Raffles University, Neemrana, Alwar, Rajasthan- 301705	
PREREQUISITES	
Course: BIOPHARMACEUTICS AND PHARMACOKINETICS	**Number of Prescribed Hours: 45**
Academic Year: 2023-24 **Programme: B.Pharmacy**	
Name of Faculty: Mr. Mantun Prasad Gupta	**Year/Semester: 3 Year VI Sem**

RAFFLES UNIVERSITY

TEACHING PLAN: BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

SCHOOL: (SOP) School Of Pharmacy		**ACADEMIC SESSION: 2023 – 2024**		**FOR STUDENTS' BATCH:**		
1	**Course No.**	**BP604 T**				
2	**Course Name**	**Biopharmaceutics and Pharmacokinetics (Theory)**				
3	**Credits**	**4 (3 Lectures+1Tutorial)**				
4	**Learning Hours**		**Theory hours**	**45**		
			Tutorial	**8**		
			Preparation and Exam	**4**		
			Flipped	**4**		
			SL/Al	**4**		
			Total hours	**65**		
5	**Course Objective**	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.				
6	**Course Outcomes**	1. Understand the drug absorption, drug distribution and elimination. 2. Understand the bioavailability and bioequivalence. 3. Write the Michaelis-menton method 4. Write about the two compartment open model.				
7	**Outline syllabus:**					
7.01	**Paper Code**	**Unit**	**Introduction**	**Lectures hours**	**Book tile**	**Page No**
	BP604T	**Unit I**	**Biopharmaceutics** **To Absorption**; Mechanisms of drug absorption through GIT, factors influencing drug absorption though 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**	Bio pharmaceutics and Pharmacokinetics- A Treatise ,by D M Brahmankar, Sunil B. Jaiswal	1-138.

7.03	**BP 604T**	**Unit II**	**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.	**10**	Bio pharmaceutics and Pharmacokinetics- A Treatise by D M Brahmankar, Sunil B. Jaiswal	141 - 211 318 - 351
		Unit III	**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 ,t1/2,Vd,AUC,Ka, Clt and CLR- definitions methods of eliminations, understanding of their significance and application	**10**	Bio pharmaceutics and Pharmacokinetis- A Treatise by D M Brahmankar, Sunil B. Jaiswal	230 - 258
		Unit IV	**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.	**08**	Biopharmaceutics and Pharmacokinetics- A Treatise by D M Brahmankar, Sunil B. Jaiswal	259 - 272 .
		Unit V	**Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.	**07**	Biopharmaceutics and Pharmacokinetics- A Treatise by D M Brahmankar, Sunil B. Jaiswal	307 - 316 .

8	**Course Evaluation**	
8.1	**Internal Assessment: Continuous Mode**	
8.11	**Attendance**	4 Marks
8.12	**Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)**	3 Marks
8.13	**Student-Teacher Interaction**	3 Marks

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9	**Text Books & References:** **Journal References:**	1) D M. Brahmankar and Sunil B.Jaiswal, "Bio pharmaceutics and Pharmacokinetics-A Treatise", Vallabh Prakashan, Delhi, 2016. 2) Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland 3) Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995. 4) Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, 5) Publishing Company,Pennsylvania 1989. 6) Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition 7) Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and 8) Basel, 1987. 9) Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

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QUESTION BANK

1) Define Absorption. Discuss in detail the various biological factors affecting drug absorption.
2) Discuss in detail the various physico-chemical factors affecting drug absorption.
3) Discuss in detail the various physiological factors affecting drug absorption.
4) Discuss in detail the various pharmaceutical factors affecting drug absorption.
5) Explain the various mechanisms of drug absorption.
6) Define drug distribution. Describe the factors affecting distribution.
7) Write in detail about protein binding and its significance.
8) Define biotransformation. Explain with examples phase I and phase II reactions.
9) What is clearance? Give the formula for the same. Explain organ clearance and hepatic extraction ratio.
10) Explain the process of renal elimination.
11) Define bioavailability. Mention the objectives of bioavailability studies.
12) Define bioequivalence. Explain various types of equivalence.
13) Explain about the subject selection criterion in bioavailability studies.
14) Discuss the various study designs in for performing bioavailability.
15) Explain the various factors leading to non-linearity.
16) Explain Michaelis –Menten equation in determining non-linearity.
17) How do you estimate Km and Vmax.