman, Pharmaceutical Dosage Forms
   Tablets, Volume 3, Marcel Dekker.
- Kim C., Controlled Release Dosage For design, Technomic Publishing Co., Basel.

#### **Pharmaceutics – III Practical**

To illustrate the topics included under theory.

# PHARMACOGNOSY & PHYTOCHEMISTRY – I

# (Advances in Pharmacognosy)

# 1. Genetics in Pharmacognosy

Chemical races, Selection, Hybridization, Polyploidy, Mutation, Plant growth hormones, their application and effect on plant growth and its constituents.

## 2. Chemotaxonomic Significance in medicinal plants

History of chemotaxonomic development, Chemotaxonomy of higher and lower plants and distribution of certain chemotaxonomic group of constituents in plant kingdom like alkaloids, glycosides and terpenoids.

# 3. Comparative Phytochemistry

Relationship between Phytochemistry and Taxonomy, Comparative Phytochemistry of alkaloids, flavonoids and C-glycosides.

# 4. (a) Plant Tissue culture techniques and its application in relation to Phytopharmaceuticals

Introduction, Techniques of initiation and maintenance of various types of cultures, Immobilized cell techniques, Biotransformation studies including recent development in production of biologically active constituents in Static, Suspension and hairy root cultures, Bioreactors for production of biologically active constituents and other application of plant tissue culture techniques.

## 4. (b) Plant Biotechnology

Protoplast isolation, Protoplast fusion, Somatic hybridization, methods of gene transfer in plants, Agrobacterium mediated gene transfer methods, use of marker and reporter genes, selection, application of transgenic plants.

# 5. Recent advances in field of Pharmacognosy

Recent advances in field of Pharmacognosy with especial reference to anticancer, antidiabetic, anti-inflammatory, hepatoprotective, adaptogenic and immunomodulatory drugs, skin irritants and sensitizing agents from plant and marine products of medicinal importance, plant sweeteners.

# Pharmacognosy & Phytochemistry - II

# (Phytochemistry and Biogenesis)

- **1.** General methods of Phytochemical and biological screening, Isolation and purification of plant constituents.
- Natural sources, extraction, purification, isolation and characterization of following phytochemicals: Alkaloids, Morphine, Quinine, Atropine, Glycosides, Sennosides, Glycyrrhizin, Diosgenin, Solasodine and Rutin.
- **3.** Cultivation and Utilization of following medicinal and aromatic plants of industrial importance: Mentha, Eucalyptus, Geranium, Cinchona, Dioscorea and Belladona.

- 4. Methods of investigation of biogenetic pathways.
- **5.** Biogenetic pathways & chemistry for the production of phytopharmaceuticals such as Alkylamine (Ephedra), Pyridine and Piperidine (Lobelia), Tropane (Belladonna), Quinoline (Cinchona), Isoquinoline (Opium), Diterpene (Aconite), Indole (Ergot), Cardiac glycosides, Coumarins, Flavones.
- **6.** Study of some herbal formulation as drug and cosmetics e.g Antiacne, antidandruff, antiwrinkles, antieczemic, nail & teethcare formulations.

# PHARMACOGNOSY - III

# (Cultivation and Standardization of Medicinal Plants)

- Preparation of herbarium specifications, use of flora and key identification, Quantitative microscopy as applied to drug evaluation and pollen grain analysis.
- 2. Agrotechnology of medicinal plants, Ecotyptic, Phenotypic and Genotypic variability affecting phytopharmaceuticals (Prospects and economics of medicinal and aromatic plants in India). Cultivation methods developed in India for the following plants of commercial significance: Glycyrrhiza, Ipecac, Mentha, Poppy

- Psyllium and Senna, Tropane alkaloids and steroid containing plants.
- Application of chromatographic techniques such as Column, TLC HPTLC, GLC, HPLC and DCCC in the isolation and purification of phytopharmaceuticals. Role of marker compounds.
- Application of UV, IR, NMR, HNMR, C-13NMR and Mass Spectroscopy for structural elucidation of phytopharmaceuticals.
- 5. Standardization and Quality control of Herbal drugs.

