



**INTEGRATED ACADEMIC
STUDIES OF PHARMACY**

FOURTH YEAR OF STUDIES

Academic year 2024/2025

Pharmaceutical biotechnology

Course: 19.DE006

Pharmaceutical biotechnology

The course is evaluated with 6 ECTS. The course consists of 5 classes of active teaching per week (3 classes of lectures and 2 classes of practice).

TEACHERS AND ASSOCIATES:

RB	Name and surname	E-mail address	Academic rank
1.	Isidora Milosavljevic	isidora.milosavljevic@fmn.kg.ac.rs	Associate Professor
2.	Jovana Novakovic	jovana.novakovic@fmn.kg.ac.rs	Assistant Professor
3.	Maja Savic	maja.savic@fmn.kg.ac.rs	Teaching Assistant
4.	Nevena Lazarevic	nevena.lazarevic@fmn.kg.ac.rs.	Teaching Assistant
5.	Jelena Terzic	jelena.terzic@fmn.kg.ac.rs	Junior Teaching Assistant

COURSE STRUCTURE:

Modul number	Name of the module	N° of weeks	Lectures	Practice	Other active classes	Teacher - head of the module
1	Introduction to biotechnology	2	3	2		Assoc. Prof. Isidora Milosavljevic
2	Production of biopharmaceuticals	8	2	2		Assoc. Prof. Isidora Milosavljevic
3	Drugs for advanced therapy	5	2	2		Asst. Prof. Jovana Novakovic
						$\Sigma 45+30+0=75$

ASSESSMENT:

The student masters the subject by modules. The grade is equivalent to the number of points earned (see tables). Points are earned in two ways:

- 1. ACTIVITY DURING THE LESSON:** In this way, the student can gain up to 30 points
- 2. FINAL EXAMINATION:** The test consists of multiple choice questions. In this way, the student can gain up to 70 points.

MAXIMUM POINTS		
1	STUDENT'S ACTIVITY DURING THE LECTURES	30
3	FINAL EXAMINATION (written)	70
Σ		100

The final grade is formed as follows:

In order to complete the course, the student must acquire at least 51 points in total.

number of acquired points	grade
0 - 50	5
51 - 60	6
61 - 70	7
71 - 80	8
81 - 90	9
91 - 100	10

LITERATURE:

the name of the textbook	authors	publisher	the library
Biopharmaceuticals: Biochemistry & Biotechnology, 3 rd Edition	Walsh G (Ed)	John Wiley & Sons Ltd., Chichester, UK, 2007	Has
Pharmaceutical Biotechnology	Guzman CA, Feuerstein GZ (Ed)	Springer Science Business Media, LCC, Landes Bioscience, 2009	Has
Pharmaceutical Biotechnology: An Introduction for Pharmacists and Pharmaceutical Scientists, 2nd Edition.	Crommelin DJA, Sindelar RD (Eds)	Taylor & Francis Ltd., London, UK, 2002	Has
Handbook of Pharmaceutical Biotechnology	Rho JP, Louie SG (Eds)	Pharmaceutical Products Press, Binghamton, N. Y., 2003	Has

PROGRAM:

FIRST MODULE: INTRODUCTION TO BIOTECHNOLOGY WITH REFERENCE TO PHARMACEUTICAL SCIENCE

TEACHING UNIT 1 (FIRST WEEK):

INTRODUCTION TO PHARMACEUTICAL BIOTECHNOLOGY

lectures - 3 classes	Practice - 2 classes
Introductory lecture, introduction to pharmaceutical biotechnology. Emergence of Biotechnology Industry. Categories of biopharmaceuticals. Development of biopharmaceuticals.	Introductory lecture, introduction to pharmaceutical biotechnology. Emergence of Biotechnology Industry. Categories of biopharmaceuticals. Development of biopharmaceuticals.

TEACHING UNIT 2 (SECOND WEEK):

RECOMBINANT DNA TECHNOLOGY

lectures - 3 classes	Practice - 2 classes
Recombinant DNA. DNA cloning. Creating the clone. Isolating the clone. Recombinant DNA creation and rDNA technology. Advantages and disadvantages of recombinant DNA technology.	Recombinant DNA. DNA cloning. Creating the clone. Isolating the clone. Recombinant DNA creation and rDNA technology. Advantages and disadvantages of recombinant DNA technology.

