	UNIVERSITY OF EAST SARAJEVO Faculty of Medicine in	
	Study program: medicine	
	Integrated academic studies / VI study year	

Full subject title	Clinical pharmacology
Department	Department of pharmacology, toxicology and clinical pharmacology, Faculty of Medicine Foca

Subject code	**Subject status**	**Semester**	**ECTS**
ME-02-1-060-11	compulsory	XI	2

Professor/-s	Professor Dragana Sokolovic ; professor Dragana Drakul
Associate/-s	Assist. Milica Radanovic

Number of lectures/ teaching workload (per week)			**Individual student workload (in hours per semester)**			**Coefficient of student workload S_o**[1]
E	**SP**	**L**	**E**	**SP**	**S_o**	**S_o**
2	1	0	2*15*0,3	1*15*0,3	0*15*0,3	0,3

Total teaching workload (in hours, per semester) 2*15 + 1*15 + 0*15 = 45	Total student workload (in hours, per semester) 2*15*0,3 + 1*15*0,3 + 0*15*0,3 = 15

Total subject workload (teaching + student): 45 + 15 = 60 hours per semester

Teaching outcomes	**1.** Getting acquainted with the subject structure, history, basic definitions and the status of clinical pharmacology in medicine and national drug policy. **2.** Mastering the subject, the student will acquire basic knowledge of application of clinical and pharmacological principles in therapy, as well as in monitoring, registration and annotations of drug side effects. **3.** Student will be able to follow and participate in the introduction of new drugs, that is in preclinical and clinical testing of new drugs. **4.** Student will be able to understand the meaning of pharmacovigilance, pharmacoeconomics, pharmacoepidemiology, clinical pharmacokinetics and pharmacogenetics. Furthermore, they will acquire knowledge of emergency treatment characteristics.
General competences	They possess broad fundamentals of theoretical knowledge and practical skills, preparing them for any type of postgraduate education as well as for collaboration with other medical professionals. They have adopted attitudes concerning medical ethics. They are prepared for further development and advances within the field of medicine. They are capable of making appropriate therapeutic decisions. They are acquainted with methodology of scientific research. They are capable of acting in accordance with rational and scientific concepts and principles.
Preconditions	Precondition for taking the exam: all year 5 exams passed
Teaching methods	Lectures, exercises, seminars
Subject content per weeks	**Lectures:** 1. Introducing new drugs: Preclinical testing of new drugs; 2. Clinical trials: Basic methodology and importance. Types of clinical trials. 3. Phases of clinical trials. The placebo effect. Study design. Organization of work at a research location. 4. Basic principles of good clinical practice. The Helsinki declaration. The role of a researcher in clinical trials of new drugs. The role of ethics committee. The role of sponsors. The role of contract research organization. Standard operating procedures for all of the participants in clinical trials. 5. Pharmacoeconomics. 6. Types of pharmacoeconomic analyses.

[1]The coefficient of student workload S_o is calculated as it follows:
a) for the study programs not going through the licensing process: S_o = (total workload in semester for all of the subjects 900 hrs – total teaching workload L+E in semester for all of the subjects 870 hrs)/ total teaching workload L+E in semester for all of the subjects _____ hrs = ____. Consult form content and its explanation.
b) for the study programs going through the licensing process, it is necessary to use form content and its explanation.

7. Pharmacogenetics: Definition. Genotype and phenotype. Gene polymorphism.
8. Pharmacoepidemiology: Definition. Tasks. Types of pharmacoepidemiological studies. Monitoring drug consumption. Importance of monitoring outpatient and inpatient drug consumption. The role of the clinical pharmacology service in monitoring drug consumption in the hospital.
9. Pharmacovigilance: Scales for assessing causal relationship between drug and adverse reaction.
10. Legal obligations of medical workers to report adverse drug reactions and the role of the clinical pharmacologist.
11. Clinical pharmacokinetics: Tasks of clinical pharmacokinetics, methods for adjusting drug dosage regimens, individualization of therapy.
12. Pharmacokinetic models, pharmacokinetic interactions and their importance in practice.
13. Bioequivalence: Reference, generic and innovative drugs. Bioavailability and bioequivalence studies. Legal regulations.
14. Biological drugs.
15. Use of drugs in special patient categories.

Seminars and exercises:

1. Guidelines for prescribing antimicrobial drugs; case study
2. Guidelines for prescribing antiaggregant and anticoagulant drugs; case study
3. Guidelines for prescribing drugs for hypertension; case study
4. Guidelines for prescribing hypolipidemic drugs; case study
5. Guidelines for prescribing drugs for asthma; case study
6. Guidelines for pharmacotherapy of diabetes; case study
7. Guidelines for pain management and analgesic use; case study
8. Guidelines for prescribing anxiolytics; case study
9. Guidelines for pharmacotherapy of depressive disorders; case study
10. Guidelines for therapy of schizophrenia and other psychotic disorders; case study
11. Guidelines for prescribing drugs for osteoporosis; case study
12. Guidelines for prescribing drugs for treating anaphylaxis; case study
13. Guidelines for treating peptic ulcer disease; case study
14. Guidelines for treating Alzheimer's dementia; case study
15. Guidelines for supportive therapy in patients with malignant diseases; case study

Compulsory literature

Author/s	Publication title, Publisher	Year	Pages (from-to)
Katzung BG	Katzung's Basic & Clinical Pharmacology , Lange, 16th edition	2023	

	Grading policy	Points	Percentage
Student responsibilities, types of student assessment and grading	Pre-exam activities		
	lecture/exercise attendance	20	20%
	seminar paper	30	30%
	Final exam		
	oral	50	50%
	TOTAL	100	100 %
Certification date	June 17th 2024		

* * the number of necessary rows is added by using *insert mode*