



Faculty of Pharmacy
Master of Pharmacy (M. Pharm.)
(W. E. F.: 2023-24)
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Name of Faculty	:	Faculty of Pharmacy
Name of Program	:	Master of Pharmacy (M. Pharm)
Course Code	:	2MPH02
Course Title	:	Advanced Biopharmaceutics & Pharmacokinetics
Type of Course	:	Pharmaceutics
Year of Introduction	:	2023-24

Prerequisite	:	To have sufficient knowledge about basics of pharmaceutical dosage forms
Course Objective	:	This course will discuss the following aspects of <ol style="list-style-type: none"> 1. The basic concepts in bio pharmaceutics and pharmacokinetics. 2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination. 3. The critical evaluation of bio pharmaceutics studies involving drug product equivalency. 4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and bio pharmaceutics parameters. 5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic
Course Outcomes	:	Upon successful completion of this course, the students will be able to
	CO1	To learn (understand) about the pharmacokinetic study of drugs for their pharmacokinetic study.
	CO2	To learn about pharmacokinetic and their study in human body in reference to drug.
	CO3	To remember various concepts in regard to pharmacokinetic and pharmacodynamics study of drugs.

Teaching and Examination Scheme

Teaching Scheme (Contact Hours)			Credits	Examination Marks				
L	T	P		Theory Marks		Practical Marks		Total Marks
			C	SEE	CIA	SEE	CIA	
04	00	00	04	75	25	00	00	100

Legends: L-Lecture; T-Tutorial/Teacher Guided Theory Practice; P - Practical, C - Credit, SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Course Content

Unit No.	Topics	Teaching Hours	Weightage	Mapping With COs
1	<p>Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption.</p> <p>Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate.</p> <p>Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.</p> <p>Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.</p>	12	20%	CO1, CO2
2	<p>Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.</p>	12	20%	CO2, CO3
3	<p>Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis-Menten equation, estimation of k_{max} and v_{max}. Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug</p>	12	20%	CO2, CO3

	interactions, drug interactions linked to transporters.			
4	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12	20%	CO2
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12	20%	CO2, CO3

Suggested Distribution of Theory Marks Using Bloom's Taxonomy						
Level	Remembrance	Understanding	Application	Analyse	Evaluate	Create
Weightage	33.33	66.67	-	-	-	-

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

Suggested Learning Websites

Sr. No.	Name of Website
1	https://pci.nic.in/pdf/Syllabus_B_Pharm.pdf
2	https://www.aicte-india.org/downloads/bpharma.pdf
3	https://www.ipc.gov.in/
4	https://www.ayush.gov.in/
5	https://ayudmla.gujarat.gov.in/home.php
6	https://www.fda.gov/

7	https://www.pharmacopoeia.com/
8	https://ipapharma.org/
9	https://gpat.nta.nic.in/
10	https://drnaitiktrivedi.com/
11	https://gdc4gpat.com/course/gpat/
12	https://niscpr.res.in/
13	https://delnet.in/
14	https://ihubgujarat.in/
15	https://www.ssipgujarat.in/

Reference Books

Sr. No.	Name of Reference Books
1	Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2	Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmkar and Sunil B. Jaiswal, VallabPrakashan, Pitampura, Delhi
3	Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2 ndedition, Connecticut Appleton Century Crofts, 1985
4	Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5	Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6	Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7	Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8	Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania
9	Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10	Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11	Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New
12	Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13	Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003