#### **Practical**

- Isolation, purification and characterization (melting point, TLC etc.)
  of following phytochemicals: Curcumin, Piperine, Glycyrrhizin,
  Caffeine, Hesperidine, Berberidine, Vasicin, Sennosides, Aloin and
  Quinine.
- Standardization and quality control of a representative of leaf and fruit plants drugs.
- 3. Soil analysis.
- 4. Separation of datura alkaloids by preparative TLC.
- 5. Isolation of cumine oil by Clavenger apparatus.
- 6. Separation of various amino acids by paper chromatography.
- 7. Experiments on Tissue Culture

- (a) Establishment of callus and suspension cultures
- (b) Study of growth characteristics
- (c) Studies on organ cultures

#### **Books recommended**

- C.K. Kokate, A.P. Purohit, Textbook of Pharmacognosy, Nirali Publishers, Pune.
- 2. M.A. Lyenger, Lab Manual of Pharmacognosy.
- 3. J.B. harborne, Phytochemical Methods, Chapmann and Halls London.
- 4. Pulok K. Mukhehrjee, Quality control of Herbal Drugs, Business Horizon, New Delhi
- S.H. Ansari, Essentials of PHARMACOGNOSY, Birla Publishers, Shahdra, Delhi.
- 6. The wealth of India Raw Materials.
- 7. S.S. Handa & M.K. Kaul, Cultivation and utilization of aromatic and medicinal plants.
- 8. Trease and Evans, Pharmacognosy.
- 9. T.E. Wallis, Textbook of Pharmacognosy, CBS Publishers Delhi.
- V.E. Tyler, L.R. Brady, Pharmacognosy, K. M. Varghese Company, Mumbai.

# **Modern Analytical Techniques**

# 1. Infrared spectroscopy and FTIR

Introduction, the Infrared absorption process, the modes of vibration and bending bond properties and absorption trends. The Hooks law and calculation of stretching frequencies for different types of bonds coupled interaction, Hydrogen bonding. Examination of infrared spectrum, survey of important functional groups with examples, Radiation sources, Detectors used, Sample handling. Quantitative Application, Advantages of FTIR.

## 2. Ultraviolet Spectroscopy

Introduction, the nature of electronics excitation, the origin of UV band structure, Principle of absorption spectroscopy, chromophore,  $\sigma \to \sigma^*$ ,  $\pi \to \sigma^*$ ,  $\pi \to \pi^*$  transition, effects of substituents, effects of conjugation, conformation and geometry, The Woodward-Fieser rules, the Fieser Kahn rules, sample handling, Applications of UV with reference to different electronic systems.

# 3. Fluorometric Analysis

Introduction; Principles of fluorescence, Fluorescence and chemical structure, Fluorescence intensity Factors affecting fluorescence

Instrumentation, Comparison of fluorometry with spectrophotometry, Application of fluorometry in pharmaceutical analysis.

# 4. Nuclear Magnetic resonance spectroscopy

### 5. Electron spin resonance spectroscopy

Introduction, Derivative Curves, g values, Hyperfine Splitting, ESR instrumentation, ESR spectra of free radicals, Applications.

## 6. Mass spectrometry

Basic principle and theory involving Instrumentation, Types of Ions, Fragmentation pattern, Molecular peak, chemical ionization, Mass spectra of representative compounds, Recognition of molecular ion peak, Chemical ionization mass spectrometry, Field desorption mass spectrometry, Fast atom bombardment mass spectrometry.

# 7. X-Rays spectroscopy

Introduction, Production and properties of X-ray Emission, X-ray absorption, Principle of X-rays diffraction, Powder diffraction, Application of X-ray diffraction technique in pharmaceutical sciences.

# 8. Raman spectroscopy

Introduction, Theory and Polarization measurement, Rule of selection and polarization, Instrumentation, Application in Pharmaceutical Sciences, Comparison of Infrared and Raman spectra.

## 9. Gravimetry

## 10. Thermal analysis

Introduction of various thermal methods of analysis, Basic Principle and theory, Pharmaceutical application of Thermogravimetric analysis (TGA), Differential Thermal analysis (DTA) and Differential Scanning Calorimetric (DSC) and Microcalorimetry, Different types of calorimeters and microcalorimetry, Advantages of microcalorimetery over DSC.

## 11. Chromatography

- (a) Principles of Separation and application of TLC, Column
   Chromatography, Paper Chromatography, Ion-exchange
   Chromatography, Counter current Chromatography,
   HPTLC and Electrophoresis.
- (b) Gas Chromatography: Gas liquid Chromatography, Gas solid Chromatography, Instrumentation and Application (GC- MC and GC-FTIR).
- (c) HPLC: Partition, Adsorption, Ion exchange, Size exclusion and Thin layer, HPTLC and its Pharmaceutical Application. (HPLC-MC), Super critical fluid Chromatography.

