



**Gyanmanjari**  
Innovative University

Course Syllabus  
Gyanmanjari Pharmacy College  
Semester-5 (B. Pharm.)

**Subject:** Biopharmaceutics and Pharmacokinetics - BPHBP15324

**Type of course:** Major

**Prerequisite:** N/A

**Rationale:** 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.

**Teaching and Examination Scheme:**

Teaching Scheme			Credits	Examination Marks					Total Marks
CI	T	P	C	Theory Marks		Practical Marks		CA	
				ESE	MSE	V	P	ALA	
3	1	-	4	75	25	-	-	50	150

*Legends: CI-Class Room Instructions; T- Tutorial; P- Practical; C- Credit; ESE - End Semester Examination; MSE- Mid Semester Examination; V- Viva; CA - Continuous Assessment; ALA- Active Learning Activities.*

**Course Content:**

Sr No.	Course content	Hrs.	% Weightage
1.	<b>Introduction</b> 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	25





2.	<b>Elimination:</b> 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	10	25
3.	<b>Pharmacokinetics:</b> 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, $t_{1/2}$ , Vd, AUC, Ka, Clt and CLR-definitions methods of eliminations, understanding of their significance and Application.	8	15
4.	<b>Multicompartment models:</b> 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.	10	20
5.	<b>Nonlinear Pharmacokinetics:</b> a. Introduction, b. Factors causing Nonlinearity. c. Michaelis-Menton method of estimating parameters, Explanation with example of drug.	7	15

**Continuous Assessment:**

Sr. No	Active Learning Activities	Marks
1.	<b>Explanation Of Absorption Pattern</b> The faculty will provide the nature of the drug, and the student needs to explain the absorption pattern and students make the report and submit on GMIU web portal.	10
2.	<b>B/E Study of Marketed Preparation</b> Students should do the bioequivalence study with marketed preparations and students make the report and submit on GMIU web portal.	10
3.	<b>Fabrication Of Compartment Model</b> Students should make the compartment model and students make the report and submit on GMIU web portal.	10
4.	<b>Therapeutic Drug Monitoring</b> Students should explain the Therapeutic drug monitoring of different drugs from the market and students make the report and submit on GMIU web portal.	10
5.	<b>Presentation</b> Students should give one Power Point presentation explaining the topic in the syllabus and students make the report and submit on GMIU web portal.	10
Total		50





**Suggested Specification table with Marks (Theory):75**

Distribution of Theory Marks (Revised Bloom's Taxonomy)						
Level	Remembrance (R)	Understanding (U)	Application (A)	Analyze (N)	Evaluate (E)	Create (C)
Weightage	30%	35 %	20%	05%	05%	05%

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

**Course Outcome:**

After learning the course, the students should be able to:	
CO1	Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
CO2	To use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, and elimination.
CO3	To understand the concepts of bioavailability and bioequivalence of drug products and their significance
CO4	Understand various pharmacokinetic parameters, their significance & applications.
CO5	Understand the Nonlinearity behavior of the drug

**Instructional Method:**

The course delivery method will depend upon the requirement of content and need of students. The teacher in addition to conventional teaching method by black board, may also use any of tools such as demonstration, role play, Quiz, brainstorming, MOOCs etc.

From the content 10% topics are suggested for flipped mode instruction.

Students will use supplementary resources such as online videos, NPTEL/SWAYAM videos, e-courses, Virtual Laboratory

The internal evaluation will be done on the basis of Active Learning Assignment

Practical/Viva examination will be conducted at the end of semester for evaluation of performance of students in laboratory.





**Reference Books:**

- [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. Merck 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
- [9]. Thomas, N. Tozen, Lea and Febrger, 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