SECOND MODULE: PRODUCTION OF BIOPHARMACEUTICALS

TEACHING UNIT 3 (THIRD WEEK):

PRODUCTION OF THERAPEUTIC PROTEINS

lectures - 3 classes	Practice - 2 classes
Sources for the production of biopharmaceuticals (<i>E. coli</i> , <i>S. Cerevisiae</i> , cell cultures and others).	Sources for the production of biopharmaceuticals (<i>E. coli</i> , <i>S. Cerevisiae</i> , cell cultures and others).

TEACHING UNIT 4 (FOURTH WEEK):

PRODUCTION OF THERAPEUTIC PROTEINS

lectures - 3 classes	Practice - 2 classes
Biosynthesis of biopharmaceuticals (upstream processes).	Biosynthesis of biopharmaceuticals (upstream processes).

TEACHING UNIT 5 (FIFTH WEEK):

PRODUCTION OF THERAPEUTIC PROTEINS

lectures - 3 classes	Practice - 2 classes
Isolation of therapeutic proteins from cell cultures (downstream processes).	Isolation of therapeutic proteins from cell cultures (downstream processes).

TEACHING UNIT 6 (SIXTH WEEK):

PRODUCTION OF THERAPEUTIC PROTEINS

lectures - 3 classes	Practice - 2 classes
Formulation of therapeutic proteins (downstream processes).	Formulation of therapeutic proteins (downstream processes).

TEACHING UNIT 7 (SEVENTH WEEK):

PRODUCTION OF THERAPEUTIC PROTEINS

lectures - 3 classes	Practice - 2 classes
General properties of therapeutic proteins	General properties of therapeutic proteins

TEACHING UNIT 8 (EIGHTH WEEK):

PRODUCTION OF THERAPEUTIC PROTEINS

lectures - 3 classes	Practice - 2 classes
Post-translational modification of proteins	Post-translational modification of proteins

TEACHING UNIT 9 (NINTH WEEK):

PRODUCTION OF THERAPEUTIC PROTEINS

lectures - 3 classes	Practice - 2 classes
Analysis of the final protein product	Analysis of the final protein product

TEACHING UNIT 10 (TENTH WEEK):

PRODUCTION OF THERAPEUTIC PROTEINS

lectures - 3 classes	Practice - 2 classes
Detection of pyrogens and protein impurities	Detection of pyrogens and protein impurities

THIRD MODULE: DRUGS FOR ADVANCED THERAPY

TEACHING UNIT 11 (ELEVENTH WEEK):

MONOCLONAL ANTIBODIES

lectures - 3 classes	Practice - 2 classes
Monoclonal antibody production technology	Monoclonal antibody production technology

TEACHING UNIT 12 (TWELFTH WEEK):

VACCINES

lectures - 3 classes	Practice - 2 classes
Conventional vaccine production technology. The role of genetic engineering in vaccine technology. Peptide vaccines. Adjuvant technology and vaccines.	Conventional vaccine production technology. The role of genetic engineering in vaccine technology. Peptide vaccines. Adjuvant technology and vaccines.

TEACHING UNIT 13 (THIRTEENTH WEEK):

GENE THERAPY

lectures - 3 classes	Practice - 2 classes
Basic approach in gene therapy. Vectors in gene therapy (viral vectors and other vectors). Gene therapy in the treatment of various pathological conditions.	Basic approach in gene therapy. Vectors in gene therapy (viral vectors and other vectors). Gene therapy in the treatment of various pathological conditions.

TEACHING UNIT 14 (FOURTEENTH WEEK):

ANTISENSE OLIGONUCLEOTIDES

lectures - 3 classes	Practice - 2 classes
Antisense technology. Antisense oligonucleotides. Advantages, disadvantages and use of oligonucleotides. Production of oligonucleotides.	Antisense technology. Antisense oligonucleotides. Advantages, disadvantages and use of oligonucleotides. Production of oligonucleotides.