# 12. Optical Rotatory Dispersion and Circular Dichroism.

## **Books Recommended:**

- R. M. Silverstiein and F. X. Webster, Spectrometric Identification of Organic Compound, 6<sup>th</sup> Ed., John Wiley and Sons, New York. 1998.
- L.G. Chatten, Pharmaceutical Chemistry, Vol. I & II, Marcel Dekker, New York (Latest Edition).
- 3. James W. Dodd and Kenneth H. Tonge, Analytical Chemistry by
  Open Learning: Thermal Method, John Wiley and Sons, New York
  (Latest Edition).
- 4. R. J. Abraham, J. Fisher and P. Bftus, Introduction to NMR spectroscopy, John Wiley and Sons, New York (Latest Edition).
- Jermy K. M. Sanders and Braink Hunter, Modern NMR Spectroscopy, A guide for Chemist's Oxford University Press (Latest Edition).
- 6. M. F. C. Ladd and R. A. Palmer, Structure determation by X-Rays crystallography, Plenum Press, NY (Latest Edition).
- Jenny P. Gulsker with M. Leuis and Rossi, Crystal structure analysis for chemist and Biologist, VCH publishers INC. 220 East, 23 Street, NY (Latest Edition).

## MORDERN ANALYTICAL TECHNIQUES - PRACTICALS

- **1.** Use of colorimeter for analysis of pharmaceutical compounds and their formulations.
- **2.** Use of spectrophotometer for analysis of Pharmacopoeial compounds and their formulations.
- **3.** Use of Flourimeter for analysis of Pharmacopoeial compounds.
- **4.** Use of flame photometer for analysis of Na, K, and Ca etc, in biological fluids and formulations.
- **5.** Use of nephelometriec and turbidimetric analysis of dispersions and limit tests.
- **6.** Experiments on electrophoresis.
- 7. Experiments in chromatography
  - (a) Thin layer chromatography
  - (b) Paper chromatography
  - (i) Ascending technique
  - (ii) Descending techniques
  - (iii) Circular techniques
  - (c) Quantitative analysis using HPLC
- **8.** Interpretation of I.R spectra and functional group analysis.

# PHARMACOLOGY - I (PL-01)

## (ADVANCE PHARMACOLOGY AND TOXICOLOGY)

#### ADVANCES IN PHARMACOLOGY OF DRUGS ACTING ON:

CNS - General & local anaesthetics, Anxiolytics & hypnotics, antipsychotics, Antiepileptics, Analgesic, Anti-migraine and Anti-parkinsonism.

ANS - Sympathomimetics, sympatholytics, Parasympathomimetics, parasympatholytics, Neuromuscular junction blocker, and Ocular pharmacology.

**CVS and blood** - Antihypertensive, Cardiotonics, Anti-arrhythmics, Anti-anginal, Hypolepidimics and Antiatherosclerotics.

GIT - Anti-ulcer, Anti-diarrhoeal, emetics, anti-emetics, Purgatives.

Urinary system - Diuretics and Anti-diuretics.

**Respiratory system** -Recent advancement in therapy of Asthma and Bronchodilators.

Endocrine system - Hormone and their antagonist-Pituitary, Thyroid-

parathyroid, Pancreatic, Male and female sex hormone, Antifertility agents and diabetes.

**Inflammation and allergy** - Histamine and Bradykinin, serotonin and their antagonist, Anti-inflammatory agents.

# Infection diseases/Chemotherapeutics agent -

Recent development, mechanism of multi drug resistance, Anti-bacterial, Anti-viral, Anti-fungal, Anti-protozoal, Anthelmintics, Cancer and leprosy, Tuberculosis, Chemotherapy.

**Immune system-** Immunomodulator, immunosuppressant and immunostimulants, AIDS.

# **Toxicology**

Definition, allied branches of toxicology, scope and general principles of toxicology. Factors affecting toxicity, Evaluation of safety, Acute poisoning, Subacute chronic poisoning, General principles of management of toxicity reaction in human. Biotransformation and toxico-kinetics, target organ toxicity (Neural and Behavioral toxicity, Kidney, Pulmonary, Hepatic, Cutaneous, Ototoxicity, Haematotoxicity, Mutagenicity, Carcinogenicity, Reproductive Toxicity).

# Pharmacology – II (PL-02)

# (Molecular/Biochemical & Clinical Pharmacology)

## **MOLECULAR & BIOCHEMICAL PHARMACOLOGY**

- 1. **The Cell** Cell cycle, Cellular aging & Death, Animal cell culture.
- 2. Receptors- Ion channels, G-protein linked receptors, Second messenger systems, Enzymes ligand gated, Gene regulating receptors, Neurotransmitter receptor mechanisms (like adrenergic dopaminergic, cholinergic, serotonergic, histaminergic). Isolation & characterization of receptors, Neurohumoral transmission.
- Mediators of inflammations & allergy Autocoids, nitric oxide, vascular substances, free radicals & their scavengers, TNF, ANF, Neuropeptides, Substance-P, Cytokines.
- 4. **Gene therapy-** Gene therapy & recent advances made in gene therapy of chronic diseases, Recombinant DNA and human genetics.
- Molecular and biochemical mechanism of chemotherapeutic agents (Antibacterial, antifungal, antiviral and cancer) multi drug resistance.
- 6. **Immunopharmacology-** Cellular mediators and their interactions.
- 7. **Nitric oxide** and other free radicals in health and disease.

