

II Semester :M.PHARM (PHARMACEUTICS)

MPH2A.1: ADVANCED PHYSICAL PHARMACEUTICS 3 Hrs/Week :THEORY

UNIT - I

Solubility: Solubility of solid in liquids, Theory of solution formation.

Solubilisation techniques using surfactants, cosolvents, complexation, inclusion compounds, drug derivatization and solid state manipulation.

UNIT - II

Solid state properties: Crystal properties and polymorphism, techniques for study of crystal properties; solid state stability, flow properties of powders.

Polymer Science: Types of polymers, properties of polymers, thermodynamics of polymer solution and polymers in solid state. Applications of polymers in pharmaceutical formulations.

UNIT - III

Diffusion: Diffusion, steady state diffusion procedures and apparatus. Diffusion principles in biological systems, thermodynamics of diffusion.

Dissolution: Theories of dissolution, dissolution models. Sink conditions in dissolution and its importance. In-vitro - in-vivo correlations.

UNIT - IV

Kinetics and Drug stability: Rate equation, kinetics of decomposition, stability testing protocol, drug degradation and methods of stabilization, methods of accelerated stability testing in dosage forms, freeze-thaw methods, centrifugal methods.

- REFERENCES:**
1. Physical Pharmacy by Martin, 4th Edition.
 2. Bentley's Text Book of Pharmaceutics by E.A. Rawlin.
 3. Pharmaceutical dosage forms: Tablets I, II, III.
 4. Theory and Practice of Industrial Pharmacy by L. Lachman.
 5. Physicochemical Principles of Pharmacy by A.T. Florence and D. Altwood.
 6. Pharmaceutical preformulation by J.T. Cartensen.

MPH2A.2 / MPH2G.2: BIO-PHARMACEUTICS & PHARMACOKINETICS 3 Hrs/Week:THEORY

UNIT - I

I. Bioequivalence and its determination, study design for the assessment of bioavailability and bioequivalence, factors influencing bioavailability and bioequivalence.

Statistical concepts in estimation of bioavailability and bioequivalence.

Software used in biopharmaceutics and pharmacokinetics study and their significance.

UNIT - II

II Basic concepts of pharmacokinetics: Compartmental models: One and two compartmental approaches to Pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine various pharmacokinetic parameters pertaining to.

i) Absorption: Mechanism and path ways of drug absorption, absorption rate constant, absorption half life, lag time and extent of absorption, AUC.

ii) Distribution: Physiological influence of drug distribution, protein binding of drug, determination of protein binding sites, clinical significance of drug protein binding. Apparent volume of distribution and its determination.

iii) Elimination: Over all apparent elimination rate constant, and half life.
under the following conditions:

a) Intravenous bolus injection ; b) Intravenous infusion ; c) Single dose oral administration

d) Multiple dosage oral administration

iv) Concept of clearance: Organ clearance, total clearance, hepatic clearance, gut wall clearance and renal clearance.

UNIT - III

III Non-linear Pharmacokinetics: Concepts of linear and non linear pharmacokinetics, Michaelis – Menton kinetics characteristics, basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological responses.

IV Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics and Chronotherapeutics.

UNIT - IV

V Non-compartmental pharmacokinetics:

i) Physiologic Pharmacokinetic Model: Concept, applications and limitations.

ii) Statistical moments theory: Concept and applications, mean residence time, mean absorption time, mean dissolution time.

REFERENCES:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Remington's Pharmaceutical Sciences by Mack publishing company, Pennsylvania.
3. Biopharmaceutics and Pharmacokinetics by Robert E. Notari.
4. Pharmaceutical Codex.
5. Applied Biopharmaceutics and Pharmacokinetics by Leon. Shargel, Andrew B.C. Yes.

**MPH2A.3 / MPH2G.3: BIOPHARMACEUTICS & PHARMACOKINETICS 6 Hrs: PRACTICAL
(A minimum of 20 experiments shall be conducted)**

1. To perform bioequivalence testing on marketed analgesic / sulphonamide tablets.
2. Comparison of dissolution of different marketed products of co-trimoxazole and other suspensions.
3. To determine K_a , biological half-life, AUC and other pharmacokinetic parameters of rifampicin / nitrofurantoin by urinary excretion method.
4. To determine protein-binding of drugs by equilibrium dialysis method (2 expts.)
5. Bioavailability studies of paracetamol or any other drug by salivary data (2 expts.)
6. To study the influence of urinary pH on salicylate excretion.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} and T_{max} from the given data (2 expts.)
8. Calculation of AUC and bioequivalence from the given data (2 expts.)

