Rajiv Gandhi Proudyogiki Vishwavidalaya, Bhopal (M.P.)

B. PHARM.-VII SEMESTER

PY-701- Pharmaceutics –VIII (Pharmaceutical Technology –I)

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

1. Solid Dosage Forms- Tablets, Tablet coatings and Capsules.
2. Liquid Dosage Forms- Liquid Orals, Dry Syrups.
3. Semisolid Dosage Forms- ointments, Creams, Suppositories, Gels.
4. Sterile Dosage Forms- Parenteral (Small Volume Parenterals & Large Volume Parenterals) and ophthalmic Preparations.
5. Pharmaceutical Aerosols

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

Books Recommended

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

List of Practicals

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. Perform the Enteric Coating coating on the given sample of Tablets.
7. Prepare and evaluate Tetracycline HCL Capsules.
8. Prepare and evaluate Antacid Suspension.
9. Prepare and evaluate B-Complex Syrup.
10. Prepare and evaluate Amoxicillin Dry Syrup.
11. Prepare and evaluate Castor Oil Emulsion.
12. Prepare and evaluate Diclofenac Sodium Suppositories.
13. Prepare and evaluate Vaporizing Ointment.
14. Prepare and evaluate Non-Staining Iodine Ointment containing Methyl Salicylate.
15. Prepare and evaluate Antiseptic Cream.
16. Prepare and evaluate Diclofenac Gel.
17. Prepare and evaluate Ciprofloxacin Eye Drop.
18. Prepare and evaluate Water for Injection.
19. Prepare and evaluate Oxytetracycline Injection.
20. Perform the Sability Studies of given sample of Paracetamol Tablets.
21. Prepare and evaluate an aqueous injection of a poorly water – soluble drug using hydrotropic solubilization technique.

PY-702- Pharmaceutics –IX (BioPharmaceutics & Pharmacokinetics)

Introduction to biopharmaceutics and pharmacokinetics development and their role in drug formulation.

Biopharmaceutics

Definition , passage of drugs across biological barrier , Physiochemical , Biological and Pharmacaceutical factors influencing biopharmaceutical performance of drugs.

1. Gastrointestinal absorption of drugs: Passage of drugs across biological membranes, nature of biological membranes, gastrointestinal absorption mechanisms.
2. Factors affecting drug absorption : Physiological factors, dietary factors,physiochemical factors, pH partition hypothesis, dosage form factors.
3. Methods of studying gastrointestinal absorption: In vitro and in vivo methods.
4. Drug disposition: Distribution in blood, cellular distribution, plasma protein binding, tissue protein binding.
   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.

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

Compartment Models
Model selection criteria, alaika information criterian, 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.

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

Biovailability and Bioequivalance
Biovailability and Bio-equivalance, 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, Hydrabad
2. Notari, R.E., Biopharmaceutics and pharmacokinetics-An Introduction, marcel Decker New York.
3. Jaiswal , Brahmankar Biopharmaquality and pharmacokinetics.
4. Leepeter I.D., Pharmacokinetic analysis
5. Niazi Textbook of Biopharmacokinetics and clinical pharmacokinetics.
6. Venkaateshwaru v , Biopharmaceutics and pharmacokinetics, phared puss, Hydrabad.
7. Wagner-pharmacokinetics for the pharmastudies.
8. Dhachinamoorthi D: Biopharmaceutics and pharmacokinetics : A practical mannd
9. Shargel : pharmacokinetics & Biopharmacokinetics & Biopharmaceutics

List of Practicals

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 weekly 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.

PY-703- Pharmaceutical Chemistry –VIII (Medicinal Chemistry –III)

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

Drugs acting on Cardiovascular system :

- Cardiac Glycosides
- Antiarrythmic drugs
- Antianginal drugs
- Antihypertensive drugs
- Antihyperlipidimic drugs

Drugs acting on Urinary system :

- Diuretics

Chemotherapeutic Agents

- Anti metabolites(Including Sulpha durgs)
- Anti viral & Anti HIV,
- Anti neoplastic,
- Anti malarials,
- AntiProtozoal
- Anti tubercular,
- Anthelmintics,
- Antifungals
- B-lactum antibiotics
- Aminoglycosides
- Protein synthesis inhibitors (Tetracyclins,chloramphenicol,Macrolides)
- Miscellaneous antibiotics (Bacitracin, Glycopeptides, Polymyxins)
- Immuno- suppressive

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, Pergarnon Press, Oxford
4. Delagado, J.N. and Remers, W.A.R, Wilson and Giswold's Text Book of Organic,Medicianl 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

PY-704- Pharmaceutical Biotechnology

Historical Development :

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

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

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.

Microbiological Transformation –
Intoduction, Types of reactions mediated by micro organisms. Design of biotransformation processes, Selection of organism, Biotransformation processes and its improvements with special refrence to steroids.

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.

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.

PY-705- Pharmacology – IV (Clinical & Drug Interactions)

Chemotherapy of Microbial Diseases

General principles
Synthetic organic antimicrobials (Sulphonamides, quinolones etc.)
B-lactum antibiotics
Aminoglycosides
Protein synthesis inhibitors (Tetracyclins,chloramphenicol,Macrolides)
Antitubercular drugs, antileprotic drugs,antiprotozoals, anthelmintics, antifungals
Antiretroviral and antiviral drugs
Miscellaneous antibiotics (Bacitracin, Glycopeptides, Polymyxins)

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
Adverse drug reactions and drug induced diseases
Drug interactions
Therapeutic drug monitoring

Clinical Toxicology

Definition of poison
General principles of treatment of poisoning
Treatment of opioid, barbiturate, organophosphorous, and atropine poisoning
Heavy metals and heavy metal antagonists

BOOKS RECOMMENDED

1) Herfindal, E.T., Gourley, D.R., (eds.) (2000) Textbook of therapeutics Drug and disease management. 7th 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) Dipiro, 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