## **CLINICAL PHARMACOLOGY**

- 8. Clinical Pharmacokinetics- Clearance concepts including organ clearance, renal clearance and excretion, hepatic clearance and elimination, concepts related to absorption and distribution, bioavailability and bioequivalence testing of dosage forms. Patient compliance and pharmacogenetics.
- 9. **Individualization-** variability, pharmacogenetics, age, weight and size, diseases, drug interactions and therapeutic drug monitoring.
- 10. **Pediatric and geriatric** Pharmacology and drug therapeutic during pregnancy and lactation.

Clinical trails – Phase-I, II, III and post marketing surveillance, data analysis and presentation.

#### **Books recommended**

- ➤ Basic & clinical pharmacology Bertram G. katzung.
- ➤ Clinical pharmacokinetics, 3<sup>rd</sup> Edition by Malcom Rowland & Thomas.
- ➤ Biopharmaceutics & Pharmacokinetics by Leon shargel,
- > Crommelin. DJA & Sindelan R.D., Pharmaceutical Biotechnology.

- ➤ Albert, B. et.at- Molecular biology of the cell- Gardlound publication New York.
- Biopharmaceuticals: Biochemistry & Biotechnology by Gary Walsh& Jhon wiley.
- Recombinant DNA by James D Watson, Michael Gilman.
- > Goodman & Gilman s, "the pharmacological Basis of therapeutics"
- ➤ Pharmacology by Rang HP Dale MM & Ritter JM.
- ➤ Clinical pharmacology by D.R Laurence & P.N. Bennett.
- > Lewis pharmacology.
- > Cray pharmacology.
- ➤ The Oxford textbook of clinical pharmacology and drug therapy by DG Grehame smith & JK Aronson.
- ➤ Pharmacology of receptor & ion transports by Jagdish.
- Clinical pharmacy and therapeutics by Walker & Edwards.

# Pharmacology – III (PL-03)

# PHARMACOLOGICAL SCREENING METHODS & CLINICAL EVALUATION

I- Study of laboratory animals, regulations and ethics-requirements.

**Bioassays** - Basic principles of bioassays, official bioassays, experimental models & Statistical design employed in biological standardization.

## II- Preclinical screening of drugs

- a) Basic principles of screening of drugs for Pharmacological activities.
- b) Screening of new drugs belonging to following categories -

Anti-psychotic agents, antianxiety agents, antidepressant agents, Anticonvulsant, Antiparkinsonian agents, analgesics, antiepileptic, models
for status epileptics, anti-inflammatory agents, antiulcer agents,
antianginals, antiarrythmics, antiatherosclerotic drugs, antimalerials,
anthelmintics, antidiabetics, drugs for myocardial infarction,
Antihypertensives, Skeletal muscle relaxant.

III- Alternatives to Animals: Type of alternatives and their Pharmacological impact, Resources screening procedures, in-vitro models, molecular biology technique, cell-line and patch-clamp technique.

## **IV- Drug Development process:**

Principles of Pharmacological Clinical Evaluation of drugs, Clinical trails, safety evaluation of new drugs.

International guideline ((ICH) Recommendations), GLP Including GCP, ICMR Guidelines.

Intact Study - Cataleptogenic effect (Extra pyramidal side effect).

## **Books Recommended:**

- Drug discovery & Evaluation pharmacological assay, 2<sup>nd</sup> Edition by
   H. Vogel.
- Fundamental of Experimental Pharmacology by M.N. Ghosh.
- Screening methods in Pharmacology Vol-I & II, Academic Press, New York by Turner & Peter Hebboru.
- ➤ Evaluation of drug Activity, Pharmacometrics Vol I & II by Laurence & Becharah.
- Analytical procedures for therapeutic Drug monitoring & Emergency

  Toxicology by Randall C. Baselt.
- > Drug-Bioscreening & Drug Evaluation Technique in Pharmacology.
- ➤ Modern Drug Research-Paths to better and safe drugs by Y.C.

  Marting, E. Dutter & V. Austel.
- Methods of clinical drug trails by Aln, Sperit & Smith.

