



**DR. B. C. ROY COLLEGE OF PHARMACY & AHS, DURGAPUR
(NBA Accredited for UG Pharmacy Program)**

VIDEO & SUPPLEMENTARY MATERIAL POSTING

Faculty: [Prof. Dr. Subhabrata Ray](#)

PROGRAM: M. PHARM (Pharmaceutics) - 1st Yr II Sem

Course Code: *MPT-2062*

Course Name: *ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS*

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

- The basic concepts in biopharmaceutics and pharmacokinetics.
- Use of raw data and derive pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, metabolism and elimination.
- 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.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetics

Syllabus portion to be covered by me

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: cause of non-linearity, Michaelis –



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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. (12 Hrs)

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 Hrs)

Suggested Books for the Course (with links):

Sl. No.	Book Name, Ed., Vol	Authors	Weblink(s)
1.	Basic Pharmacokinetics [The Virtual University Press]	Michael C. Makoid, Phillip J. Vuchetich, Umesh V. Banakar	Link [3 MB]
2.	Applied Biopharmaceutics & Pharmacokinetics, 7th Ed	Leon Shargel; Andrew B. C. Yu Eds.	Link [15 MB]
3.	Basic Pharmacokinetics, 2nd Ed.	Sunil S. Jambhekar, Phiip J. Breen	Link [14 MB]
4.	Pharmacokinetics, 2nd Ed	Milo Gibaldi, Donald Perrier	Link [14 MB]
5.	Pharmacokinetics in Drug Discovery and Development	Ronald D. Schoenwald	Link [7 MB]
6.	Foundations of Pharmacokinetics	Aldo Resigno	Link [5 MB]
7.	Modeling in Biopharmaceutics, Pharmacokinetics and Pharmacodynamics: Homogeneous and	Panos Macheras, Athanasios Iliadis	Link [9 MB]



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	Heterogeneous Approaches		
8.	Pharmacokinetics: Regulatory - Industrial - Academic Perspectives	Peter Welling	Link [3 MB]
9.	Computational Pharmacokinetics	Anders Kallen	Link [2 MB]
10.	Essential Pharmacokinetics: A Primer for Pharmaceutical Scientists	Thorsteinn Loftsson	Link [14 MB]
11.	Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications, 4th Ed	Malcolm Rowland, Thoma N Tozer	Link [34 MB]
12.	Drug Disposition and Pharmacokinetics From Principles to Applications	Stephen Curry, Robin H. Whelpton,	Link [6 MB]
13.	Essentials of Pharmacokinetics and Pharmacodynamics	Thomas N. Tozer, Malcolm Rowland	Link [23 MB]
14.	Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists	Younggil Kwon	Link [4 MB]
15.	Basic Pharmacokinetics and Pharmacodynamics: An Integrated Textbook and Computer Simulations, 2nd Ed	Sara E. Rosenbaum	Link [21 MB]

Book #1,2,3: Most closely follows the syllabus



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Book #4: The grand old reference for mathematical concepts in PK

Book #5: Advanced and contemporary treatment of the subject

Book #6: Philosophical readings for the genesis of PK

Book #7,9,14: Advanced mathematical treatment of PK

Book #8: PK from an Industrial and Regulatory Perspective

Book #10 - 13,15: Supplementary Readers for further grasp of the subject (A good strategy would be to read them after going through Book #1-3)

Supplementary Materials for Reference and Self Study:

Date	Module (as per Lesson Plan)	Topic	Live Recording Link	Powerpoint Presentation Link	Supplementary Notes / Resources	Remarks, if any
16-04-2021	3	PK - Basic Considerations	YouTube	Class Snapshots	1. For the basic parts of the syllabus follow the excellent online course by Prof. David Bourne (University of Colorado): www.boomer.org 2. Excellent list of PK books https://www.pharmpk.com/book.html 3. Follow primarily the green highlighted books preliminary chapters	
23-04-2021	3	PK Models	YouTube	Class Snapshots	Additional Notes	
30-04-2021	3	PK Models	YouTube	Class Snapshots	-do-	Also see Book # 1 for Compartment Model basics
07-05-2021	3	One	YouTube	Unfortunat		



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		Compartment Open Model		ely, Whiteboard Snapshots were lost due to abrupt connection losses		
21-05-2021	3	Discussion on CA2 questions	YouTube	Snapshots		
28-05-2021	3	One Compartment Model, Laplace Transforms	YouTube	Snapshots	For LT, see Book #1	
29-05-2021	3	Laplace Transforms	YouTube Session 1 YouTube Session 2 YouTube Session 3 YouTube Session 4	Snapshots Session 1 Snapshots Session 2 Snapshots Session 3 Snapshots Session 4		
31-05-2021	3	One Compartment Model - IV Infusion & Extravascular route	YouTube Session 1 YouTube Session 2 YouTube Session 3 YouTube Session 4	Snapshots Session 1 Snapshots Session 2 Snapshots Session 3 Snapshots Session 4	<ol style="list-style-type: none"> 1. Visit www.boomer.org for numerical examples 2. Visit MAKAUT website for previous years QPs (practice on problems) 	
04-06-2021	3	Two Compartment Model - IV Bolus	YouTube	Snapshots		
18-06-2021	3	Two	YouTube	Snapshots		



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		Compartment Model - IV Infusion			
09-07-2021	3	Limitations of CM Non-Linear PK	YouTube	PPT Snapshots	1. Link to Notari on Limitations of CM 2. Additional Notes
11-07-2021	3	Non-Linear PK _Estimation of Km & Vm	YouTube	Snapshots	Notes NLPK Additional materials for NL PK: 1. From Gibaldi - Derivation of MM Eqn 2. From Gibaldi - NL PK mathematical concepts 2. From Southwood - Clinical PK angle of Nonlinear processes 3. From Shargel - Basics of NL PK 4. From Jambhekar (2nd Ed) - Basics and advanced NL PK
	3	DRUG INTERACTIONS	Recorded Session YouTube: Part 1 Part 2 Part 3	PPT	Study Jambhekar (Book#3) Drug Interactions chapter and also Sharget (Book#2) Supplementary Notes: 1. Drug Interactions
12-07-2021	4	BA & BE	YouTube	Snapshots	Study Sharget (Book#2) - BA/BE Chapters (Chapter 16) Resources: 1. Additional Notes 2. FDA BA Studies 3. FDA BE Studies
23-07-2021	4	BA & BE	YouTube	Snapshots	
	4	BCS & Permeability	External Video 1 Video 2 Video 3	External PPT1 PPT 2	Notes1 Notes 2



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05-08-2021	4	Biosimilars		PPI	Study Sharget (Book#2) - BA/BE Chapters (Chapter 16) Additional Resources: Resource 1 Resource 2 FDA Overview FDA Biosimilars
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