UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-445E	Βιοφαρμακευτική/Φαρμακοκινητική/ Biopharmaceutics –Pharmacokinetics	6
Prerequisites	**Department**	**Semester**
PHAR-206E, PHAR-215E, PHAR-365E, PHAR-366E	Life and Health Sciences	Fall/Spring
Type of Course	**Field**	**Language of Instruction**
Compulsory	Pharmacy	English/Greek
Level of Course	**Lecturer(s)**	**Year of Study**
1st Cycle	Dr Prapopoulou Maria	4
Mode of Delivery	**Work Placement**	**Corequisites**
Face-to-Face	N/A	N/A

Course Objectives:

Biopharmaceutics and pharmacokinetics is a cross-disciplinary course. It is a main specialized course of pharmacy and pharmaceutics. Biopharmaceutics is a subject that introduces the absorption, distribution, metabolism and excretion of medicine in the body, and illuminates the interrelationship among preparation, biology and drug treatment. According to dynamics and mathematical method, pharmacokinetics describes quantitatively the dynamic changes of drug in transfer processes such as absorption, distribution, metabolism and excretion.

The primary aims of the course are:

- to help students grasp the basic theories and basic skills of biopharmaceutics and pharmacokinetics
- develop the students' ability to analyze and solve problems

Learning Outcomes:

After completion of the course students are expected to be able to:

1. Understand the basic concepts of pharmacokinetics and biopharmaceutics
2. Describe the different pharmacokinetic models
3. Determine the basic pharmacokinetic parameters that describe drug absorption and disposition

4. Compare and Differentiate between compartmental and non-compartmental analysis
5. Identify the physiological, physicochemical and dosage form-related factors that affects drug absorption from different dosage forms
6. Evaluate the in vitro-in vivo correlation for different drug products
7. Understand the pharmacokinetic basis of prolonged release medications
8. Define various terms related to bioavailability and bioequivalence
9. Examine the absolute and relative bioavailability of drugs from different dosage forms using either plasma or urine data
10. Understand the biopharmaceutical classification system.
11. Identify the different study designs applied in bioequivalence studies
12. Understand the statistical tests applied in bioequivalence studies
13. Compare the bioequivalence of two drug products
14. Recognize the age, weight, sex and genetic related factors that can cause pharmacokinetic variability
15. Recognize the disease related factors that can cause pharmacokinetic variability
16. Identify drug-drug and drug-food interactions that can cause pharmacokinetic variability

Course Content:

1. **Compartmental Analysis of Pharmacokinetics**
   - pharmacokinetic parameters of drugs after administration of a single dose of the drug through IV or PO routes or after constant IV infusion of drugs; knowing the kinetics, predict the plasma concentration-time profile after different dosage regimens and design a dosage regimen to achieve a desired plasma concentration-time profile; predict the effects of alteration in the kinetic parameters on the plasma concentration-time courses
   - Calculate relevant pharmacokinetic parameters after multiple dose administration of drugs; knowing the kinetic parameters after single dose administration, predict the time to reach steady state and maximum, minimum, and average concentrations at steady-state; knowing the kinetics, design a dosage regimen to achieve a certain plasma concentration-time profile at steady state
   - Explain the relationship among the most important pharmacokinetic parameters, namely the clearance, volume of distribution and elimination half-life
   - Differentiate between linear and non-linear pharmacokinetics from plasma and/or urine data; define Michaelis-Menten kinetics; estimate Michaelis-Menten parameters from dose-plasma concentration time profiles; use the patient-specific or population Michaelis-Menten parameters to design dosage regimens
   - Differentiate between one- and multi-compartment kinetic models from the plasma concentration time data, and calculate the kinetic parameters for drugs with 2-compartment kinetic model

2. Analysis of Pharmacokinetics

- Predict the qualitative and quantitative effects of relevant physiologic factors on drug distribution; predict the effects of alterations in physiologic parameters on the drug distribution
- Define and calculate the effects of various physiological parameters (organ blood flow, intrinsic clearance, and free fraction in blood) on the hepatic, renal, and total clearances of drugs with different extraction ratios; estimate the values of extraction ratio, availability, and intrinsic clearance from the plasma concentration-time data; predict the effect of changes in the physiologic parameters on the blood concentration-time courses of drugs; adjust dosage regimens according to the changes in the physiologic parameters affecting clearance

Pharmacokinetic/Pharmacodynamic Relationship:

Define the relationship between the plasma concentration and effect based on different pharmacodynamic (PD) models and predict the effect for different concentrations based on the Emax (the maximum possible effect for the drug)

Learning Activities and Teaching Methods:

Lectures, workshops, assignments

Assessment Methods:

Final exam, Midterm exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
Applied Biopharmaceutics & Pharmacokinetics	Leon Shargel, Susanna Wu-Pong, Andrew B.C. Yu	The McGraw-Hill Companies	2015	978-0071830935