- Alternatives to animal experiments: Developing in-vitro methods and changing legislation.
- International aspects of drug evaluation and usage by Jouhar & Grayson.
- > Screening methods in Pharmacology by Robert A Jerner.
- Essential of animal physiology by Rastogi.
- ➤ Hand Book of practical pharmacology by Ravindra Rao T.
- ➤ Hand book of practical pharmacology by Kulkarni.
- R. Ghosh's Modern concepts on Pharmacology and Therapeutics;
   M.N. Das and S.K. Dutta.
- Experimental topics in Pharmacology: U.K. Seth, Dadkar & Kamath.
- ➤ Animal Experiments Pharmacological Analysis : Floyd R. Jormer.
- Basic and Clinical Evaluation of Drugs : Nodine & Seigler Vol. I &II.

# List of practical Experiments in Pharmacology

Pharmacological screening & Clinical evaluation:Toxicology & Molecular Biology

 Study of CPCSEA, ICMR guidelines – Common lab animals, Breading, Maintenance and handling.

- 2. Simulated experiments on behavioral action of animals. Frog heart ciliary movement, Rabbit eye etc. using software.
- 3. Pharmacological evaluation of analgesic activities by radiation analgesiometer, Eddy's hot plate, pin prick method.
- Pharmacological evaluation of analgesics by acetic acid induced writhing in mice.
- 5. Pharmacological evaluation of anti-inflammatory property of Ibuprofen against formalin induced acute paw edema using plathysmometer & against xylene induced mice ear edema.
- Pharmacological evaluation of anticonvulsant activity of Phenobarbitone on PTZ induced MES induced convulsion in mice & Strychnine induced.
- Pharmacological evaluation of antiulcer effect of ranitidine on cold swim & stress induced gastric ulcer in rats.
- 8. Pharmacological evaluation of antianxiety activity of alprazolam in rats.
- 9. Bioassay of histamine using guinea pig ileum.
- 10. Bioassay of 5 HT using rat fundus preparation.
- Determination of PA value of Anticholinergic using guinea pig ileum.

- 12. To study oestrous cycle in rats using vaginal smear.
- 13. To study loco motor activity using photoactometer.
- To Determine neurotoxic potential of drugs using rota rod apparatus.
- 15. To develop animal model for screening of antiparkinsonian drug.
- To study effect of Pentobarbitone on righting reflex (hypnosis) in mice.
- 17. To develop animal model for screening of antiparkinsonian drugs.
- 18. To study local anaesthetic activity using rat and guinea pig.
- To study antianxiety effect of Diazepam in mice using elevated plus maize apparatus
- 20. To record CRC of Oxytocin using rat uterus preparation.
- 21. To record temperature using thermal transducer.
- 22. To measure DRC, curve using isotonic transducer.
- 23. To study various transducers and couplers.
- 24. To record CRC of Oxytocin using rat uterus.
- 25. Effect of autonomic drugs on at phronic nerve diaphragm.
- To study effect of various drugs (Autonomic on rat blood pressure).

- Evaluation of mech. of action of antidiabetic activity of glibeneclamide using rats.
- Evaluation of mechanism of hepatoprotective activity of polyherbal formulation using rats.
- 29. To study anti-diarrhoreal activity of atropine using rats.
- 30. Study of in-vitro & in-vivo toxicity of drugs.
- 31. Isolation and estimation of DNA & RNA and plasmids.
- 32. Evaluation of Bioavailability and absorption of drugs.
- 33. Evaluation of half-life of drug using rabbit.

# PHARMACEUTICAL CHEMISTRY-I (ADVANCED ORGANIC CHEMISTRY)

# 1. Reaction of Carbon Nucleophiles with Carbonyl Groups

Aldol condensation: The general mechanism, Mixed Aldol Condensation with aromatic aldehydes, control of regiochemistry and stereochemistry of mixed aldol condensations of aliphatic aldehydes and ketones, Intramolecular Aldol Condensations and the Ribinsons annulations. Condensation reactions of imines and iminium Ions, The Mannich reaction, Amine catalyzed condensation reactions. Acylation of carbanions, The Witting and related reaction, Reactions of carbonyl compounds with alphatrimethylsilyl carbanions, Nucleophilic addition, Cyclization reactions.

# ${\bf 2.}\ Functional\ Group\ Interconversion\ by\ Nucleophilic\ substitution$

Conversion of alcohol to alkylating agents: Sulphonate Esters, Halides. Introduction of functional group by Nucleophilic substitution at saturated carbon: General Solvent effect, Nitriles, Azides, Alkylation of Amines and Amide, Oxygen nucleophiles, Summary of nucleophilic substitution at saturated carbons. Nucleophilic cleavage of Carbon- oxygen bonds in ethers and esters. Interconversion of carboxylic acid derivatives; Preparation of reaction reagent for Acylation, Preparation of esters, Preparation of amides.

