

Subject code: 13PH0604

Subject name: Biopharmaceutics and Pharmacokinetics

**Scope:** This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen, and in solving the problems raised therein.

**Objective:** Upon completion of the course the student shall be able to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

**Teaching and assessment scheme:**

Teaching Scheme (Hours)			Credits	Theory/ Tutorial Marks			Practical Marks		Total Marks
Theory	Tutorial	Practical		CSE	IA (I)	ESE (E)	TW	Viva (V)	
3	1	0	4	10	15	75	00	00	100

**Theory syllabus:**

**Teaching hours: 45 Hours**

**Unit-1**

**10 Hours**

**Introduction biopharmaceutics to absorption:** Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of the drug from Non per oral extra-vascular routes Distribution Tissue permeability of drugs, binding of drugs, apparent, the volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.

**Unit-2**

**10 Hours**

**Elimination:** Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non-renal routes of drug excretion of drugs Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

**Unit-3**

**10 Hours**

**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartment models, Non-compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extravascular administrations. Pharmacokinetics parameters  $K_e$ ,  $t_{1/2}$ ,  $V_d$ , AUC,  $K_a$ ,  $Cl_r$ , and CLR definitions methods of eliminations, understanding of their significance and Application.

**Unit-4**

**8 Hours**

**Multicompartment models:** Two compartment open model. IV bolus Kinetics of Multiple

dosing, steady-state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.

#### Unit-5

7 Hours

**Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with an example of drugs.

**Tutorials will be based on the above syllabus.**

**Teaching hours: 15 Hours**

#### **Recommended References (Latest edition):**

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari.
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International Edition. USA.
4. Biopharmaceutics and Pharmacokinetics: A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi.
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi, and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick.
8. Clinical Pharmacokinetics, Concepts, and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence, By Abdou H. M, Mack, Publishing Company, Pennsylvania 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York, and Basel, 1987.
11. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.