**GUJARAT TECHNOLOGICAL UNIVERSITY**
PHARM.D
4th Year

**Subject Name: Biopharmaceutics & Pharmacokinetics**
**Subject Code: 848805**

**Scope:** The course will provide students with necessary information related to different factors affecting the performance of various drug dosage forms *in vitro* and *in vivo*, deliver specialized knowledge that is essential to understand the concept of bioavailability and bioequivalence and explore the kinetics of the drug in human body in relation to the in vivo performance and determination of drug dose and regimen for therapy individualization

**Objectives: At the successful completion of the course the student will be able to:**

1) define the basic concepts in biopharmaceutics and pharmacokinetics
2) **s**elect the correct pharmacokinetic model based on plasma level or urinary excretion data that best describes the process of drug absorption, distribution, metabolism and elimination (ADME)
3) determine the effect of Pharmacokinetic (ADME) parameters on the biological effects of the drug
4) **c**arry out biopharmaceutical studies and use data so obtained in the development of new drugs or dosage forms
5) **c**alculate various pharmacokinetic parameters from plasma and urinary excretion data applying compartment modeling and model independent methods
6) design dosage regimens for patients based on calculated pharmacokinetic parameters
7) **d**esign Bioavailability and Bioequivalence studies of new drugs or dosage forms
8) **e**valuate drug-protein binding as a tool to predict pharmacokinetics of drugs

**Teaching scheme and examination scheme:**

| Teaching Scheme | | | | Evaluation Scheme | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|
| Theory | Tutorial | Practical | Total | Theory | | Practical | | |
| | | | | External | Internal | External | Internal | |
| 3 | 1 | 3 | 7 | 70 | 30 | 70 | 30 | 200 |

**Detailed syllabus:**

| Sr. | Topic | Hr | % Weightage |
|---|---|---|---|
| | **Biopharmaceutics** | | |
| **1.** | Introduction to Biopharmaceutics a. Absorption of drugs from gastrointestinal tract. b. Drug Distribution. c. Drug Elimination. | **7** | **8** |
| | **Pharmacokinetics** | | |
| **2.** | Introduction to Pharmacokinetics. a. Mathematical model b. Drug levels in blood. c. Pharmacokinetic model d. Compartment models e. Pharmacokinetic study. | **8** | **10** |
| **3.** | One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion. | **5** | **6** |
| **4.** | Multicompartment models. a. Two compartment open model. b. IV bolus, IV infusion and oral administration | **10** | **12** |
| **5.** | Multiple – Dosage Regimens. a. Repititive Intravenous injections – One Compartment Open Model b. Repititive Extravascular dosing – One Compartment Open model c. Multiple Dose Regimen – Two Compartment Open Model | **15** | **16** |
| **6.** | Nonlinear Pharmacokinetics. a. Introduction b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters | **15** | **16** |
| **7.** | Noncompartmental Pharmacokinetics. a. Statistical Moment Theory. b. MRT for various compartment models. c. Physiological Pharmacokinetic model. | **15** | **16** |

| | | | |
|---|---|---|---|
| **8.** | Bioavailability and Bioequivalence. a. Introduction. b. Bioavailability study protocol. c. Methods of Assessment of Bioavailability | **15** | **16** |

**Practical : 3 Hrs./Week**

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of Ka, Ke, t1/2, Cmax, AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

**Reference Books:**


1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi latest edition
2. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
3. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc. latest edition
4. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press. latest edition
5. Biopharmaceutics and Pharmacokinetics; By Robert F Notari latest edition
6. Biopharmaceutics; By Swarbrick g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi latest edition
7. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, latest edition
8. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania latest edition
9. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, latest edition
10. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York latest edition


**Scheme of Practical Examination:**

| | **Sessionals** | **Annual** |
|---|---|---|
| Synopsis | 05 | 15 |
| Major Experiment | 10 | 25 |
| Minor Experiment | 03 | 15 |
| Viva | 02 | 15 |
| **Max Marks** | **20** | **70** |
| **Duration** | **03hrs** | **04hrs** |

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).