# 3. Stereochemistry

Element of Symmetry: Plane of symmetry, centre of symmetry, alternating axis of symmetry, simple axis of symmetry, kinds of molecule displaying optical activity: compounds with a chiral carbon, compounds with other quadrivalent chiral atoms, compounds with tervalent chiral atom, suitably substituted adamantanes. Optical isomerism in compounds containing no chirality atoms: Biphenyl, allenes, compounds with exocyclic double bonds, spiranes, chirality due to a helical shape, chirality caused by restricted rotation of other types. Cis-trans isomerism: resulting from double bonds, monocyclic compounds, fused ring systems, out-in isomerism. Enantiotropic and Diastereotropic atoms and faces, Stereospecific and Stereoselective synthesis.

### 4. Reactive Intermediates

Generation of carbonium, carbanions, carbenes, Nitrenes / Nitrenium ions and free radicals; Stability, Structure and Reactivity of these intermediates.

# 5. Alkylation of Nucleophilic Carbon, Enolates and Enamines

Generation of carbanions by deprotonation, Regioselectivity and stereo selectivity in enolate formation, Other means of generating enolates,

Generation and alkylation of dianions, medium effect in alkylation of enolates, Oxygen versus carbon as the site of alkylation, Alkylation of aldehydes, esters, amides and nitriles. The nitrogen analogues of enols and enolates- enamines and imine anion, Alkylation of carbon nucleophiles by conjugate additions.

**6. Racemic modification** - Nature, formulation, properties and resolution.

## 7. Configuration - absolute and relative.

Conformations - Five, six, seven, and eight membered ring systems, conformations of six membered hetro-cyclic rings (an introductory approach). Atropimerism.

- 8. SNi, SNl, SN2, and SNAr.
- **9.** Hydrolysis of ester, El and E2 mechanism, Hofmann and Saytezeef elimination.

# 10. Reduction of Carbonyl and Other Functional Groups

Addition of hydrogen: Catalytic hydrogenation, Group III hydride donor reagents: Reduction of carbonyl compounds, reduction of other functional groups by hydride donors. GroupIV hydride-donors. Dissolving-Metal

reductions: addition of hydrogen. Reductive removal of functional groups,
Reductive carbon -carbon bond formation. Reductive deoxygenation of
carbonyl group.

# 11. Rearrangements: - General Principles

- 11.1. Carbon to carbon migration: Wager-Meerwein and related reactions, Expansion and contraction of rings, acid catalyzed rearrangement of aldehydes and ketones, Dienones-phenol rearrangement, Benzil-Benzilic acid rearrangement, Favorskii rearrangement, Arndt- Eistert synthesis, homologization of aldehydes and ketones, Neber's rearrangements.
- 11.2. Carbon to nitrogen migration; Hofmann rearrangement, Cutius rearrangement, Lossen rearrangement, Schmidt rearrangement, Beckmann rearrangement, Stieglitz and related rearrangements.
- 11.3. Carbon to Oxygen migrations, Bayer- Villiger rearrangement, Rearrangement of hydroperoxides.
- 11.4. Nitrogen to carbon migrations, Oxygen to carbon migrations; Steven's rearrangement, Witting rearrangement.

## **BOOKS RECOMMENDED.**

- Francies A. Carey and Rechard J. Sundberg, Advanced Organic Chemistry, Third Edition, Part B; Reactions and synthesis, Plenum Press, New York, London. Latest Edition.
- Eliel, I. Ernest and Samuel H, Stereochemistry of Organic compounds,
   John Wiley and Sons, New York, Latest Edition.
- 3. Roland E. Lehr and Alan P. Marchand, Orbital symmetry; A Problem solving Approach, academic Press, New York, Latest edition.
- 4. J. March, Advanced organic Chemistry, Reaction Mechanisms and Structures, john Wiley and Sons, New York, Latest Edition.

# PHARMACEUTICAL CHEMISTRY-I PRACTICALS

To illustrate the topics included under theory.

# PHARMACEUTICAL CHEMISTRY-II

# (CHEMISTRY OF NATURAL PRODUCT)

- 1. Natural products as Leads for New pharmaceutical.
- 2. The natural products obtained from terrestrial and microbial sources will be discussed in the light of various degradative and synthetic approaches supported by spectral data. Important members representing the following classes of natural products shall be discussed.

#### 2.1 ALKALOIDS

General introduction and classification, Isolation and purification. Morphine, Reserpine.

## 2.2 STEROIDS

General introduction, Stereochemistry, Nomenclature and Structure elucidation of sterols (cholesterol), Sapogenin (diosgenin) and Cardiac glycosides.

