UNIVERSITY OF NICOSIA
ΠΑΝΕΠΙΣΤΗΜΙΟ ΛΕΥΚΩΣΙΑΣ

Course Code	**Course Title**	**Credits (ECTS)**
PHAR445	Biopharmaceutics – Pharmacokinetics/ Βιοφαρμακευτική/Φαρμακοκινητική	6
Department	**Semester**	**Prerequisites**
Life & Health Sciences	Fall	PHAR 206, 215, 365,366,
Type of Course	**Field**	**Language of Instruction**
Required	Pharmacy	Greek/English
Level of Course	**Year of Study**	**Lecturer**
1st Cycle	4th year	Yiota Gregoriou/Zacharia Lefteris
Mode of Delivery	**Work Placement**	**Co-requisites**
face-to-face	N/A	None

Objectives of the Course:

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 aim of the course is to help students grasp the basic theories and basic skills of biopharmaceutics and pharmacokinetics, develop the students' ability to analyze and solve problems. All these work will construct steady base for the students who are mainly dedicated to pharmaceutical research and clinic pharmacy work in the future.

Learning Outcomes:

After completion of the course students are expected 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. 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. Assess 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. Judge 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 Contents:

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

Learning Activities and Teaching Methods:

Lectures, class discussion, assignments, practicals

Assessment Methods:

Final Examination 60%, course work 40%

Required Textbooks/Reading:

Authors	**Title**	**Publisher**	**Year**	**ISBN**
ΠΑΝΑΓΙΩΤΗΣ ΜΑΧΑΙΡΑΣ, ΧΡΗΣΤΟΣ ΡΕΠΠΑΣ	Βιοφαρμακευτική			
Βιζιριανάκης Ιωάννης	Κλινική Φαρμακοκινητική	Εκδόσεις Σταύρος Σαρτίνας		

Recommended Textbooks/Reading:

Authors	Title	Publisher	Year	ISBN
Katzung Bertram	Pharmacology			