

Study program: Integrated academic studies of Pharmacy			
Type and level of the study program: integrated academic studies			
Course title: SELECTED CHAPTERS IN CLINICAL PHARMACOKINETICS (PhV-SPHKC)			
Teacher: Mihalj M. Poša, Nataša P. Milošević			
Course status: elective			
ECTS Credits: 3			
Condition: Pharmacokinetics			
Course aim To understand the kinetic processes, which the drug in the body is subject to, kinetic analysis, and to apply pharmacokinetics in clinical practice, particularly in determining dosage regimes for the implementation of rational pharmacotherapy.			
Expected outcome of the course: After passing the exam students are expected to be familiar with pharmacokinetic processes and factors that affect them, know different approaches to pharmacokinetic data analysis, understand factors affecting the variability of therapeutic response, know the ways of testing the biological availability and biological equivalence of medicinal products, the terms related to drug clearance, volume distribution, half-elimination time, state of balance and their clinical importance, how drug pharmacokinetics determines the optimal time of application, the optimal dose, dose interval and duration of drug administration, population pharmacokinetics, therapeutic drug monitoring (measuring the concentration in plasma or measure response to the drug), the link between concentration of drug in plasma and response. Upon completion of the course, students are expected to be able to calculate pharmacokinetic parameters of single and multiple dosing in the clinical conditions, assess the need for therapeutic drug monitoring, interpret the measured concentrations of drugs, apply the principles of clinical pharmacokinetics, adjust dose based on its measured concentration in serum; design and implement Pharmacokinetic studies, statistically process the results of their own research.			
Course description <i>Theoretical education</i> 1. Definition of clinical pharmacokinetics 2. Clinical pharmacokinetics of absorption 3. Determination of the biological usability of the "first-pass" elimination, during the absorption of only one dose 4. Clinical pharmacokinetics of distribution 5. Clinical pharmacokinetics of metabolism of drugs 6. Clinical pharmacokinetics of drug excretion 7. Models in clinical pharmacokinetics 8. Single compartment and two compartment models 9. oncompartmental pharmacokinetic analysis 10. Ways to study the biological availability and biological equivalence of medicinal products 11. The terms drug clearance, volume of distribution, time of half-elimination, state of balance and their clinical significance 12. Cure kinetics model with simultaneous linear and nonlinear elimination and solution for multiple dosing 13. Population pharmacokinetics 14. Factors affecting interindividual variation in response to the drug (Pharmacokinetic specificity; pharmacogenetic variations, variations in the formulation of the drug) 15. Therapeutic drug monitoring 16. The importance of monitoring the effects of the drug in the body for clinical pharmacokinetics 17. Methods of monitoring the effects of drugs 18. The importance of monitoring drug concentration in plasma for clinical pharmacokinetics 19. Methods of measuring drug concentrations in plasma and saliva 20. The link between drug plasma concentrations and response to drug 21. Application of pharmacokinetic parameters in the individual manner of dosing drugs in clinical conditions 22. Effects of combined therapy of dosing in clinical conditions 23. Influence of age on the mode of dosing in clinical conditions 24. Dosage of drugs for children in clinical conditions 25. The influence of different pathological conditions on dosing regime 26. Determination of the initial dose and the new dose when the original did not achieve the desired concentration in clinical conditions 27. Dosing interval 28. Examples of clinical pharmacokinetics of drugs and the calculation of basic parameters - single dose 29. Examples multiple drug administration in clinical conditions with concentrations presented graphically 30. Influence of pharmacokinetic parameters on the appearance of pharmacokinetic curves in multiple drug administration in clinical conditions 31. Influence of the initial dose on the drug concentration in multiple drug administration in clinical conditions <i>Practical education: exercises, other forms of education, research related activities</i> 1. Methods of measuring drug concentration in serum: chromatographic and immunological methods 2. Plan of clinical studies for the examination of drug absorption 3. Plan of clinical studies which examine the distribution of drugs 4. Plan of clinical studies which examine the elimination of drugs 5. Plan of bioequivalence studies 6. Anticonvulsant dosing individualization based on measurements of drug concentrations in serum and saliva 7. Practical development of pharmacokinetic studies 8. Basic statistical methods in clinical pharmacokinetics			
Literature <i>Compulsory</i> 1. Ritschel W. Kearns G, Handbook of Basic Pharmacokinetics, APhA Publications, 6 th edition, 2004. <i>Additional</i> -			
Number of active classes			Other:
Lectures: 30	Practice: 15	Other types of teaching: Research related activities:	
Teaching methods			
Student activity assessment (maximally 100 points)			
Pre-exam activities	points	Final exam	points
Lectures	25	Written	50
Practices	25	Oral	
Colloquium		
Essay			