

Pharmaceutics- VIII (Pharmaceutical Technology -I) (BPH701)

Formulation considerations, technology involved, equipment (machine) employed problems to be encountered, packaging evaluation and CMP (India, WHO & USFDA) requirements of the following dosage forms.

Unit-1

Solid Dosage Forms: Tablets, Tablet coatings and Capsules.

Semisolid Dosage Forms: ointments, Creams, Suppositories, Gels.

Unit-2

Liquid Dosage Forms: Liquid Orals, Dry Syrups.

Pharmaceutical Aerosol: Method of Preparation & Evaluation of Aerosol.

Unit-3

Sterile Dosage Forms: Parenteral (Small Volume Parenteral & Large Volume Parenteral) and ophthalmic Preparations, Evaluation of Sterile Dosage Forms.

Unit-4

Surgical products:

Definition, surgical cotton, surgical gauzes, bandages, adhesive tapes, absorbable and non-absorbable sutures, ligatures and catguts, Medical prosthetics and organ replacement materials.

Unit-5

Blood Products and Plasma Substitutes:

Collection, processing and storage of whole human blood, concentrated human RBC, dried human plasma, human normal immunoglobulin, plasma substitutes, ideal requirements, PVP, Dextran, etc. for control of blood pressure,

Books Recommended

1. Rawlins, E.A., Text Book of Pharmaceutics, Bailliere Tindall.
2. Liberman, H.A., Lachman, L. and Ker Inc. New York.
3. Pharmacopoeia Of India, Ministry of Health and family Welfare, Govt. of India, New Delhi.
4. Avis, K.E., Lachman, L. and Liberman, H.A., Pharmaceutical Dosage Forms-Parenteral Medication Vol.1-2, Marcel Decker Inc., New York.
5. Banker G.S. and Rhode C.T., Modern Pharmaceutics, Marcell Decker Inc., New York.
6. Bean, H.S., Beckett, A.H. and Carless, A.H., Advances in Pharmaceutical Sciences, Vol.1-4, Academic Press, London.

List of Practical

1. Prepare and evaluate Paracetamol Compressed Tablets.
2. Prepare and evaluate Effervescent Tablets of Aspirin.
3. Prepare and evaluate Dispersible tablets of Diclofenac Sodium.
4. Perform the Sugar Coating on the given sample of Tablets.
5. Perform the Film Coating on the given sample of Tablets.
6. Prepare and evaluate Antacid Suspension.
7. Prepare and evaluate B-Complex Syrup.
8. Prepare and evaluate Amoxicillin Dry Syrup.
9. Prepare and evaluate Castor Oil Emulsion.
10. Prepare and evaluate Diclofenac Sodium Suppositories.
11. Prepare and evaluate Vaporizing Ointment.
12. Prepare and evaluate Antiseptic Cream.
13. Prepare and evaluate Diclofenac Gel.
14. Prepare and evaluate Ciprofloxacin Eye Drop.
15. Prepare and evaluate Water for Injection.
16. Perform the Stability Studies of given sample of Paracetamol Tablets.

Pharmaceutics -IX (Bio Pharmaceutics & Pharmacokinetics) (BPH702)

Unit-1

Introduction to bio pharmaceutics and pharmacokinetics development and their role in drug formulation.

Bio Pharmaceutics Definition, passage of drugs across biological barrier, Physiochemical, Biological and

Pharmaceutical factors influencing biopharmaceutical performance of drugs.

- **Gastrointestinal absorption of drugs:** Passage of drugs across biological membranes, nature of biological membranes, gastrointestinal absorption mechanisms.
- **Factors affecting drug absorption:** Physiological factors, dietary factors, physiochemical factors, pH partition hypothesis, dosage form factors.
- **Methods of studying gastrointestinal absorption:** In vitro and in vivo methods.
- **Drug disposition:** Distribution in blood, cellular distribution, plasma protein binding, tissue protein binding. Drug Excretion: Routes of drug excretion, renal excretion of drugs, factor affecting renal excretion, biliary and salivary excretion of drugs.
- **Drug Excretion:** Routes of drug excretion, renal excretion of drugs, factors affecting renal excretion, biliary and salivary excretion of drugs.
- **Drug biotransformation:** Pathways of drug metabolism, drug metabolizing enzymes, factors affecting drug metabolism and drug response, inhibition and stimulation of drug metabolism.

Unit-2

Pharmacokinetics

Absorption, distribution metabolism and excretion of drugs, fluid compartment and circulatory system, protein binding, significance of plasma drug concentration measurement.

Linear and Non Linear Pharmacokinetics

Reasons for non-linearity (saturation mechanism), Michaelis-menten equation, Definition and determination method of V_{max} and K_m .

Unit-3

Clinical Pharmacokinetics

Urinary excretions, computation of pharmacokinetic parameters from urine data, hepatic clearance, biliary excretion, excretion ratio, dosage regimen adjustment in patients with and without renal failure, pharmacokinetic drug interaction and their significance in combination therapy.

Unit-4

Compartment Models

Model selection criteria, alaiika information criteria, one - compartment and two compartment models, Wagner-Nelson and loo Riegelman methods for estimation of absorption constants. Curve fittings, regression procedure and area under blood level curves.