## 2.3 AMINO ACIDS AND PEPTIDES, NUCLEIC ACIDS

General introduction, Synthesis of peptides and amino acid, End group analysis, structural feature of Insulin, Vasopressin and Oxytocin, Structural feature of RNA and DNA.

## 2.4 ANTIBIOTICS

Classification of antibiotics, structural detail of Penicillins and Tetracyclines, Cephalosporin, Chloramphenicol.

## 2.5 FLAVONOIDS

Detailed chemical account of Rutin and Quercetin.

## 2.6 TERPENOIDS

A general chemical treatment and elucidation of Terpenoids.

## 2.7 COUMARINS

General methods of Isolation and purification, Structure determination of Xanthotoxin and Psoralene.

**3.** Marine products with therapeutic potential.

- **4.** Biosynthetic approach to plant secondary metabolites.
- (a) Acetate- Malonate pathway
- (b) Acetate- Mevalonate pathway
- (c) Shikmic acid Pathway

## **BOOKS RECOMMENDED.**

- 1. I. L. Finar, Organic Chemistry, VoL-II, The English Language Books Society and Longman Group Limited.
- 2. G.A. Cordell, Introduction to Alkaloids, John Wiley and Sons, New York.
- 3. M.L.Wickery and B. Wickery, Secondary Plant Metabolism, McMillan Press Ltd London.
- 4. L.F.Fieser and M. Fieser, Steroids, Reinhold Publishing Co. New York.
- 5. K.B.G. Torsell, Natural Product Chemistry, John Wiley and sons, New York.
- 6. J.B.Horborne, Phytochemical Methods, Chapman and Hall, London.

7. Burger's Medicinal Chemistry and discovery, Vol.-I, Principle and Practice, 5<sup>th</sup> Edition, John Wiley Sons, New York.

# PHARMACEUTICAL CHEMISTRY-II PRACTICALS

To illustrate the topics included under theory.

# PHARMACEUTICAL CHEMISTRY-III

## (DRUG DESIGNING AND ADVANCE MEDICINAL CHEMISTRY)

The following topics would be dealt with incorporating the latest advances.

1. Chemistry of cell membrane.

Receptors: Drug receptor interaction; G-protein coupled receptors; ion channel linked receptors, Ligand gated ion channels (LGIC), Ligand receptor theories: Clarks Occupancy theory, Rate theory, Induced fit theory, Macromolecular perturbation theory and Activation aggregation theory.

- Quantitative Structure Activity Relationship (QSAR); Introduction to molecular modeling; Analogue synthesis v/s rational design; Discovery of lead compounds / Pharmacophoric identification.
- 3. Rational Design of Enzyme Inhibitors.
- 3.1 Design of non-covalently binding enzymes inhibitors: Rapid reversible inhibitors; slow, tight and slow-tight inhibitors; transition state analogues; multisubstrates inhibitors. One representatives example each from reverse transcriptase, catechol-o-methyl transferase, ACE, glycinamide ribonucleotide transformylase, HMG CoA reductase inhibitors; Antimetabolites: dihydrofolate reductase inhibitors.
  - 3.2 Design of covalently binding enzyme inhibitors: Mechanism based

inhibitors: affinity labels; pseudoirriversible inhibitors. One representative example each from pyridoxyl phosphate dependent enzyme; GABA transferase; ornithine decarboxylase; MAO; Thymidylate synthase; Creatine kinase and  $\beta$ -Glucosidase inhibitors.

- 3.3 Prodrug concept for drug design, drug targeting and antibody directed enzyme prodrug therapy (ADEPT), soft drug design.
- 4. A basis of designing drugs and drug combinations, drug interactions and factors affecting them (an introductory approach).

#### 5. Psychopharmacological agents

- 5.1 **Antipsychotic agents:** Introduction, biochemical basis of mental disorders, Development of Antipsychotic agents: Phinothiazines, Butyrophenones, Atypical antipsychotic agent.
- 5.2 **Antidepressant drugs:** Introduction, development of tricyclic antidepressants, Monoamine oxidase inhibitors; Selective serotonin-reuptake inhibitors; Atypical antidepressant, Lithium salts.
- 5.3 **Antianxiety agents:** Introduction, Medicinal chemistry of Benzodiazepines; SAR of benzodiazepine derivatives, Medicinal chemistry

