



**PHARMACY**  
**INTEGRATED ACADEMIC STUDIES**  
**FIFTH YEAR OF STUDY**

**PHARMACOKINETICS**

2023/2024

Title of the course:

## **PHARMACOKINETICS**

This course is assigned 6 ECTS credits.

It consists of 4 active teaching hours per week: 2 hours of lectures and 2 hours of practical classes.

## TEACHERS:

	Name and surname	E-mail	Title
1.	Natasa Djordjevic	<a href="mailto:natashadj2002@yahoo.com">natashadj2002@yahoo.com</a>	Full professor
2.	Mihajlo Jakovljevic	<a href="mailto:jakovljevicm@medf.kg.ac.rs">jakovljevicm@medf.kg.ac.rs</a>	Full professor
3.	Jasmina Milovanovic	<a href="mailto:jasminamilo@yahoo.com">jasminamilo@yahoo.com</a>	Full professor
4.	Slobodan Jankovic	<a href="mailto:slobodan.jankovic@medf.kg.ac.rs">slobodan.jankovic@medf.kg.ac.rs</a>	Full professor
5.	Srdjan Stefanovic	<a href="mailto:sstefanovic@medf.kg.ac.rs">sstefanovic@medf.kg.ac.rs</a>	Associate professor

## COURSE STRUCTURE:

Module No	Title	No of weeks	Hours of lectures per week	Hours of practical classes per week	Responsible teacher
1.	<b>Introduction to Pharmacokinetics</b>	5	2	2	Natasa Djordjevic
2.	<b>Clinical Pharmacokinetics 1</b>	5	2	2	Natasa Djordjevic
3.	<b>Clinical Pharmacokinetics 2</b>	5	2	2	Natasa Djordjevic
					<b>Σ 30+30=60</b>

## GRADING:

Students should master the course by modules. The grade will be equivalent to the number of points achieved (see the tables). The points will be awarded according to the following scheme:

Module No	Title	Maximal No of points			$\Sigma$
		Pre-exam	Exam		
		Activities	Written exam	Oral exam	
1.	Introduction to Pharmacokinetics	10	14	10	34
2.	Clinical Pharmacokinetics 1	10	12	10	32
3.	Clinical Pharmacokinetics 2	10	14	10	34
$\Sigma$		30	40	30	100

## FINAL EXAM:

To pass this course, student must pass all modules.

To pass the module, the student must achieve more than 50% of the maximal number of points for the module, i.e. at least 18, 17, and 18 points for module 1, 2, and 3, respectively.

The final grade will be formed according to the following table:

Grading system		
Grade	Total No of points	Description
10	91-100	Excellent
9	81-90	Exceptionally good
8	71-80	Very good
7	61-70	Good
6	51-60	Passing
5	< 51	Failing

## Literature

Atkinson AJ, et al. Principles of Clinical Pharmacology. 2nd ed. Burlington: Elsevier; 2007.
Katzung B. Basic and Clinical Pharmacology. 10th ed. New York: McGraw-Hill; 2004.
Brunton LL, editor. Goodman & Gilman's The Pharmacological Basis of Therapeutics. 11th ed. New York: McGraw-Hill; 2006.
DiPiro JT, et al. Pharmacotherapy: a pathophysiologic approach. 7th ed. New York: McGraw-Hill; 2008.
Baxter K, editor. Stockley's drug interactions. 8th ed. London, UK; Pharmaceutical Press; 2008.
Gibaldi M, et al. Pharmacokinetics. New York: Informa Healthcare USA, Inc; 2007.
Shargel L, et al, editors. Applied Biopharmaceutics & Pharmacokinetics. New York: McGraw-Hill Education; 2016.

# Schedule

## Module 1: INTRODUCTION TO PHARMACOKINETICS

### COURSE UNIT 1 (WEEK 1):

Lectures: 2 hours	Practical classes: 2 hours
Basic concepts, parameters and principles of drug absorption. Routes of drug administration. Factors affecting drug absorption. Bioavailability and bioequivalence.	Pharmacokinetic calculations of drug absorption parameters. Clinical significance and examples.