MPH2A.4 / MPH2G.4: NOVEL DRUG DELIVERY SYSTEMS 3 Hrs/Week : THEORY

UNIT - I

Fundamentals of controlled drug delivery systems, terminology, potential advantages, drug properties relevant to formulation, pharmacokinetic and pharmacodynamic basis of controlled drug delivery.

Design, fabrication, evaluation and applications of the following controlled release systems:

1. Controlled release oral drug delivery systems.
2. Modulated GI retentive drug delivery systems.

UNIT - II

3. Parenteral controlled drug delivery systems ; 4. Implantable therapeutic systems.
5. Transdermal therapeutic systems. ; 6. Ocular and intrauterine delivery systems.

UNIT - III

7. Bioadhesive drug delivery systems. ; 8. Proteins and peptide drug delivery
9. Resealed erythrocytes
10. Colloidal drug delivery systems: Liposomes, microspheres, nanoparticles and polymeric micelles

UNIT - IV

Drug targeting: Concepts and drug carrier systems.

Approaches to active drug targeting: Monoclonal antibodies, Targeting to particular organs such as brain, lungs, liver and targeting to neoplastic diseases.

REFERENCES:

1. Remington's Pharmaceutical Sciences.
2. Novel Drug Delivery Systems by Y.W. Chein, Marcel Dekker, Inc.
3. Controlled Drug Delivery Systems by Joseph R. Robinson and Vincent ILL. Lee.
4. Bentley's Text book of Pharmaceutics by Rawlins, EL. Publications.
5. Microencapsulation by Simon Benita, Pub. By Marcel Dekker Inc.
6. Drug Targeting and Delivery edited by H.E. Junginger
7. Specialized Drug Delivery Systems edited by Praveen Tyle, Pub. By Marcel Dekker Inc.
8. Colloidal Drug Delivery System by Jorg Kreuter.

MPH2A.5 / MPH2G.5 NOVEL DRUG DELIVERY SYSTEMS 6 Hrs/Week : PRACTICAL

(A minimum of 20 experiments shall be conducted)

1. Study on diffusion of drugs through various polymer members (2 expts.)
2. Preparation and study on invitro dissolution of various sustained action products and comparison with marketed products (3 expts.)
3. Preparation of matrix tablets using various polymers like PVP etc and studying their release patterns (2 expts.)
4. Preparation and evaluation of microcapsules by different microencapsulation techniques like:
 - (a) Simple coacervation techniques: Gelatin-water-ethanol.
 - (b) Coacervation by temperature changes : Ethylcellulose in cyclohexane for phenobarbitone.
 - (c) Coacervation by non-solvent-addition: cellulose acetate butyrate in methyl ethyl ketone using isopropylether as non-solvent (1 expt. in each).
5. Preparation and evaluation of wax embedded micro-spheres of diclofenac sodium and theophylline (2 expts.)
6. Preparation of various polymer films containing different drugs and studying the film characteristics and release patters (3 expts.).
7. To perform sugar coating and nonenteric and enteric film coating on tablet and their evaluation (3 expts.)

MPH2A.6: / MPH2G.6 ADVANCED PHARMACEUTICAL TECHNOLOGY 3 Hrs/Week:THEORY

UNIT - I

1. Formulation Development:

(a) Solid dosage forms:

Improved production techniques for tablets: New materials, process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development, physics of tablet compression and computerization for in process quality control of tablets.

(b) Powder dosage forms: Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.

(c) Liquid and semi-solid dosage forms:

Recent advances in formulation aspects and manufacturing of monophasic dosage forms, recent advances in formulation aspect and manufacturing of suspensions and semi-solid dosage forms.

(d) Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers & formulation aspects in aerosol formulation, manufacture & quality control.

UNIT - II

2. Aseptic processing operation and parenteral dosage form development:

Introduction, Contamination control, Microbial environmental monitoring, Microbiological testing of water, Microbiological air testing, Characterization of aseptic process, Media and incubation conditions, Theoretical evaluation of aseptic operations. Advances in materials and production techniques for parenteral dosage forms.

UNIT - III

3. Scale-up Techniques:

Effect of scale up on formulation, process parameters like mixing, granulation, drying, compression, coating, packaging, stability, selection and evaluation of suitable equipments.

4. Process Validation:

Regulatory basis, Validation of solid dosage forms, Sterile products, Liquid dosage forms, Process validation of raw materials, Validation of analytical methods, Equipment and Process.

UNIT - IV

5. Optimization techniques in pharmaceutical and processing:

Optimization parameters, statistical design and other applications, design, development and optimization of in-vitro test systems to evaluate and monitor the performance of different types dosage forms, the relevance and importance of in-vitro/in-vivo associations at every stage of product development and manufacture, the regulatory evolution and current thinking on this aspect, application of statistical techniques in product development and evaluation including quality control.