- of Non-benzodiazepines; serotonin-reuptake inhibitors, Development of meprobamate and analogues; Atypical anxiolytic agents.
- Endorphins: Discovery of enkephalins and endorphins, Dynarphin.
   Latest advances.
- Antineoplastic agents: Molecular mechanism of cancer; Oncogenes;
   Alkylating agents; Antimetabolites; Antibiotics; Natural products;
   Miscellaneous agents.
- 8. **Antiviral agents:** DNA and RNA viruses; Retroviruses, strategies to design Anti-HIV drugs, viral replication, Medicinally significant negative strand viruses; FDA approved anti-viral agents for RNA-virus infections; Development of new drug and drug discovery.
- 9. Cardiovascular agents: Digitalis and cardiac glycosides.
- 9.1 **Antiarrhythmic agents**: Basis of cardiac arrhythmias; Classes of drugs in regular use; Mechanism of action; Molecular features essential for Antiarrhythmic Activity.
- 9.2 **Antianginal agents**: Pathophysiology of Angina; Drug used as antianginal agents; Mode of action of each class of drugs; Vasodilators.

- 9.3 **Antihypertensive agents:** Etiology of hypertension; Basis of drug design; Agents affecting peripheral sympathetic nerves; Drugs acting directly on smooth Muscles; Angiotensin converting enzyme inhibitors; Mode of action of clinically used drugs; Role of diuretics in hypertension.
- 9.4 **Antihyperlipidemic agents:** Classes of lipoproteins; hyper lipoproteinaemia; Development of Antihyperlipidemic agents; Product and their mode of action.
- 10. **Antifertility agents**: Methods of fertility control; Steroidal antifertility agents; Chemical contraceptives; Abortifacients.
- 11. Drug affecting immune responses. Latest Edition.
- 12. Radioprotective drugs.
- 13. Analgesic and anti-inflammatory agents, prostaglandins, non-steroidal drugs, Steroidal drugs and Eicosanoids.
- 14. Diuretics.

#### **BOOKS RECOMMENDED**

- M. E. Wolff, Burger's Medicinal Chemistry and Drug Discovery, John Wiley and Sons, New Yark, Latest Edition.
- 2. Martindale, The Extra Pharmacopoeia, Pharmaceutical Press, London,

Latest Edition

- T. Nogrady, Medicinal Chemistry, A Biochemical approach, Oxford University Press, Oxford, Latest Edition
- 4. Monographs and relevant review articles appearing in various Periodicals and Journals.

#### PHARMACEUTICAL CHEMISTRY - PRACTICALS

# (Including tutorial/ workshops/seminars/ field work etc.)

- (a) Quantitative analysis of organic mixtures, Synthesis of organic compounds of medicinal value, Organic reactions by names of the scientists, Isolation and chemical study of natural products.
- (b) Workshops on use Stereo models; Q.S.A.R., Organic synthesis and Spectral Interpretations.

# **COMPUTER APPLICATION IN**

# PHARMACEUTICAL SCIENCES AND

# **BIOSTATISTICS THEORY**

#### **BIOSTATISTICS**

- Method of collection of data, classification of data, graphical representation of data, frequency, polygon, histogram, measure of central tendency, mean, mode and median, dispersion and standard deviation.
- 2. Confidence level, Null hypothesis, calculation of statistical significance between two means, analysis of variance.
- 3. Association of attributes contingency, classification of attributes, coefficient of association, Chi -Square tests.
- 4. Theory of probability, Sample probability, law of probability, permutation and combinations, ratios percentages and proportions and statistical difference between proportions. Analysis of variance, two ways ANOVA and multiple comparison procedures.
- Correlation and regression, least square method and its application, significance of coefficient of correlation, non-linear regression.
- 6. Calculation of ED-50, LD-50, probity analysis.

#### **COMPUTER**

# **UNIT-I: - Introduction to Computer**

What is Computer, History of computer, Development & Respective generations, Need to use computer, Types of computer hardware and software, Evolution and Generation of computer, basic computer organization, Number system, Storage devices- primary and secondary storage devices, I/P and *O/P* devices-printer, key board, scanner, punch card, mouse. Computer languages.

# **UNIT-II: - Operating System**

Concept and evolution of Operating System, Batch Processing, Spooling, multi programming, Multiprocessing, Time sharing, On line processing, real time processing, Virtual storage, OS-Controlled software, Introduction to DOS commands.

# **UNIT-III: - Computer Software**

Software, Type of Software (Application, System) Development of software, Use of MS WORD, MS EXCEL, MS POWERPOINT etc.

# **UNIT-IV: - Computer Networking & Internet**

Computer Networking, Network Topologies, LAN, WAN, MAN etc. Introduction to INTERNET, Browser, URL, Search Engine, Mailing etc., Domain names, Protocols- Like, FTP, Web site, Modem, Introduction to HTML.

# **UNIT -V: - Application of Computer in Pharmacy**

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