

**MPH2A.2 / MPH2G.2 / MPH2H.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.