



Shree H. N. Shukla Institute of Pharmaceutical Education & Research

(Affiliated to Gujarat Technological University, Approved by PCI)

Shree H. N. Shukla College Campus, Nr. Lalpari Lake, B/H. Marketing Yard,
Amargadh – Bhichari, Raikot. Mo. 9099063150, 9727753360

M.Pharm Pharmaceutics (20) SEMESTER: II

Subject Name: Advanced Biopharmaceutics & Pharmacokinetics
Subject Code: MPH202T

Scope: This 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.

Objectives: Upon completion of the course student shall be able to understand

1. The basic concepts in biopharmaceutics and pharmacokinetics.
2. The use 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

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
4	0	0	4	80	20	0	0

Sr.	Topic	Hr
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
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
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:	12



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	cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max} . 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.	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
5.	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

REFERENCES:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A Treatise, D .M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick, J., Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987
10. Biopharmaceutics and Relevant Pharmacokinetics by John.G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James.G. Boylan, Marcel Dekker Inc, New York, 1996
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003

LEARNING OUTCOMES:

UNIT	LEARNING OUTCOME
1	Knowledge regarding the Absorption at the gastrointestinal site.



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2	Understand the Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance.
3	Understand the parameters of pharmacokinetics.
4	Appreciate the Drug Product Performance, In Vivo.
5	Knowledge regarding the Application of Pharmacokinetics.

BOOK LIST:

Sr. no	Book name	Price (Rs.)
1	Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Leaand Febiger,1991.	468/-
2	Biopharmaceutics and Pharmacokinetics, A. Treatise, D M. Brahmkar and Sunil B. Jaiswal.,Vallab Prakashan, Pitampura, Delhi.	275/-
3	Applied Biopharmaceutics and Pharmacokinetics by ShargelLandYuABC,2ndedition,ConnecticutAppletonCenturyCrofts,1985.	1,850/-
4	Textbook of Biopharmaceutics andPharmacokinetics, Dr. Shobha Rani R. Hiremath,PrismBook.	226/-
5	Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel DekkerInc.,New York,1982.	468/-
6	Current Concepts in Pharmaceutical Sciences: Biopharmaceutics,Swarbrick.J,LeaandFebiger,Philadelphia,1970.	11,489/-
7	Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom N. Tozer, Lea and Febiger, Philadelphia.	1,995/-
8	Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised andexpande byRobert. E. Notari, Marcel Dekker Inc,New YorkandBasel,1987.	550/-
9	BiopharmaceuticsandRelevantPharmacokineticsbyJohn.G Wagnerand M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.	2,792/-
10	Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James.G.Boylan,MarcelDekkerInc,New York,1996.	6,094/-
11	Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceuticalpress,RPS Publishing,2009.	1,002/-
12	Absorption and Drug Development- Solubility, Permeability, and Charge State,AlexAvdeef,JohnWiley&Sons,Inc,2003.	4698/-