

## Philadelphia University Faculty of Pharmacy Department of clinical Sciences Second Semester, 2017/2018

# **Course Syllabus**

Course Title: Biopharmaceutics & Pharmacokinetics 2	. Course code: 0510424
Course Level: 4 <sup>th</sup> year	. Course Co-requisite (s): Biopharmaceutics & Pharmacokinetics-1 (0510423)
Lecture Time: 10-11	1. Credit hours: 2-credit hours

		Academic Staff Specifics		
Name	Rank	Office Number and Location	Office Hours	E-mail Address
Yazan Bataineh	Assistant Professor	5517	From 12 To 1,00	ybatineh@philadelphia.edu.jo

## **Course module description and objectives:**

This course is devoted to the exploration and examination of the physical and physicochemical behavior of drugs, dosage forms, and drug delivery systems in physiological milieu and their implications for pharmaceutical care. Drug absorption processes, bioavailability, and bioequivalence will be highlighted. Pharmacokinetic and Pharmacodynamic concepts, including absorption kinetics, volume of distribution, and compartmental models, will be introduced to the student.

# **Course/ module components**

## • Books

Applied Biopharmaceutics and Pharmacokinetics., Shargel and A.B.C. Yu., Appleton & Lange/MacGraw-Hill, New York., 4th edition 1999. ISBN 0-8385-0129-X

- Support material (s)
- Specialized softwares as WinNonlin® standard and PowerPoint presentations.
- Pharmacokinetic Cases.

Prepared by the lecturer, adapted from the text book and other references.

# **Teaching methods:**

Lectures and seminars.

#### Learning outcomes:

At the end of this module, student will be able to:

- 1. Understand the compartmental modeling and it's significance
- 2. Understand drug absorption, distribution and elimination
- 3. Understand drug clearance including (total, renal and hepatic clearance)
- 4. Understand pharmacokinetics and biopharmaceutics after I.V bolus, I.V infusion, and oral administration of drugs.
- 5. Understand protein binding and its effects
- 6. Understand bioavailability and bioequivalence
- 7. Understand Multiple dosage regimen
- 8. Have a knowledge on biopharmaceutics considerations in dosage form design
  - Cognitive skills (thinking and analysis).

The student should be able to analyze and scientifically use equations which will help him understand the processes that the drug undergoes inside the system and the fate of this drug.

- Communication skills (personal and academic).
  - Adapting a problem solving approach through allowing the student to argue his point of view to his colleagues.
  - Adapting group discussion technique.
- Practical and subject specific skills (Transferable Skills).
  - Handle the semi-log and standard graph papers, and distinguish the resulted curves generated by ordered processes, and ability to calculate slopes and intercepts to extract pharmacokinetic processes according to the model under question.
  - Use raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution and elimination.

## Assessment instruments

Allocation of Marks		
Assessment Instruments	Mark	
First Exam	20%	
Second Exam	20%	
signment / Seminar / Quizzes.	20%	
Final examination	40%	
1	100%	

## **Documentation and academic honesty**

<b>eek</b>	Basic and support material to be covered
(1)	Review of the following
(_)	rates and orders of reactions
	ONE-COMPARTMENT OPEN MODEL: INTRAVENOUS BOLUS
	MINISTRATION: IV route, elimination, volume of distribution, calculation from plasma and
	urinary excretion data
	MULTICOMPARTMENT MODELS: INTRAVENOUS BOLUS ADMINISTRATION: two-
	compartment model
(2)	
	Intravenous infusion: one-compartment model drugs, infusion plus loading dose. Two compartment drugs •
8-4)	Clinical application :
,	determination of route of administration,
	PHYSIOLOGIC FACTORS RELATED TO DRUG ABSORPTION:
5-6)	Clinical application :
, ,,	Pharmacokinetics of drug absorption: zero order absorption model, first order absorption model
7-8)	Clinical application :
	Dose Adjustment in Renal and Hepatic Disease, RENAL IMPAIRMENT,
	HARMACOKINETIC CONSIDERATIONS, GENERAL APPROACHES FOR DOSE
	DJUSTMENT IN RENAL DISEASE, Dose Adjustment Based on Drug Clearance
-10)	Dese Adjustment Reserve on Changes in the Elimination Pate Constant
	Dose Adjustment Based on Changes in the Elimination Rate Constant, MEASUREMENT OF GLOMERULAR FILTRATION RATE, SERUM CREATININE
	CONCENTRATION AND CREATININE CLEARANCE, Calculation of Creatinine
	Clearance from Serum Creatinine
	Concentration in ADULTS and CHILDREN
(11-	<ul> <li>Application of pharmacokinetics in clinical situations: individualization of drug dosage</li> </ul>
12)	regimen, design of dosage regimen, determination of dose and dosing interval.
	DOSE ADJUSTMENT FOR UREMIC PATIENTS, Basis for Dose Adjustment in Uremia,
	Nomograms, Fraction of Drug Excreted Unchanged (fe) Methods, Comparison of the
	Various Methods for Dose Adjustment in Uremic
	Patients, EXTRACORPOREAL REMOVAL OF DRUGS, Dialysis, PERITONEAL
10)	DIALYSIS, HEMODIALYSIS, CLINICAL EXAMPLES
13)	EFFECT OF HEPATIC DISEASE ON PHARMACOKINETICS, Dosage Considerations in Hepatic Disease, Hepatic elimination of drugs: pharmacokinetics of drugs and
	metabolites, short summary about hepatic enzymes clearance, biliary secretion of drugs
14)	sing of drugs in elderly, dosing of drugs in obese patients, dosing of drugs in infants, short
14)	overview of population pharmacokinetics
15)	Final Exam Week

# **Expected workload:**

On average you should expect to spend at least (6) hours per week on this module.

Absence from lectures and/or tutorials shall not exceed 15%. Students who exceed the 15% limit without a medical or emergency excuse acceptable to and approved by the Dean of the relevant college/faculty shall not be allowed to take the final examination and shall receive a mark of zero for the course. If the Dean approves the excuse, the student shall be considered to have withdrawn from the course.

#### **Module references**

#### **Textbook:**

Shargel and A.B.C. Yu. Applied Biopharmaceutics and Pharmacokinetics, 5th edition 2004. Appleton & Lange/MacGraw-Hill, New York. ISBN 0-8385-0129-X

In addition to the above, the students will be provided with handouts by the lecturer.

#### **Other References:**

Students will be expected to give the same attention to these references as given to the Module textbook(s)

1. Merck Index: An Encyclopedia of Chemicals, Drugs, & Biologicals by Merck, Co, Maryadele J. Oneil (Editor), Ann Smith (Editor) 13th edition (October 2001), Merck & Co; ISBN: 0911910131

2. Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences by Alfred Martin, Pilar Bustamante, A.H.C. Chun (Illustrator)
622 pages 4th edition (January 15, 1993), Lea & Febiger; ISBN: 0812114388

3. Remington: The Science and Practice of Pharmacy by Alfonso R. Gennaro (Editor) 20th edition (December 15, 2000), Lippincott, Williams & Wilkins; ISBN: 0683306472

#### Website(s):

http://www.philadelphia.edu.jo/pharmacy/resources.html