Program	Master of Pharmacy (M.Pharm)	**Semester - 2**
Type of Course	-	
Prerequisite		
Course Objective	-	
Effective From A.Y.	2023-24	

Teaching Scheme (Contact Hours)				Examination Scheme				
				Theory Marks		Practical Marks		
Lecture	Tutorial	Lab	Credit	External Marks (T)	Internal Marks (T)	External Marks (P)	Internal Marks (P)	Total Marks
4	-	-	4	75	25	-	-	100

SEE *- Semester End Examination,* ***CIA*** *- Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)*

Course Content

T - Teaching Hours | **W** - Weightage

Sr.	Topics	T	W
1	**Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. 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. 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.	12	20
2	**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.	12	20
3	**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 kmax and vmax. Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, and drug interactions linked to transporters.	12	20
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
5	**Application of Pharmacokinetics:**	12	20

Course Content

T - Teaching Hours | **W** - Weightage

Sr.	Topics	T	W
	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.		
	Total	**60**	**100**

Suggested Distribution Of Theory Marks Using Bloom's Taxonomy

Level	Remembrance	Understanding	Application
Weightage	30	50	20

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.

Course Outcomes

At the end of this course, students will be able to:	
CO1	Students shall be able to understand basic concepts of biopharmaceutics and pharmacokinetics.
CO2	Students shall be able to understand various terminologies and concepts to analyse pharmacokinetic parameters.
CO3	Students shall be able to understand application of biopharmaceutics and pharmacokinetics in the field of pharmacy.

Reference Books

1.	**Biopharmaceutics and Clinical Pharmacokinetics (TextBook)** By Milo Gibaldi | Pharma Book Syndicate | 4
2.	**Biopharmaceutics and Pharmacokinetics- A Treatise (TextBook)** By D.M. BRAHMANKAR, S.B. JAISWAL | Vallabh Prakashan | 2009
3.	**Applied Biopharmaceutics and Pharmacokinetics** By Leon Shargel & Andrew B.C. Yu | McGraw Hill | 7
4.	**Textbook of Biopharmaceutics and Pharmacokinetics (TextBook)** By Dr. Shobha Rani R. Hiremath | Prism Book
5.	**Pharmacokinetics** By Milo Gibaldi and D. Perrier | Marcel Dekker Inc., New York, | 2, Pub. Year 1992
6.	**Current Concepts in Pharmaceutical Sciences: Biopharmaceutics** By James Swarbrick (Ed.). Lea & Febiger | Philadelphia, Pub. Year 1970
7.	**Clinical Pharmacokinetics, Concepts and Applications** By Malcolm Rowland and Thom N. Tozer, Lea and Febiger | Philadelphia | 3, Pub. Year 1955
8.	**Dissolution, Bioavailability and Bioequivalence** By Abdou. H.M | Mack Publishing Company, Pennsylvania, Pub. Year 1989
9.	**Biopharmaceutics and Clinical Pharmacokinetics** By Robert. E. Notari | Marcel Dekker Inc, New York and Basel | 4, Pub. Year 1987
10.	**Encyclopedia of Pharmaceutical Technology** By James Swarbrick, James. G.Boylan | Marcel Dekker Inc, New York, Pub. Year 1996