1. COURSE DECRIPTION – GENERAL INFORMATION			
1.1. Course teacher	Full professor Jelena Filipović-Grčić, PhD Associate professor Anita Hafner, PhD Assistant professor Jasmina Lovrić, PhD	1.6. Year of study	3rd
1.2. Name of the course	**Biopharmaceutics and pharmacokinetics**	1.7. Credit value (ECTS)	5
1.3. Associate teachers	Assistant professor Ivan Pepić, PhD	1.8. Type of instruction (number of hours L+E+S+e-learning)	15+30+15
1.4. Study programme (undergraduate, graduate, integrated)	Pharmacy integrated study programme	1.9. Expected enrolment in the course	130
1.5. Status of the course	Compulsory	1.10. Level of use of e-learning (1, 2, 3 level), percentage of instruction in the course on line (20% maximum)	2nd
2. COURSE DESCRIPTION			
2.1. Course objectives	Student will adopt fundamentals of biopharmaceutics and understand the relationship between the drug absorption, distribution, metabolism and elimination processes and efficacy/safety of drug administration; student will understand the influence of dosage form, route of administration and dosage regimen on therapeutic outcomes. Accomplished knowledge and skills represent required entry competences for courses Drug formulation, Pharmacology, Clinical pharmacy an pharmacotherapy, Pharmaceutical care and Vocational training for pharmacist.		
2.2. Enrolment requirements and required entry competences for the course	Enrolment requirements: Pharmaceutics course completed.		
2.3. Learning outcomes at the level of the study programme to which the course contributes	• Select and apply technological processes in the production of pharmaceuticals. • Critical skills in the development and implementation of solutions for practical problems in the production of pharmaceuticals and the monitoring of safe and appropriate application of pharmaceuticals. • Informing and advising patients on the effects and proper application of pharmaceuticals as well as monitoring the treatment course and outcomes. • Apply expert knowledge and skills to provide advice on pharmacotherapy.		
2.4. Expected learning outcomes at the level of the course (4-10	After passing the exam student will be able to:		

learning outcomes)	1. Correlate the processes of absorption, distribution, metabolism and elimination with efficacy/safety of drug administration; 2. Compare different routes of drug administration and explain the possibilities and limitations of each one; 3. Discuss the influence of dosage form, route of administration and dosage regimen on therapeutic outcomes; 4. Calculate absolute and relative bioavailability of the drug; 5. Calculate (recommend) the dosage regimen for single/multiple intravenous/oral drug administration using population/individual pharmacokinetic parameters; 6. Calculate plasma drug concentration at single/multiple intravenous/oral drug administration prior to or at steady-state.
2.5. Course content broken down in detail by weekly class schedule (syllabus)	LECTURES: • Introduction to biopharmaceutics and pharmacokinetics • Basic principles of biopharmaceutics • Fate of drugs in the body (absorption, distribution, metabolism, elimination) • Oral drug administration • Bioavailability • Biopharmaceutical classification system • Relationship between oral bioavailability and physicochemical properties of the drug and dosage form • Parenteral routes of administration • Introduction to pharmacokinetics, basis of pharmacodynamics, therapeutic drug monitoring • Pharmacokinetics – compartment models; plasma drug concentration-time curve, apparent volume of distribution, physiological fluids, clearance • One-compartment model – IV bolus, elimination rate, elimination rate constant, elimination half-life, interdependence of pharmacokinetic parameters • One-compartment model – IV infusion, loading dose + IV infusion • Two-compartment model – IV bolus, pharmacokinetic parameters • Enteral drug administration: one-compartment model, multiple dose administration • Non-linear pharmacokinetics • Controlled-release formulation pharmacokinetics, drug delivery systems • Bioequivalence, IVIVC SEMINARS: • Routes of drug administration: advantages, disadvantages, requirements of (trans)dermal, pulmonary, vaginal, rectal, nasal, intravenous, subcutaneous, ocular drug administration; Examples: approved medicinal products or drug formulations in certain phase of clinical investigations • Bioavailability

<table>
<tr><td></td><td colspan="6">• Compartment models, clearance, apparent volume of distribution
• Pharmacokinetics – IV drug single dose/multiple dose/continuous administration
• Pharmacokinetics – two-compartment model, extravascular drug administration
• Determination of the fraction of the absorbed drug
• Therapeutic drug monitoring
• Bioequivalence
LABORATORY:
• Rheology of pharmaceuticals
• Micrometry
• Stability testing of pharmaceuticals
• Microencapsulation by phase separation or coacervation
• Drying processes of pharmaceuticals, and Mass transfer phenomena
• In vitro drug dissolution testing - Drug release mechanisms and kinetics in vitro</td></tr>
<tr><td rowspan="2">2.6. Type of instruction</td><td colspan="2" rowspan="2"><u>lectures</u>
<u>seminars</u> and workshops
<u>exercises</u>
online in entirety
mixed e-learning
field work</td><td colspan="2" rowspan="2">independent study
multimedia and the internet
<u>laboratory</u>
work with the mentor
(other)</td><td colspan="2">2.7. Comments:</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>2.8. Student responsibilities</td><td colspan="6"></td></tr>
<tr><td rowspan="6">2.9. Screening of student’s work (specify the proportion of ECTS credits for each activity so that the total number of CTS credits is equal to the credit value of the course)</td><td>Class attendance</td><td>1</td><td>Research</td><td></td><td>Practical training</td><td></td></tr>
<tr><td>Experimental work</td><td>1</td><td>Report</td><td></td><td></td><td></td></tr>
<tr><td>Essay</td><td></td><td>Seminar essay</td><td></td><td>(Other--describe)</td><td></td></tr>
<tr><td>Tests</td><td></td><td>Oral exam</td><td></td><td>(Other—describe)</td><td></td></tr>
<tr><td>Written exam</td><td>3</td><td>Project</td><td></td><td>(Other—describe)</td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>2.10. Grading and evaluation of student work over the course of instruction and at a final exam</td><td colspan="6">Continuous assessment (ISVU system) – 3 written examinations during semester and/or final written examination, assessment of practical skills in laboratory</td></tr>
<tr><td rowspan="2">2.11. Required literature (available at the library and via other media)</td><td colspan="6">Title</td></tr>
<tr><td colspan="6">I. Jalšenjak, V. Jalšenjak, J. Filipović-Grčić, Farmaceutika, Školska knjiga, Zagreb 1998.
Worksheets
Alexander T. Florence and David Attwood, Physicochemical Principles of Pharmacy, Fourth edition, Pharmaceutical Press, London, UK, 2007.</td></tr>
<tr><td>2.12. Optional literature</td><td colspan="6">G.L. Amidon, M. Bermejo, Modern Biopharmaceutics, Version 6, Computer based training software. TSRL Inc., University of Michigan, Ann Arbor, MI, 2003.</td></tr>
<tr><td>2.13. Methods of monitoring quality that ensure acquisition</td><td colspan="6">Assessment of learning outcomes through practical exams, continuous assessment by exams during semester and final examination. Analysis of assessment results to improve the quality of teaching.</td></tr>
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of exit competences	