



Shree H. N. Shukla Institute of Pharmaceutical Education & Research

(Affiliated to Gujarat Technological University, Approved by PCI)

Shree H. N. Shukla College Campus, Nr. Lalpari Lake, B/H. Marketing Yard,
Amargadh – Bhichari, Raikot. Mo. 9099063150. 9727753360

Bachelor of Pharmacy

Subject Code: BP604TT

SEMESTER: VI

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 arising therein

Objectives: 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 scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	Introduction Biopharmaceutics To Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes, 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	10
2.	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, <i>in-vitro</i> drug dissolution models, <i>in-vitro-in-vivo</i> correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.	10
3.	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) Extra vascular administrations. Pharmacokinetics parameters - KE , $t_{1/2}$, V_d , AUC , K_a , Cl_t and CLR - definitions methods of eliminations, understanding of their significance and Application	10



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4.	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	8
5.	Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.	7

Recommended Books (Latest Editions)

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. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Merckel 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.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania

LEARNING OUTCOMES:

UNIT	LEARNING OUTCOME
1	To know basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2	Knowledge and use of plasma drug concentration time data to calculate the pharmacokinetic parameters to describe pharmacokinetic properties of drug.
3	Understanding the concepts of bioavailability and bioequivalence of drug products and their significance.
4	Understanding various pharmacokinetic parameters, their significance and its applications.

BOOK LIST:

Sr.no	Book name	Price (Rs.)
1	Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.	1,641/-
2	Biopharmaceutics and Pharmacokinetics; By Robert F Notari.	7,979/-
3	Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International edition, USA.	8,064/-
4	Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi.	240/-
5	Pharmacokinetics: By Milo Gibaldi Donald, R. Merckel Dekker Inc.	2,569/-



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6	Hand Book of Clinical Pharmacokinetics, ByMilo Gibaldi and Laurie Prescott by ADIS Health Science Press.	2,226/-
7	Biopharmaceutics; By Swarbrick.	1,295/-
8	Clinical Pharmacokinetics, Concepts and Applications: ByMalcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995	6,424/-
9	Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.	5,209/-
10	Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York and Basel, 1987.	2,588/-
11	Remington's Pharmaceutical Sciences, ByMack Publishing Company, Pennsylvania.	11,167/-