### COURSE UNIT 2 (WEEK 2):

Lectures: 2 hours	Practical classes: 2 hours
Basic concepts, parameters and principles of drug distribution. Factors affecting drug distribution. Binding of drugs to plasma proteins.	Pharmacokinetic calculations of drug distribution parameters. Clinical significance and examples.

### COURSE UNIT 3 (WEEK 3):

Lectures: 2 hours	Practical classes: 2 hours
Basic concepts, parameters and principles of drug biotransformation. Factors influencing the biotransformation of drugs. First pass metabolism.	Pharmacokinetic calculations of drug biotransformation parameters. Clinical significance and examples.

### COURSE UNIT 4 (WEEK 4):

Lectures: 2 hours	Practical classes: 2 hours
Basic concepts, parameters and principles of drug excretion. Factors affecting drug excretion.	Pharmacokinetic calculations of drug excretion parameters. Clinical significance and examples.

COURSE UNIT 5 (WEEK 5):

Lectures: 2 hours	Practical classes: 2 hours
Principle of steady-state. Loading dose and maintenance dose. Superposition principle. Missed dose problem. Accumulation of the drug in the body.	Pharmacokinetic calculations after repeated dosing. Clinical significance and examples.

**Module 2:  
CLINICAL PHARMACOKINETICS 1**

COURSE UNIT 6 (WEEK 6):

Lectures: 2 hours	Practical classes: 2 hours
Pharmacokinetic models with one, two and three compartments. Clinical application of pharmacokinetic models. First- and zero-order pharmacokinetics. Michaelis–Menten and saturation kinetics.	Pharmacokinetic calculations using one- and multiple-compartment models and the Michaelis–Menten model. Clinical significance and examples.

COURSE UNIT 7 (WEEK 7):

Lectures: 2 hours	Practical classes: 2 hours
Basic concepts, methods and importance of therapeutic drug monitoring. Indications and candidate drugs for therapeutic monitoring.	Interpretation of therapeutic drug monitoring results. Correction of the drug dose based on its serum concentration. Clinical significance and examples.

COURSE UNIT 8 (WEEK 8):

Lectures: 2 hours	Practical classes: 2 hours
Basic concepts, methods and importance of population pharmacokinetics. Types of population pharmacokinetic studies. NONMEM software package.	Application of the NONMEM program on the validation data set. Analysis of population pharmacokinetic studies.

COURSE UNIT 9 (WEEK 9):

Lectures: 2 hours	Practical classes: 2 hours
Basic concepts, principles and importance of pharmacogenetics. Indications for routine use of pharmacogenetic test in clinical practice.	Interpretation of results of pharmacogenetic analyses. Analysis of pharmacogenetic studies.

COURSE UNIT 10 (WEEK 10):

Lectures: 2 hours	Practical classes: 2 hours
Pharmacogenetics of metabolizing enzymes. Pharmacogenetics of transporters. Routine application of the pharmacogenetic test in clinical practice.	Individualization of drug dosing based on pharmacogenetic analyses. Patient counseling.

**Module 3:**  
**CLINICAL PHARMACOKINETICS 2**

COURSE UNIT 11 (WEEK 11):

Lectures: 2 hours	Practical classes: 2 hours
Basic concepts, principles and importance of pharmacokinetic drug-drug interactions. Clinically significant interactions between drugs and drugs with food and herbal preparations.	Case report analysis of clinically significant adverse drug interactions.

COURSE UNIT 12 (WEEK 12):

Lectures: 2 hours	Practical classes: 2 hours
The influence of growth and development on the pharmacokinetics of drugs in children. The influence of age, accompanying diseases and obesity on the pharmacokinetics of drugs. Dosing and selection of drugs in children, the elderly, and the obese.	Pharmacokinetic calculations in children, the elderly, and the obese. Clinical significance and examples. Patient counseling.

COURSE UNIT 13 (WEEK 13):

Lectures: 2 hours	Practical classes: 2 hours
Pharmacokinetics of drugs in pregnancy. The role of the placenta. Fetal pharmacokinetics. Pharmacokinetics of drugs in lactation. Dosage and selection of drugs in pregnant and lactating women.	Pharmacokinetic calculations in pregnant and lactating women. Patient counseling.

