Dr. Rafiq Zakaria Campus
Maulana Azad Educational Trust's
Y. B. CHAVAN COLLEGE OF PHARMACY
(B. Pharm, M. Pharm & Research Centre)
ISO 21001:2018 & ISO 14001:2015 CERTIFIED | NIRF-2022 ALL INDIA RANK 65TH
NAAC ACCREDITATION "A" GRADE WITH 3.23 CGPA SCORE

# COURSE MODULE

| | |
|---|---|
| **Program Title** | B. Pharmacy |
| **Department** | Pharmaceutics |
| **Course Title** | 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** : B. PHARM.

**4.1. Program Outcomes (PO):**

**PO 01: Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.

**PO 02: Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

**PO 03: Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.

**PO 04: Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.

**PO 05: Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and wellbeing.

**PO 06: Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).

**PO 07: Pharmaceutical Ethics:** Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

**PO 08: Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

**PO 09: The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.

**PO 10: Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

**PO 11: Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

## 5. COURSE SPECIFICATION :

### 5.1.Course Identification and General Information

| | | |
|---|---|---|
| a. Course Title: | | |
| b. Course Number/Code | | |
| c. Credit Hours | Theory | Practical |
| | 45(3 Hrs/Week) | 60 (4Hrs. / Week) |
| d. Study level/semester at which this course is offered | B.Pharm Sem VI | |
| e. Pre-requisite | HAP I and II, PP I and Pharmacology | |
| f. Co-requisite | Revision of previous lecture taught | |
| g. Program in which the course is offered | B Pharm | |
| h. Language of teaching the course | English | |
| i. Prepared by | Dr. Maria Saifee | |
| j. Approved by HOD | Dr. S. R. Lahoti | |

### 5.2.Course Description:

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 arised therein.

### 5.3. Course Objectives:

Upon completion of the course 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

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

**(Use Bloom's Taxonomy words)**

| CO Code | Course outcome |
|---|---|
| CO 604.01 | Define and describe the basic principles of biopharmaceutics and pharmacokinetics |
| CO 604.02 | Define, describe and explain various mechanism of drug absorption, distribution, biotransformation, excretion and various factors affecting it. |
| CO 604.03 | 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 604.04 | Assess the Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting. |
| CO 604.05 | Describe the concept of bioavailability and bioequivalence and apply its concept in assessing bioequivalence of the drug product. |

**6.1. Knowledge and Understanding**

**(Alignment of POs to COs)**

| CO Code | Program Outcome (PO) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | PO7 | PO8 | PO9 | PO10 | PO11 |
| CO 604.01 | H | - | M | S | - | - | - | - | M | S | M |
| CO 604.02 | H | - | M | M | - | - | - | - | M | S | M |
| CO 604.03 | H | - | M | M | - | M | - | - | M | S | M |
| CO 604.04 | H | - | M | M | - | S | - | - | M | S | M |
| CO 604.05 | H | S | M | H | - | - | - | - | M | S | M |

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)**<br>**Collaborative learning (Discussion)**<br>**Project based Learning**<br>**Blended learning**<br>**Inquiry based learning**<br>**Flash cards**<br>**Video**<br>**Equipment models** | **Formative Assessment**<br>**Case study**<br>**Class test**<br>**Multiple choice questions**<br>**Assignments**<br>**Seminar**<br>**Viva Voce**<br>**Synopsis**<br>**Tutorials**<br>**Summative Assessment** |

**6.3.Tools for the Teaching and learning**

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

## 6.4. COURSE CONTENT

### 6.1. Theoretical Aspect:

| Order | Topic list/units | Subtopics list | Number of Weeks | Contact Hours |
|---|---|---|---|---|
| **1** | **Unit I** | **Introduction to Biopharmaceutics**<br>**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 | 3 and Half week | 10 |
| **2** | **Unit II** | **Elimination:**<br>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<br>**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 and Half week | 10 |
| **3** | **Unit III** | **Pharmacokinetics:**<br>Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open | 3 and Half week | 10 |

| | | | | |
|---|---|---|---|---|
| | | model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extravascular administrations. Pharmacokinetics parameters - KE ,t1/2,Vd,AUC,Ka, Clt and CLR- definitions methods of eliminations, understanding of their significance and application | | |
| **4** | **Unit IV** | **Multicompartment models:**<br>Two compartment open model. IV bolus<br>Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settings. | 2 and half week | 8 |
| **5** | **Unit V** | **Nonlinear Pharmacokinetics:**<br>a. Introduction, b. Factors causing Non-linearity.<br>c. Michaelis-menton method of estimating parameters, Explanation with example of drugs. | 2 and half week | 7 |
| | **TOTAL** | | | 45 |

## 7.0. ASSESSMENT MECHANISM :

| Sr. No. | Assessment Mechanism | Week due | Marks | Proportion of Final Assessment |
|---|---|---|---|---|
| 1 | Assignments, Exercises & Home works | 2nd week of every month | 10 | 6% |
| 2 | Sessional (Internal Theory exam) | As per scheduled examination | 15 | 10% |
| 3 | Continuous Practical Assessment (Sessional Practical exam) | Weekly during practicals | 15 | 10% |
| 4 | Final exam (theory) | As per University at end of course | 75 | 50% |
| 5 | Final exam( practical) | | 35 | 24% |
| Total | | | 150 | **100%** |

## 8.0.STUDENT SUPPORT:

| Office hours/week | Other procedures |
|---|---|
| **Two hours minimum** | **Google classroom, whatsapp** |

## 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 | 1. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernational edition.USA<br>2 Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi |
| 2 | Essential references (as per syllabus) | 3. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.<br>4. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.<br>5. Biopharmaceutics; By Swarbrick<br>6. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995. |
| 3 | Reference material | |
| 4 | E-materials and websites | |
| 5 | Other learning material | |

## 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:

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

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|---|---|
| **Name** | Dr. Moizul Hasan |
| **Location** | Pharmaceutics Lab Cabin (Near Store room) |
| **Contact Detail (e-mail & Cell No.)** | 9623465178, moizulhasan@gmail.com |
| **Office Hours** | 10:00 AM to 5:00 PM |