



Study program: Pharmacy			
Course title: Gene Therapy Medicines			
Teacher: Nataša S. Vučinić, Mladena N. Lalić-Popović, Boris Ž. Milijašević			
Course status: Elective			
ECTS Credits: 3			
Condition: Biology with human genetics, Immunology with virology, Pharmaceutical technology I			
Course aim Introduction to the characteristics of gene therapy medicines.			
Expected outcome of the course: Knowledge: Introduction to the all aspects of gene therapy medicines that are essential for the work of future pharmacists: formulation, therapy, regulation. Skills: Application of acquired knowledge in the research, development and registration of this group of medicines.			
Course description <i>Theoretical education</i> <ol style="list-style-type: none"> 1. General principles of gene therapy 2. Ethical aspect of gene therapy 3. Specificity of advanced therapy medicinal products. Domestic and international regulations 4. Gene therapy medicines formulation: general concepts. Drug Delivery Models. 5. Adenoviruses and adeno-associated viruses as drug carriers of gene therapy medicines 6. Retroviruses as drug carriers of gene therapy medicines 7. Inorganic drug carriers in gene therapy medicine formulations 8. Lipid drug carriers in gene therapy medicine formulations 9. Polymer drug carriers in gene therapy medicine formulations 10. Implementation of synthetic or recombinant DNA 11. Gene therapy of cancer 12. Gene therapy of blood disease 13. Gene therapy of neurological diseases 14. Gene therapy of metabolic diseases 15. Pharmacovigilance of gene therapy medicines <i>Practical education</i> Current researches and development of gene therapy medicine formulations. Discussing the basics of gene therapy medicine formulation. Different types of delivery of the active pharmaceutical ingredient in gene therapy. Clinical trials and registration of gene therapy medicines. Review and analysis of gene therapy drugs approved in the European Union and the United States. Post-marketing monitoring of gene therapy medicines.			
Literature <i>Compulsory:</i> <ol style="list-style-type: none"> 1. Turnpenny P, Ellard S. Emery's Elements of Medical Genetics. Elsevier; 2012. (selected chapters) 2. Rang HP, Ritter JM, Flower RJ, Henderson G. Rang and Dale: Pharmacology. Elsevier; 2016. (selected chapters) 3. Nimesh S. Gene therapy – Potential application of nanotechnology. Woodhead Publishing; 2019. (selected chapters) <i>Additional (freely available on internet):</i> <ol style="list-style-type: none"> 1. General principles to address virus and vector shedding (EMA/CHMP/ICH/449035/2009) 2. Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials. European Medical Agency. 2019 3. Regulation (EC) No 1394/2007 			
Number of active classes	Theoretical classes: 30	Practical classes: 15	
Teaching methods Theoretical and practical teaching.			
Student activity assessment (maximally 100 points)			
Pre-exam activities	points	Final exam	points

Lectures	15	Written	-
Practices	15	Oral	70
Colloquium	-		
Essay	-		