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| **INSTITUTE** | **FACULTY OF PHARMACY** |
| **PROGRAM** | **MASTER OF PHARMACY (PHARMACEUTICS)** |
| **SEMESTER** | **2** |
| **COURSE TITLE** | **ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS** |
| **COURSE CODE** | **13MC0202** |
| **COURSE CREDITS** | **4** |

**Objective:**

1 This course is designed to impart knowledge and skills necessary for dose calculations, and dose adjustments and to apply biopharmaceutics theories in practical problem-solving.

2 Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

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**Course Outcomes:** After completion of this course, student will be able to:

1 The use of raw data and deriving the pharmacokinetic models and parameters best describe the process of drug absorption, distribution, metabolism, and elimination.

2 The basic concepts in biopharmaceutics and pharmacokinetics

3 The critical evaluation of biopharmaceutic studies involving drug product equivalency & the design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters

4 The potential clinical pharmacokinetic problems and application of basics of pharmacokinetics.

**Pre-requisite of course:**Nil

**Teaching and Examination Scheme**

| Theory Hours | Tutorial Hours | Practical Hours | ESE | IA | CSE | Viva | Term Work |
|---|---|---|---|---|---|---|---|
| 4 | 0 | 0 | 75 | 15 | 10 | 0 | 0 |

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DR. LALJI HAKUBHAI BALDANIYA
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| Contents : Unit | Topics | Contact Hours |
|---|---|---|
| 1 | **Unit-1**<br>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 |
| 2 | **Unit-2**<br>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 |
| 3 | **Unit-3**<br>Pharmacokinetics: Basic considerations, pharmacokinetic models, , Compartment modeling: one-compartment model- IV bolus, IV infusions, 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. | 12 |
| 4 | **Unit-4**<br>Bioequivalence: drug product performance, the 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. The biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ, and In-vivo methods. Generic biologics (biosimilar drug products), the clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, and generic substitution. | 12 |

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| Contents : Unit | Topics | Contact Hours |
|---|---|---|
| 5 | **Unit-5**<br>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 |
| **Total Hours** | | **60** |

**Textbook :**


1 Biopharmaceutics and Clinical Pharmacokinetics , Milo Gibaldi, Lea and Febiger, 1991

2 Applied Biopharmaceutics and Pharmacokinetics , Shargel. Land YuABC, Connecticut Appleton Century Crofts, 1985

3 Pharmacokinetics, Milo Gibaldi and D. Perrier, Marcel Dekker Inc, 1982

4 Clinical Pharmacokinetics, Concepts, and Applications , Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, 1995

5 Dissolution, Bioavailability, and Bioequivalence, Abdou. H.M,, Mack PublishingCompany, Pennsylvania , 1989

6 Biopharmaceutics and Relevant Pharmacokinetics , John. G Wagner and M.Pemarowski, Drug Intelligence Publications, 1971

7 Encyclopedia of Pharmaceutical Technology, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, , 1996

8 Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009

9 Absorption and Drug Development- Solubility, Permeability, and Charge State,, Alex Avdeef, John Wiley & Sons, Inc,, 2003


**Suggested Theory Distribution:**

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

| Distribution of Theory for course delivery | | | | | |
|---|---|---|---|---|---|
| **Remember / Knowledge** | **Understand** | **Apply** | **Analyze** | **Evaluate** | **Higher order Thinking / Creative** |
| 20.00 | 25.00 | 25.00 | 15.00 | 15.00 | 10.00 |

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**Instructional Method:**

1 The course delivery method will depend upon the requirement of content and the need of students. The teacher in addition to the conventional teaching method by the blackboard may also use any tools such as demonstration, role play, quiz, brainstorming, MOOCs etc.

2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.

3 Students will use supplementary resources such as online videos, NPTEL videos, MOOCs/ e-courses, virtual laboratories.