

1.	Subject	CLINICAL PHARMACOLOGY		
2.	Code	OM 425		
3.	Study Program	General Medicine		
4.	Institution (Unit, Institute, Chair, Department)	Ss Cyril and Methodius University, Medical Faculty, Department of Pharmacology		
5.	Degree of education (first or second cycle)	Integrated cycle		
6.	Study year/semester	Fourth /VIII	7. Number of credits	1.5
8.	Responsible teacher	Assoc.Prof. Dimce Zafirov, PhD, MD		
9.	Preconditions	Fulfilled condition to inroll in the VII semestar		
10.	<p>Teaching goals:</p> <ul style="list-style-type: none"> • Introduction to the subject and tasks of the clinical pharmacology and its practical meaning in the todays therapy; • Understanding the basics of clinical pharmacology and training the students to use its principles in practise, in particular to specific patients groups; • Introduction to basic knowlege in managing clinical studies; • Trainig the students to identify, follow and report adverse effects of drugs; • Optimisation, therapy individualisation and dosing regiments of specific drugs; • Knowlege of clinical importance of drug interactions. 			
11.	<p>Brief content:</p> <p>Theoretical course:</p> <ul style="list-style-type: none"> • Introduction to clinical pharmacology; • Design and conduct of clinical drug studies; bioequivalence studies and good clinical practice standards during study performance; • Drug interactions and its clinical significance; • Use of drugs in elderly patients, children, during pregnancy and lactation and in patients with renal and hepatic impairment; • Adverse drug reactions and Pharmacovigilance. <p>Practical lessons:</p> <ul style="list-style-type: none"> • Preparation of key documents for conduct of clinical trials (study protocol, case report file, informed consent); • Individual dosing models for drugs, determination of dosing regiments according to drug blood concentrations and according to therapeutic effect of specific drug groups; 			

	<ul style="list-style-type: none"> • Practical aspects of adverse effects reporting using electronic reporting system. 			
12.	Methods of studying: Interactive teaching during lectures, practical trainings/seminars			
13.	Total available time:	45 classes		
14.	Organization of the course		30 classes - theoretical course, practical course, seminars 15 classes - home individual learning	
15.	Forms of teaching activities	15.1.	Theoretical course	20 classes
		15.2.	Practical course, Seminars	10 classes
16.	Other forms of activities	16.1.	Practice	classes
		16.2.	Individual tasks	classes
		16.3.	Individual (home) learning	15 classes
17.	Method of assessment			

17.1	Tests	<p style="text-align: right;">min – max</p> <p>Continual assessment* - points 18-30</p> <p>Continual knowledge assessment:</p> <p>Written test (min.12-max 20 points)</p> <p>1 study case of individual dosage regiment (tim work) (min. 6-max. 10 points)</p> <ul style="list-style-type: none"> • Oral examination (intergrative knowledge) – 3 questions in order to determine the integrative knowledge of the material learnt in Clinical Pharmacology relevant for understanding the course purpose. • Practical examination (grading accordingly to skills catalogue): Text materials prepared for the practical course <p>The student has to fulfill the minimum required points for every part of the examination in order to be able to get the scores for the final examination. In conterary the exam can not be passed.</p>
17.2	Seminar paper/project (oral/written presentation)	<p style="text-align: right;">min – max</p>

17.3	Active participation	<p>Theoretical course Practical course</p> <p>Theoretical course attendance</p> <p>51%-60% 1 point 61%-70%-2 points 71%-85%- 3 points 86%-100%- 4 points</p> <p>Practical course attendance</p> <p>4 points</p> <p>Interactive knowledge check : min 6 points-max. 10 points</p> <p>Practical course colloquium: 2 point</p>	<p>min – max 1-4 9 – 14</p>												
18.	Grading criteria (points / grade)	<table border="1"> <tr> <td data-bbox="756 1010 1073 1066">up to 59 points</td> <td data-bbox="1073 1010 1552 1066">5 (five) F</td> </tr> <tr> <td data-bbox="756 1066 1073 1123">from 60 to 68 points</td> <td data-bbox="1073 1066 1552 1123">6 (six) E</td> </tr> <tr> <td data-bbox="756 1123 1073 1180">from 69 to 76 points</td> <td data-bbox="1073 1123 1552 1180">7 (seven) D</td> </tr> <tr> <td data-bbox="756 1180 1073 1236">from 77 to 84 points</td> <td data-bbox="1073 1180 1552 1236">8 (eight) C</td> </tr> <tr> <td data-bbox="756 1236 1073 1293">from 85 to 92 points</td> <td data-bbox="1073 1236 1552 1293">9 (nine) B</td> </tr> <tr> <td data-bbox="756 1293 1073 1367">from 93 to 100 points</td> <td data-bbox="1073 1293 1552 1367">10 (ten) A</td> </tr> </table>	up to 59 points	5 (five) F	from 60 to 68 points	6 (six) E	from 69 to 76 points	7 (seven) D	from 77 to 84 points	8 (eight) C	from 85 to 92 points	9 (nine) B	from 93 to 100 points	10 (ten) A	
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19.	Requirement for signature and taking the final exam	The student is required to actively follow all of the planned activities.													

		<p>Conditional criteria for assessment of knowledge:</p> <p>In order to get a signature, the student should obtain minimum points in both theoretical and practical courses, and to present a seminar paper;</p> <p>In order to take the final exam, the student should obtain the minimum points in the three continual assessments;</p> <p>If the student has not obtained the minimum points in the continual assessments, he/she will be obligated to pass them before the final exam.</p> <p>The grade in the final exam is given according to the grading table, and on the basis of the sum of points obtained in all of the activities.</p>			
20.	Language of instruction	Macedonian			
21.	Method of monitoring the quality of teaching process	Students anonymous evaluation for the course, teachers and associates that participate in the lessons.			
22.	Textbooks				
		Mandatory			
	22.1.	1.	Department of pharmacology and toxicology	Authorized lectures	
		2.	Rang and Dale: H.P.Rang, M.M.Dale, J.M. Ritter, R. Flower	Pharmacology	Akademski pecat 2013
		3.	James M Ritter, Lionel D Lewis, Timothy GK Mant, Albert Ferro	A Textbook of Clinical Pharmacology and Therapeutics	Hodder Arnold, an imprint of Hodden Education 2008
		Additional			
	22.2.	1.	Arthur J. Atkinson	Principles of Clinical Pharmacology, Second Edition	Elsevier 2007

