Study Programme: Pharmaceutical engineering

Course Unit Title: Microbiological control of pharmaceutical and cosmetic

products and processes

Course Unit Code: FI403

Name of Lecturer(s): Assoc. Prof. Dragoljub Cvetković, PhD; Ass. Prof. Aleksandra Ranitović, PhD

Type and Level of Studies: Undergraduate academic studies

Course Status (compulsory/elective): Elective

Semester (winter/summer): Winter

Language of instruction: English

Mode of course unit delivery (face-to-face/distance learning): Face-to-face

Number of ECTS Allocated: 7

Prerequisites: Microbiology

## **Course Aims:**

Acquisition of basic scientific and academic knowledge and skills in the field of microbiological control of the processes and products in pharmaceutical and cosmetic industries, with the understanding of HACCP principles and respective standards for this type of industry.

### **Learning Outcomes:**

Students are trained to understand theoretical and practical principles of microbiological control of pharmaceutical and cosmetic products, ecological and physiological characteristics of microorganisms important for technological microbiology, understanding of role and significance of microorganisms of water, production of sterile products, antimicrobial agents, hygiene and disinfection, understanding of biofilm and HACCP principles.

### Syllabus:

Theory

Microorganisms important for pharmaceutical and cosmetic industry. Pathogens and their indicators. Sources of contamination of products - raw materials, water, air, equipment. Legislation. Biotic and abiotic factors. Sterilization and aseptic production. Important Gram-positive and Gram-negative bacteria, fungi, yeasts and protozoa. Basic concepts of immunology and serology. Basic mechanisms of microbial pathogenicity. Bacterial resistance to antibiotics. Water microbiology. Biofilms. Hygiene of equipment, air and people. Cleaning and disinfection - implementation and monitoring of sanitation, cleaning and disinfection. Relevant ISO standars and HACCP.

# Practice

Experimental exercises in preparation culture media for certain groups of microorganisms, microbiological testing of products, as well as samples from the production environment and water, effects of physical, physico-chemical and chemical factors, as well as biotic factors on microorganisms, procedures for monitoring of biofilms, methods for quality testing of disinfectants, implementation of HACCP.

# **Required Reading:**

- 1. Mara D., Horan N.: Water and Wastewater Microbiology, Academic Press, San Diego, 2003.
- 2. Denyer S.P., Hodges N.A., Gorman S.P.: Pharmaceutical Microbiology, Blackwell, 2004.
- 3. Lightfoot N.F., Maier E.A.: Microbiological Analyses of Food and Water, Guidelines for Quality Assurance,

Weekly Contact Hours: 6		Lectures: 3		Practical work: 3	
Teaching Methods:					
Lectures and students gr	oup work				
Knowledge Assessmen	t (maxim	um of 100 points	):		
Pre-exam obligations	points		Final exam		points
Active class	5		written exam		
participation	3		written exam		-
Practical work	25		oral exam		30
Preliminary exam(s)	20				
Seminar(s)	20				
The methods of knowled	dge assess	ment may differ;	the table presents	only some	of the options: written exam, oral exam,