TEACHING UNIT 15 (FIFTEENTH WEEK):

CELL-BASED THERAPY

lectures - 3 classes	Practice - 2 classes
Stem cells. Tissue regeneration. Immunotherapy (such as CAR-T cells)	Stem cells. Tissue regeneration. Immunotherapy (such as CAR-T cells)

LECTURES SCHEDULE

MONDAY

08:00 – 10:30

Hall 2- Dentistry

PRACTICE SCHEDULE

WEDNESDAY

08:00 – 09:30

Hall 2- Dentistry

LESSON SCHEDULE FOR THE SUBJECT PHARMACEUTICAL BIOTECHNOLOGY

Module	Week	Type	Method unit name	Teacher	
1	1	L	Introduction to Pharmaceutical Biotechnology.	Assoc. Prof. Isidora Milosavljevic	
		P	Introduction to Pharmaceutical Biotechnology.	Assoc. Prof. Isidora Milosavljevic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic	
	2	L	Recombinant DNA technology	Assoc. Prof. Isidora Milosavljevic	
		P	Recombinant DNA technology	Assoc. Prof. Isidora Milosavljevic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic	
	3	L	Sources for the production of biopharmaceuticals	Asst. Prof. Jovana Novakovic	
		P	Sources for the production of biopharmaceuticals	Asst. Prof. Jovana Novakovic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic	
	4	L	Biosynthesis of biopharmaceuticals (upstream processes).	Asst. Prof. Jovana Novakovic	
		P	Biosynthesis of biopharmaceuticals (upstream processes).	Asst. Prof. Jovana Novakovic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic	
	5	L	Isolation of therapeutic proteins from cell cultures (downstream processes).	Assoc. Prof. Isidora Milosavljevic	
		P	Isolation of therapeutic proteins from cell cultures (downstream processes).	Assoc. Prof. Isidora Milosavljevic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic	
	2	6	L	Formulation of therapeutic proteins (downstream processes).	Assoc. Prof. Isidora Milosavljevic
			P	Formulation of therapeutic proteins (downstream processes).	Assoc. Prof. Isidora Milosavljevic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic

LESSON SCHEDULE FOR THE SUBJECT PHARMACEUTICAL BIOTECHNOLOGY

Module	Week	Type	Method unit name	Teacher
2	7	L	General properties of therapeutic proteins	Asst. Prof. Jovana Novakovic
		P	General properties of therapeutic proteins	Asst. Prof. Jovana Novakovic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic
	8	L	Post-translational modification of proteins	Asst. Prof. Jovana Novakovic
		P	Post-translational modification of proteins	Asst. Prof. Jovana Novakovic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic
2	9	L	Analysis of the final protein product	Assoc. Prof. Isidora Milosavljevic
		P	Analysis of the final protein product	Assoc. Prof. Isidora Milosavljevic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic
	10	L	Detection of pyrogens and protein impurities	Assoc. Prof. Isidora Milosavljevic
		P	Detection of pyrogens and protein impurities	Assoc. Prof. Isidora Milosavljevic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic
3	11	L	Monoclonal antibodies production technology	Asst. Prof. Jovana Novakovic
		P	Monoclonal antibodies production technology	Asst. Prof. Jovana Novakovic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic
	12	L	Vaccine production	Asst. Prof. Jovana Novakovic
		P	Vaccine production	Asst. Prof. Jovana Novakovic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic

LESSON SCHEDULE FOR THE SUBJECT PHARMACEUTICAL BIOTECHNOLOGY

Module	Week	Type	Method unit name	Teacher
3	13	L	Gene therapy	Assoc. Prof. Isidora Milosavljevic
		P	Gene therapy	Assoc. Prof. Isidora Milosavljevic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic
	14	L	Antisense oligonucleotides	Assoc. Prof. Isidora Milosavljevic
		P	Antisense oligonucleotides	Assoc. Prof. Isidora Milosavljevic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic
	15	L	Cell-based therapy	Asst. Prof. Jovana Novakovic
		P	Cell-based therapy	Asst. Prof. Jovana Novakovic TA Maja Savic TA Nevena Lazarevic JTA Jelena Terzic