

(B. Pharm.)
(Semester - VI)

L	T	P	C
3	1	-	4

Course Code	BP604T
Course Title	Biopharmaceutics and Pharmacokinetics - Theory

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 arised therein.

Objectives:

Upon completion of this course the student should be able to:

1. Understand 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 concepts of bioavailability & bioequivalence of drug products and significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the concept of ADME of drug in human body
2. Describe pharmacokinetics of drug after intravenous and oral administration
3. Explain development of BA-BE protocol for various formulation
4. Calculate pharmacokinetic parameters of drug by solving numerical
5. Determine various pharmacokinetic rate constants
6. Interpret various regulations related to BA-BE studies

Syllabus:

Teaching hours: 45 Hours

UNIT I

10 Hours

Introduction to Biopharmaceutics - Absorption: Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from non-peroral extra-vascular routes.

Introduction to Biopharmaceutics - Distribution: Tissue permeability of drugs, binding of drugs, apparent, 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 II

10 Hours

Introduction to Biopharmaceutics – 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 (IVIVC), bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT – III**10 Hours**

Introduction to Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, non-compartment models, physiological models.

One compartment open model: Intravenous injection (Bolus), Intravenous infusion and extra vascular administrations. Pharmacokinetics parameters (i.e. elimination rate constant, half-life, volume of distribution, area under the curve, total clearance, and renal clearance) definitions, methods of estimations, understanding of their significance and applications.

UNIT – IV**08 Hours**

Multi-compartment model: Two compartment open model for Intravenous Injection (Bolus).

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

UNIT – V**07 Hours**

Nonlinear Pharmacokinetics: Introduction, Factors causing Non-linearity, Michaelis-Menten method of estimating parameters, Explanation with example of drugs.

Tutorials**Teaching hours: 15 Hours**

Tutorials will be based on above syllabus

Suggested Readings[^]: (Latest edition)

1. Gibaldi M. *Biopharmaceutics and Clinical Pharmacokinetics*, Pharmamed Press.
2. Notari R.F. *Biopharmaceutics and Pharmacokinetics – An Introduction*, Marcel Dekker.
3. Shargel L., *Applied Biopharmaceutics and Pharmacokinetics*. New York: Mc-Graw Hill.
4. Brahmankar M., D., Jaiswal B., S., *Biopharmaceutics and Pharmacokinetics A Treatise*, Delhi: Vallabh Prakashan.
5. Gibaldi M., Perrier D. *Pharmacokinetics*, Taylor & Francis
6. Gibaldi M., Prescott L.F. *Hand Book of Clinical Pharmacokinetics*, ADIS Health Science Press.
7. Rowland M., Tozer T.N., *Clinical Pharmacokinetics : Concepts and Applications*, Lippincott Williams & Wilkins
8. Abdou H.M. *Dissolution, Bioavailability and Bioequivalence*, Mack Publishing Company.
9. Notari R.F. *Biopharmaceutics and Clinical Pharmacokinetics-An introduction*, Marcel Dekker.
10. Remington: *The Science and Practice of Pharmacy*, Lippincott Williams and Wilkins.
11. Madan P.L. *Biopharmaceutics and Pharmacokinetics*, Jaypee Brothers Medical Publishers.
12. Venkateswarlu, V., *Biopharmaceutics and Pharmacokinetics*, India: Nirali Prakashan.
13. Jambhekar S.S., Breen P.J. *Basic Pharmacokinetics*, Pharmaceutical Press.

L= Lecture, T= Tutorial, P= Practical, C= Credit

[^] this is not an exhaustive list