Unit-5

Bioavailability and Bioequivalence

Bioavailability and Bio-equivalence, Federal requirements, Methods of determination of bioavailability using blood level and urinary excretion data, design and evaluations, bioavailability assessment.

Books recommended

1. Gibaldi, M. and Perrier, D., Pharmacokinetics, 4th edn. Pharma mid press, Hyderabad
2. Notari, R.E., Biopharmaceutics and pharmacokinetics- An Introduction, Marcel Dekker, New York.
3. Jaiswal, Brahmankar Biopharmaceutical quality and pharmacokinetics.
4. Leepeter I.D., Pharmacokinetic analysis
5. Niazi Textbook of Biopharmacokinetics and clinical pharmacokinetics.
6. Venkaateshwaru, Biopharmaceutics and pharmacokinetics, Phared Press, Hyderabad.
7. Wagner- pharmacokinetics for the pharmaceutical studies.
8. Dhachinamoorthi D: Biopharmaceutics and pharmacokinetics: A practical manual
9. Shargel: pharmacokinetics & Biopharmacokinetics & Biopharmaceutics

List of Practical

1. Determine the percentage protein binding of the given drug.
2. Determine oral bioavailability of the given drug/formulation by urinary excretion method using animal model.
3. Perform bioequivalence study of two different brands of the marketed tablets of the given drug using animal model.
4. Determine the rate of in-vitro absorption of the given drug using everted intestinal sack.
5. Determine the effect of different pH condition on solubility of a weakly acidic or basic drug and study pH partition hypothesis.
6. Establish IVIVC for the given sample of drug.
7. Calculate elimination rate constant and elimination half-life of given excretion data by sigma minus method.
8. Calculate elimination rate constant and elimination half-life of the given drug data administered by i.v. bolus injection represented by one compartment model.
9. Calculate various pharmacokinetic parameters from the given data generated after single extra vascular administration of drug represented by one compartment model.
10. Calculate various pharmacokinetic parameters from the given data obtained by using two compartment open model.

PHARMACEUTICAL CHEMISTRY-VIII

(MEDICINAL CHEMISTRY-III)

(BPH-703)

The synthesis of the selected drugs, mode of action, classification, uses, SAR of the following category of drugs:

Unit-I

Drugs Acting on Cardiovascular System:

- Cardiac Glycosides
- Anti-arrhythmic Drugs
- Anti-anginal Drugs
- Anti-hypertensive Drugs
- Anti-hyperlipidemic Drugs

Unit-II

Drugs acting on Urinary System:

- Diuretics

Unit-III

Chemotherapeutic Agents-I

- Anti-metabolites (Including Sulpha drugs)
- Anti-tubercular
- Anthelmintics
- Anti-fungals
- β -lactam Antibiotics
- Aminoglycosides
- Protein synthesis inhibitors (Tetracyclins, Chloramphenicol, Macrolides)
- Miscellaneous Antibiotics (Bacitracin, Glycopeptides, Polymyxins)

Unit-IV

Chemotherapeutic Agents-II

- Anti-viral & Anti-HIV
- Anti-malarials
- Anti-protozoal
- Immuno-suppressive
- Anti-neoplastic

Unit-V

Drugs Affecting Uterine Motility

- Oxytocins (including prostaglandins and Ergot alkaloids).

Books Recommended:

1. Foye, W.C., Principles of Medicinal Chemistry, Lea and Febiger, Philadelphia.
2. Wolff, M.E. Ed., Burger's Medicinal Chemistry, John Wiley and Sons, New York.
3. Hansch, C., Comprehensive Medicinal Chemistry, Pergamon Press, Oxford
4. Delgado, J.N. and Remers, W.A.R, Wilson and Giswold's Text Book of Organic, Medicinal and Pharmaceutical Chemistry, J.Lippincott Co., Philadelphia.
5. Nogrady, T., Medicinal Chemistry-A Biochemical Approach, Oxford University Press, New York, Oxford.
6. Kar, A., Medicinal Chemistry, Willey Eastern Ltd., New Delhi.
7. Patrick, G., An Introduction to Medicinal Chemistry, Scientific Distributors, Mumbai.
8. Malone, Dyson and Purey, May's Chemistry of Synthetic Drugs.
9. Parimoo, P., Text Book of Medicinal Chemistry, CBS Publishers and Distributors, New Delhi.
10. Thomas, G., Introduction to medicinal Chemistry, CBS Publishers and Distributors, New Delhi.
11. Sten lake B.J. medicinal and pharm. Chemistry pharma mid press, Hyderabad.

BPH -704 : Pharmaceutical Biotechnology

UNIT-I

Historical Development:

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

Immunology and Immunological Preparations: Principles, Antigens and antibodies, Antigen-antibody reactions and their applications, Immune system. Cellular humoral immunity, Immunological tolerance, Hypersensitivity, Immunological and diagnostic preparations: Methods of their preparation, standardization and storage.

