

<b>Study program:</b> Integrated Academic Studies in Pharmacy			
<b>Course title:</b> Biopharmacy 2			
<b>Teacher:</b> Mirjana B. Bećarević			
<b>Course status:</b> Compulsory			
<b>ECTS Credits:</b> 2			
<b>Condition:</b> Biopharmacy 1, Pharmaceutical Chemistry, Pharmaceutical Technology I, II, III, Immunology			
<b>Course aim</b> The aim of the course is to introduce students with the structure of protein biopharmaceutics and with the biopharmaceutical aspects of their formulation and preparation of their pharmaceutical dosage forms. Students will be introduced to techniques of biopharmaceutics production and purification and with all aspects of their application. Also, the adverse effects and regulatory aspects of biopharmaceutics application will be considered.			
<b>Expected outcome of the course:</b> Students will acquire the knowledge that would provide biopharmaceutical aspects for considerations of efficient and safe biopharmaceutics formulation. In addition, students should develop the skill of formulation of therapeutic peptides and proteins in the most adequate forms that would provide optimal therapy and satisfactory patients' compliance.			
<b>Course description</b> <i>Theoretical education</i> 1. The basic terms and definitions of protein biopharmaceutics 2. Techniques for proteins production and purification 3. Biopharmaceutical aspects of protein biopharmaceutics and their formulations 4. Mechanisms of targeted delivery of biopharmaceutics 5. Biopharmaceutics with „targeted“ activity: antibodies (antibody fragments, monoclonal and polyclonal antibodies, antibody derivatives, immunoglobulin-like protein scaffolds), Fc-fusion proteins, non-antibody binding proteins (anticalins, designed ankyrin-repeat proteins, adnectins, avimers) 6. Biopharmaceutics with regulatory activity: biopharmaceutics that regulate glucose levels (insulins and glucagon-like peptide 1 receptors analogues), cytokines (interferons, interleukines, colony - stimulating growth factors), growth factors (growth hormone, follicle-stimulating hormone), factors that regulate coagulation and fibrinolysis 7. Biopharmaceutics with enzymatic activity (recombinant DNAsal, therapeutic enzymes for the lysosomal diseases treatment) 8. Non-protein biopharmaceutics (peptide, carbo-hydrates). 9. Vaccines (definition, design, therapeutic vaccines). 10. Processing of biopharmaceutics in the organism. 11. Safety and efficiency of biopharmaceutics application.  <i>Practical education:</i> Students will be introduced to specific features of the representatives of biopharmaceuticals classes approved by the regulatory Agencies (Food and Drug Administration, European Medicine Agency, Drugs and Medical Devices Agency of Republic of Serbia).			
<b>Literature</b> <i>Compulsory</i> 1. Crommelin DJA, Sindelar RD, Meibohm B. Pharmaceutical biotechnology. Fundamentals and applications. Informa Healthcare London-New York, 2008. 2. Hillery AM, Lloyd AW, Swarbrick J. Drug delivery and targeting. Taylor & Francis, London-New York, 2001. 3. Banga AK. Therapeutic peptides and proteins. Formulation processing and delivery systems. Technomic Lancaster, Pennsylvania 1995. <i>Additional</i> 1. Shargel L, Wu-Pong S, Yu ABC. Applied biopharmaceutics and pharmacokinetics. McGraw-Hills Pharmacy 2004.			
<b>Number of active classes</b>		<b>Theoretical classes:</b> 30	<b>Practical classes:</b> 15
<b>Teaching methods:</b> Lectures. Interactive practical classes			
<b>Student activity assessment</b> (maximally 100 points)			
<b>Pre-exam activities</b>	<b>points</b>	<b>Final exam</b>	<b>points</b>
Lectures	15	Written	70

Practices	15	Oral	/
Colloquium	/	.....	
Essay	/		