COURSE MODULE

Program Title	M. Pharmacy
Department	Pharmaceutics
Course Title	Advanced Biopharmaceutics and Pharmacokinetics

1. **NAME OF INSTITUTION** : Y. B. CHAVAN COLLEGE OF PHARMACY, AURANGABAD

2. **AFFILIATED UNIVERSITY** : DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

3. **DEPARTMENT** : Pharmaceutics

4. **PROGRAM TITLE** : M. PHARM.

4.1. Program Specific Outcome:

PSO-1: Independently carry out research and development work by utilizing modern tools like Artificial Intelligence (AI), Computer based Informatics and Simulations Models.

PSO-2: Highlight advancement in knowledge associated with novel as well as conventional drug delivery systems

PSO-3: Build professional, Statistical, computational, analytical, critical thinking and Problem-solving skills.

PSO-4: Apply Good manufacturing Practices and Regulations to Drugs and Cosmetics.

PSO-5: Explain and apply the concepts of Biopharmaceutical, Molecular and Biological aspects in formulation development and drug targeting

5.1.Course Identification and General Information

a. Course Title:	**M.Pharmacy Pharmaceutics**	
b. Course Number/Code	**MPH 202T**	
c. Credit Hours	Theory	Practical
	4	-
d. Study level/semester at which this course is offered	Semester II	
e. Pre-requisite	Biopharmaceutics and Pharmacokinetics B.Pharm VIth Sem	
f. Co-requisite	Revise the topic covered in previous lecture	
g. Program in which the course is offered	M Pharm	
h. Language of teaching the course	English	
i. Prepared by	Dr. Maria Saifee	
j. Approved by HOD		

5.2. Course Description:

The course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

5.3. Course Objectives:

Upon completion of this course it is expected that students will be able understand,

1. The basic concepts in biopharmaceutics and pharmacokinetics.

2. The use of 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 biopharmaceutic studies involving drug product equivalency.

4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

6.0. Course Outcomes (COs) : (Min. 4 and Max. 6)

(Use Bloom's Taxonomy words)

CO Code	Course outcome
CO 202.01	Define, describe and explain various mechanism of drug absorption, various factors affecting it and correlation of in vivo data with in vitro dissolution.
CO 202.02	Understand biopharmaceutics consideration in designing of drug product and in vitro product performance.
CO 202.03	Interpret plasma drug concentration measurement by application of compartment and non compartmental model and plan strategy for good patient care based on the pharmacokinetic data
CO 202.04	Describe the concept of bioavailability and bioequivalence and apply its concept in assessing bioequivalence of the drug product.
CO 202.05	Apply the knowledge of biopharmaceutics and pharmacokinetics in novel and biotechnological product development and understand the basics of drug interactions and pharmacokinetic and pharmacodynamics of drugs.

6.1. Knowledge and Understanding

(Alignment of PSOs to COs)

Course Code	Program Specific Outcome				
	PSO-1	**PSO-2**	**PSO-3**	**PSO-4**	**PSO-5**
CO 202.01	**H**	**S**	**S**	**-**	**H**
CO 202.02	**H**	**S**	**M**	**S**	**H**
CO 202.03	**H**	**S**	**M**	**-**	**H**
CO 202.04	**H**	**S**	**H**	**-**	**H**
CO 202.05	**M**	**H**	**M**	**M**	**H**

Correlation levels 1, 2 or 3 as defined below:

1: Slight (Low); 2: Moderate (Medium); 3: Substantial (High); If there is no correlation, put '-'

6.2.Teaching and Assessment Methods for achieving learning outcome:

Teaching Strategies(methods)/Tools used	Methods of Assessment
Lectures (Constructivist learning) **Collaborative learning (Discussion)** **Project based Learning** **Blended learning** **Inquiry based learning** **Flash cards** **Video** **Equipment models**	**Formative Assessment** **Case study** **Class test** **Multiple choice questions** **Assignments** **Seminar** **Viva Voce** **Synopsis** **Tutorials** **Summative Assessment**

