

INSTITUTE	FACULTY OF PHARMACY
PROGRAM	BACHELOR OF PHARMACY
SEMESTER	6
COURSE TITLE	BIOPHARMACEUTICS AND PHARMACOKINETICS
COURSE CODE	13PH0604
COURSE CREDITS	4

Objective:

- 1 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.

Course Outcomes: After completion of this course, student will 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.

Pre-requisite of course: 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 Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
3	1	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	Unit-1: 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.	
2	Unit-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, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.	
3	Unit-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) Extravascular administrations. Pharmacokinetics parameters K_E , $t_{1/2}$, V_d , AUC , K_a , Cl_t , and CL_R definitions methods of eliminations, understanding of their significance and Application.	
4	Unit-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.	
5	Unit-5: Nonlinear Pharmacokinetics a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with an example of drugs.	
Total Hours		

Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
1	Tutorials Workshop no.1, Workshop no.2, Workshop no.3, Workshop no.4, Workshop no.5, Workshop no.6, Workshop no.7, Workshop no.8, Workshop no.9, Workshop no.10, Workshop no.11, Workshop no.12, Workshop no.13, Workshop no.14, Workshop no.15	
Total Hours		

Textbook :

- 1 Biopharmaceutics , and Clinical Pharmacokinetics, by Milo Gibaldi., 1977

References:

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

Suggested Theory Distribution:

The suggested theory distribution as per Bloom’s taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery					
Remember / Knowledge	Understand	Apply	Analyze	Evaluate	Higher order Thinking / Creative
20.00	35.00	20.00	15.00	10.00	0.00

Instructional Method:

- 1 The course delivery method will depend upon the requirement of content and the need of students. The teacher in addition to the conventional teaching method by the blackboard may also use any tools such as demonstration, role play, quiz, brainstorming, MOOCs etc.
- 2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.
- 3 Students will use supplementary resources such as online videos, NPTEL videos, MOOCs/ e-courses, virtual laboratories.

Supplementary Resources:

- 1 https://www.youtube.com/watch?v=vyeW9eTI2uI&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0

Supplementary Resources:

- 2 https://www.youtube.com/watch?v=MMKPQAIUopo&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=2
- 3 https://www.youtube.com/watch?v=4gwR9fy1zag&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=3
- 4 https://www.youtube.com/watch?v=tiO7tFMsDNM&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=4
- 5 https://www.youtube.com/watch?v=ckgO4K92wVw&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=5
- 6 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=6
- 7 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=7
- 8 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=8
- 9 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=9
- 10 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=10
- 11 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=11
- 12 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=12
- 13 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=13
- 14 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=14
- 15 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=15
- 16 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=16
- 17 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=17
- 18 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=18
- 19 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=19
- 20 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=20
- 21 https://www.youtube.com/watch?v=bv57FY7xc4o&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=21
- 22 https://www.youtube.com/watch?v=XObB7J5c0vs&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=7
- 23 https://www.youtube.com/watch?v=8yiHPbgl0bA&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=8

Supplementary Resources:

- 24 https://www.youtube.com/watch?v=nlHfjIij_UQ&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=9
- 25 <https://www.youtube.com/watch?v=kkUxUBoM-hM>
- 26 <https://www.youtube.com/watch?v=gD9LiXpq0Tk>
- 27 <https://www.youtube.com/watch?v=qvucMHUVZA4>
- 28 <https://www.youtube.com/watch?v=k04PQiAFJbY>
- 29 https://www.youtube.com/watch?v=FfTHS9QsDtY&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=10
- 30 https://www.youtube.com/watch?v=SJ6OgxV0gCQ&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=11
- 31 https://www.youtube.com/watch?v=0QtUnKo9yow&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=12
- 32 https://www.youtube.com/watch?v=vmqgUPvINJk&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=13
- 33 https://www.youtube.com/watch?v=lOudcrPodgs&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=14
- 34 https://www.youtube.com/watch?v=gAqftNg2wmU&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=15
- 35 https://www.youtube.com/watch?v=S26_tGjuuMA
- 36 <https://www.youtube.com/watch?v=5FZmJa7K-eE>
- 37 <https://www.youtube.com/watch?v=ysCtZke9JLc>
- 38 <https://www.youtube.com/watch?v=ffoNsSI8MOw>
- 39 https://www.youtube.com/watch?v=Ez-GV266rIw&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=16
- 40 https://www.youtube.com/watch?v=hgUk3elvIXQ&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=17
- 41 https://www.youtube.com/watch?v=5nFAIqemZLg&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=18
- 42 https://www.youtube.com/watch?v=rvkCefrQKi0&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=19
- 43 https://www.youtube.com/watch?v=ZfM6UWEF5jg&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=20
- 44 https://www.youtube.com/watch?v=9X92hPV35Bc&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=21
- 45 https://www.youtube.com/watch?v=AyBCnBFK88Y&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=22
- 46 https://www.youtube.com/watch?v=rnVu6BjJbgE&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=23
- 47 <https://www.youtube.com/watch?v=VHevyXi0wHc>
- 48 <https://www.youtube.com/watch?v=cGdBAVDqi3w>
- 49 <http://youtube.com/watch?v=HvBF0KkvCFI>
- 50 https://www.youtube.com/watch?v=cGdBAVDqi3w&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IGeTKbR0&index=24

Supplementary Resources:

- 51 https://www.youtube.com/watch?v=HvBF0KkvCFI&list=PLGqAGyTS_oVFCIS0aHGmtW6S_IgeTKbR0&index=25