COURSE UNIT 14 (WEEK 14):

Lectures: 2 hours	Practical classes: 2 hours
The influence of liver and kidney insufficiency on drug pharmacokinetics. Dosage and selection of drugs in patients with impaired liver or kidney function.	Pharmacokinetic calculations in liver and kidney damage. Clinical significance and examples. Patient counseling.



COURSE UNIT 15 (WEEK 15):

Lectures: 2 hours

Practical classes: 2 hours

Pharmacokinetics of overdose.  
The difference between acute and chronic poisoning.  
Factors affecting toxicokinetics.  
Risk assessment based on toxicokinetic parameters.

Characteristic examples of drugs and poisons with known toxicokinetics.

## PHARMACOKINETICS: COURSE SCHEDULE

Module	Week	Type	Title	Teacher
<b>1</b>	1	<b>L</b>	<b>Drug absorption.</b>	Natasa Djordjevic
		<b>P</b>	Pharmacokinetic calculations of drug absorption parameters.	
	2	<b>L</b>	<b>Drug distribution.</b>	Natasa Djordjevic
		<b>P</b>	Pharmacokinetic calculations of drug distribution parameters.	
	3	<b>L</b>	<b>Drug biotransformation.</b>	Natasa Djordjevic
		<b>P</b>	Pharmacokinetic calculations of drug biotransformation parameters.	
	4	<b>L</b>	<b>Drug excretion.</b>	Mihajlo Jakovljevic
		<b>P</b>	Pharmacokinetic calculations of drug excretion parameters.	
	5	<b>L</b>	<b>Steady-state principle and repeated dosing.</b>	Natasa Djordjevic
		<b>P</b>	Pharmacokinetic calculations after repeated dosing.	
		<b>E</b>	<b>WRITTEN EXAM 1</b>	

## PHARMACOKINETICS: COURSE SCHEDULE

Module	Week	Type	Title	Teacher	
2	6	L	<b>Pharmacokinetic models and saturation kinetics.</b>	Jasmina Milovanovic	
		P	Pharmacokinetic calculations using one- and multiple-compartment models and the Michaelis–Menten model.		
	7	L	<b>Therapeutic drug monitoring.</b>	Jasmina Milovanovic	
		P	Interpretation of therapeutic drug monitoring results. Correction of the drug dose based on its serum concentration.		
	8	L	<b>Population pharmacokinetics.</b>	Slobodan Jankovic	
		P	Application of the NONMEM program on the validation data set. Analysis of population pharmacokinetic studies.		
	9	L	<b>Basic concepts of pharmacogenetics.</b>	Natasa Djordjevic	
		P	Interpretation of results of pharmacogenetic analyses. Analysis of pharmacogenetic studies.		
	10	L	<b>Pharmacogenetics in clinical practice.</b>	Natasa Djordjevic	
		P	Individualization of drug dosing based on pharmacogenetic analyses.		
			E	<b>WRITTEN EXAM 2</b>	
	3	11	L	<b>Pharmacokinetic drug-drug interactions.</b>	Natasa Djordjevic
P			Case report analysis of clinically significant adverse drug interactions.		

## PHARMACOKINETICS: COURSE SCHEDULE

Module	Week	Type	Title	Teacher	
<b>3</b>	12	<b>L</b>	<b>Pharmacokinetics of drugs in children, the elderly, and the obese.</b>	Srdjan Stefanovic	
		<b>P</b>	Pharmacokinetic calculations in children, the elderly, and the obese.		
	13	<b>L</b>	<b>Pharmacokinetics of drugs in pregnancy and lactation.</b>	Natasa Djordjevic	
		<b>P</b>	Pharmacokinetic calculations in pregnant and lactating women.		
	14	<b>L</b>	<b>Pharmacokinetics of drugs in liver and kidney insufficiency.</b>	Srdjan Stefanovic	
		<b>P</b>	Pharmacokinetic calculations in liver and kidney damage.		
	15	<b>L</b>	<b>Toxicokinetics.</b>	Natasa Djordjevic	
		<b>P</b>	Characteristic examples of drugs and poisons with known toxicokinetics.		
			<b>E</b>	<b>WRITTEN EXAM 3</b>	
			<b>E</b>	<b>ORAL EXAM</b>	

L-lectures; P – Practical classes, E-exam