6.3.Tools for the Teaching and learning

Theory subjects	Practical Subjects
• **PowerPoints presentation** • **Videos** • **Flash Card** • **Models** • **Software** • **Charts** • **Smart Boards** • **White boards** • **Online Platform**	• **White boards** • **Glassware** • **Chemicals** • **Instruments** • **Equipment** • **Software** • **Models** • **Plants/Crude Drugs** • **Animal**

6.4. COURSE CONTENT

6.1. Theoretical Aspect:

Order	Topic list/units	Subtopics list	Number of Weeks	Contact Hours
1	**Unit I**	Drug Absorption from the Gastrointestinal Tract:	**3 Weeks**	**12**

		Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation 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.		
2	**Unit II**	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.	**3 Weeks**	**12**
3	**Unit III**	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion,	**3 Weeks**	**12**

		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,drug interactions linked to transporters.		
4	**Unit IV**	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.	**3 Weeks**	**12**
5	**Unit V**	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.	**3 Weeks**	**12**

	TOTAL		**15 Weeks**	**60**

7.0. ASSESSMENT MECHANISM:

Sr. No.	Assessment Mechanism	Week due	Marks	Proportion of Final Assessment
1	Continuous Assessment (Theory)	2nd week of every month	10	4%
2	Sessional (Internal Theory exam)	As per schedule of examination	15	6%
3	Continuous Practical Assessment (Sessional Practical exam)	Weekly during practical	20	8%
4	Sessional (Internal Practical exam)	As per schedule of examination	30	12%
5	Final exam (theory)	As per University at end of course	75	30%
6	Final exam(practical)		100	40%
Total			150	**100%**

8.0.STUDENT SUPPORT:

Office hours/week	Other procedures
Two hours minimum	

9.0.TEACHER'S AVAILABILITY FOR STUDENT SUPPORT:

Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time	**4.00-5.00**	**4.00-5.00**	**4.00-5.00**	**4.00-5.00**	**4.00-5.00**	**4.00-5.00**

10.0. LEARNING RESOURCES:

Sr. No.	Title of Learning Material	Details
1	Text books	Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi
2	Reference material	Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985

		Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, MarcelDekker Inc.,New York, 1982 Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003
3	E-materials and websites	
4	Other learning material	Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970 Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995 Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989 Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

11.0. FACILITIES REQUIRED:

Sr. No.	Particular of Facility Required
1	Lecture Rooms (capacity for 60 students)
2	Laboratory (capacity for 20 students)
3	Computing resources: PC with latest version and hardware/software and utilization of open source and licensed application software
4	Other resources: Appropriate laboratory tools, Chemicals, Glass ware, Apparatus, Instrumentation

12.0. COURSE IMPROVEMENT PROCESSES:

12.1. Strategies for obtaining student feedback on effectiveness of teaching:

Course delivery evaluation by students using: Questionnaire forms and online questionnaires

12.2. Other strategies for evaluation of teaching by the instructor or by the department:

Periodic review by Academic Planning & Monitoring Committee and departmental review committee, Observations and assistance of colleagues, External assessments by advisors/ examiners and auditors.

12.3. Process for improvement of teaching:

Use of ICT tools, teaching aids, Simultaneous practical orientation and theory classes (SPOT), Adoption of reflective teaching.

12.4. Describe the planning procedures for periodically reviewing of course effectiveness and planning for improvement:

Periodic review by departmental meeting , Review of course delivery and outcome through assessment and feedback from all stake holders.

12.5. Course development plans:

Provide inputs for course improvement and update to University Course development Committees (Board of Studies)

13.0. INFORMATION ABOUT FACULTY MEMBER RESPONSIBLE FOR THE COURSE:

Name	Dr.Maria Saifee
Location	Academic Incharge Cabin
Contact Detail (e-mail &cell no.)	9970070232 , saifeemaria@gmail.com
Office Hours	10:00 AM to 5:00 PM