UNIT-II

Enzyme Immobilization – Techniques of Immobilization of enzymes, Kinetics and factors affecting enzymes kinetics, Enzymes based sensors, Study of enzymes such as Hyaluronidase, Penicillinase, StreptoKinase, Amylases etc. Immobilization of bacteria and plant cells, Applications of Immobilization.

UNIT-III

Genetic Recombination : Transformation, Conjugation, Transduction, Protoplast fusion, Gene cloning and their applications, Monoclonal antibodies and hybridoma technology, Recombinant DNA technology: Concepts, Methodology and Pharmaceutical applications. Study of drugs produced by biotechnology such as Activase, Humulin, Humatrope, Introne A, Monoclate, Orthoclone OKT3, Referon-A, Recombivax HB etc. Drug delivery systems in Gene therapy.

UNIT-IV

Microbiological Transformation – Introduction, Types of reactions mediated by microorganisms. Design of biotransformation processes, Selection of organism, Biotransformation processes and its improvements with special reference to steroids.

UNIT-V

Industrial Biotechnology – Historical development, Fermenter and its design, Control of different parameters in fermentation process, Isolation of mutants, Use of mutagenic agents, Factors in influencing rate of mutation. Design of fermentation process, Fermentative, production of Alcohol, Acetic acid, Penicillin, Streptomycin, Riboflavin, Vitamin B12.

B.Pharm. Semester- VII. BPH 704 Pharmaceutical Biotechnology

List of Practicals

1. Detect the presence of the amylase enzyme in saliva.
2. Isolate the DNA from cauliflower.
3. Perform VDRL test for the given sample of blood.
4. Isolate the phospholipid from egg yolk.
5. Perform WIDAL test for the given sample of blood.
6. Perform DOT ELISA test of the given sample of blood.
7. Isolate the total RNA from yeast tablet.
8. Immobilize the given enzyme by adsorption method using calcium alginate beads.
9. Perform titre value of antibody in given blood sample.

BOOKS RECOMMENDED

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldsby et.al. Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd Edition, Aditya books Ltd., New Delhi

PHARMACOLOGY –IV (Clinical & Drug Interactions)

(BPH-705)

UNIT- I

Classification and general consideration of antimicrobials drugs - Sulphonamides, quinolones B-lactam antibiotics Aminoglycosides Protein synthesis inhibitors
(Tetracyclins, chloramphenicol, Macrolides)

UNIT -II

Classification and mechanism of action of Antitubercular drugs, antileprotic drugs, antiprotozoals, anthelmintics, antifungals Antiretroviral and antiviral drugs Miscellaneous antibiotics (Bacitracin, Glycopeptides, Polymyxins)

UNIT-III

Chemotherapy of cancer and immunosuppressive agents Basic concepts of Pharmacotherapy Individualization of drug therapy : Clinical pharmacokinetic and pharmacodynamics Drug use during pregnancy, Pediatrics and Geriatrics.

UNIT-IV

Classification and mechanism of action of drug acting on skin and mucus membrane.

UNIT-V

Miscellaneous drugs antiseptics, disinfectants, ectoparasiticides, chelating agents, vaccines and sera. Treatment of opioid, barbiturate, organophosphorous, and atropine poisoning Heavy metals and heavy metal antagonists

BOOK RECOMMENDED

- 1) Herfindal, E.T., Gourley, D.R., (eds.) (2000) Textbook of therapeutics Drug and disease management. 7 th ed. Baltimore : Lippincott Williams and Wilkins
- 2) Hardmen, J.G. Limbird, L.E. Gilman A., G., (eds.) (2001) Goodman and Gilman's The pharmacological basis of therapeutics. 10th ed. USA : The McGraw Hill Companies
- 3) Barar, F.S.K., (2000) Essential of therapeutics. New Delhi: S. Chand and Company (P) Ltd.
- 4) Satoskar, R.S. Bhandarkar, S.D., Rege, N.N., (2007) Pharmacology and Pharmacotherapeutics. 12th ed. Mumbai: Popular Prakashan

- 5) Seth, S.D., (ed.) (2005) Textbook of Pharmacology. 2nd ed. New Delhi. Elsevier.
- 6) Tripathi, K.D. (1999) Essentials of Medical pharmacology. 4th ed. New Delhi : Jaypee Brothers Medical Publishers (P) Ltd.
- 7) Rang, H.P., et. (eds.) (2003) Pharmacology. 5th ed. Philadelphia Elsevier.
- 8) Katzung , B.G., (2004) Basic and clinical pharmacology. 9th ed. USA : The Mcgraw Hill Companies.
- 9) Dipro, J.T., et al. (eds.) (1997) Pharmacotherapy. A pathophysiologic approach. 3rd ed. Stanford, Connecticut: Appleton and Longe.
- 10) Craig, C.R., Stitzel, R.E. (1999) Modern pharmacology with clinical applications. 5th ed. USA.
- 11) Guideliness for poison control. (1999) WHO, Geneva: AITBS Publisher, Delhi
- 12) Curry – Drug disposition and pharmacokinetics with a consideration of pharmacokinetics with a consideration of pharmacological and elinical relationships, 3rd edn., pharmumed pre
- 13) Kenakin Terry P: A pharmacological Primer – theory applications & methods, pharma med prre