



**INTEGRATED ACADEMIC  
STUDIES OF PHARMACY**

**FOURTH YEAR OF STUDIES**

academic year 2023/2024

**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	vocation
1.	Isidora Milosavljevic	isidora.stojic@medf.kg.ac.rs	Assistant Professor
2.	Jovana Novakovic	jovana.jeremic@medf.kg.ac.rs	Assistant Professor

## 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		asst. prof. Isidora Milosavljevic
2	Production of biopharmaceuticals	8	2	2		asst. 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.

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

### **The final grade is formed as follows:**

In order to complete the course, the student must acquire at least 51 point in summary.

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

## LITERATURE:

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

## **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 in the pharmaceutical biotechnology. Emergence of Biotechnology Industry. Categories of biopharmaceuticals. Development of biopharmaceuticals.	Introductory lecture, introduction in the 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. Making recombinant DNA and rDNA technology. Advantages and disadvantages of recombinant DNA technology.	Recombinant DNA. DNA cloning. Creating the clone. Isolating the clone. Making recombinant DNA 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 (E. Coli, S. Cerevisiae, cell cultures and others).	Sources for the production of biopharmaceuticals (E. Coli, S. Cerevisiae, 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 protein	Post-translational modification of protein

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
Technology for production of monoclonal antibodies	Technology for production of monoclonal antibodies

TEACHING UNIT 12 (TWELFTH WEEK):

**VACCINE**

lectures - 3 classes	Practice - 2 classes
Conventional vaccine production technology. The role of genetic engineering on vaccine technology. Peptide vaccines. Adjuvant technology and vaccines.	Conventional vaccine production technology. The role of genetic engineering on 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 uses of oligonucleotides. Production of oligonucleotides.	Antisense technology. Antisense oligonucleotides. Advantages, disadvantages and uses of oligonucleotides. Production of oligonucleotides.

TEACHING UNIT 15 (FIFTEENTH WEEK):

**STEM CELLS**

lectures - 3 classes	Practice - 2 classes
Aptamers. Stem cells.	Aptamers. Stem cells.

**LECTURES SCHEDULE**

<p><b>Thursday</b></p> <p><b>09:00 - 11:15</b></p>
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**SCHEDULE OF PRACTICE**

<p><b>Friday</b></p> <p><b>12:30 - 14:00</b></p>
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## LESSON SCHEDULE FOR THE SUBJECT PHARMACEUTICAL BIOTECHNOLOGY

module	Sunday	type	method unit name	a teacher
<b>1</b>	<b>1</b>	<b>L</b>	Introduction to Pharmaceutical Biotechnology.	asst. prof. Isidora Milosavljevic
		<b>P</b>	Introduction to Pharmaceutical Biotechnology.	asst. prof. Isidora Milosavljevic
	<b>2</b>	<b>L</b>	Recombinant DNA technology	asst. prof. Isidora Milosavljevic
		<b>P</b>	Recombinant DNA technology	asst. prof. Isidora Milosavljevic
	<b>3</b>	<b>L</b>	Sources for the production of biopharmaceuticals	asst. prof. Jovana Novakovic
		<b>P</b>	Sources for the production of biopharmaceuticals	asst. prof. Jovana Novakovic
	<b>4</b>	<b>L</b>	Biosynthesis of biopharmaceuticals (upstream processes).	asst. prof. Jovana Novakovic
		<b>P</b>	Biosynthesis of biopharmaceuticals (upstream processes).	asst. prof. Jovana Novakovic

## LESSON SCHEDULE FOR THE SUBJECT PHARMACEUTICAL BIOTECHNOLOGY

module	Sunday	type	method unit name	a teacher
1	5	L	Isolation of therapeutic proteins from cell cultures (downstream processes).	asst. prof. Isidora Milosavljevic
		P	Isolation of therapeutic proteins from cell cultures (downstream processes).	asst. prof. Isidora Milosavljevic
2	6	L	Formulation of therapeutic proteins (downstream processes).	asst. prof. Isidora Milosavljevic
		P	Formulation of therapeutic proteins (downstream processes).	asst. prof. Isidora Milosavljevic
	7	L	General properties of therapeutic proteins	asst. prof. Jovana Novakovic
		P	General properties of therapeutic proteins	asst. prof. Jovana Novakovic
	8	L	Post-translational modification of protein	asst. prof. Jovana Novakovic
		P	Post-translational modification of protein	asst. prof. Jovana Novakovic

## LESSON SCHEDULE FOR THE SUBJECT PHARMACEUTICAL BIOTECHNOLOGY

module	Sunday	type	method unit name	a teacher
2	9	L	Analysis of the final protein product	asst. prof. Isidora Milosavljevic
		P	Analysis of the final protein product	asst. prof. Isidora Milosavljevic
	10	L	Detection of pyrogens and protein impurities	asst. prof. Isidora Milosavljevic
		P	Detection of pyrogens and protein impurities	asst. prof. Isidora Milosavljevic
3	11	L	Technology for production of monoclonal antibodies	asst. prof. Jovana Novakovic
		P	Technology for production of monoclonal antibodies	asst. prof. Jovana Novakovic
	12	L	Vaccine production	asst. prof. Jovana Novakovic
		P	Vaccine production	asst. prof. Jovana Novakovic

## LESSON SCHEDULE FOR THE SUBJECT PHARMACEUTICAL BIOTECHNOLOGY

module	Sunday	type	method unit name	a teacher
<b>3</b>	<b>13</b>	<b>L</b>	Gene therapy	asst. prof. Isidora Milosavljevic
		<b>P</b>	Gene therapy	asst. prof. Isidora Milosavljevic
	<b>14</b>	<b>L</b>	Antisense oligonucleotides	asst. prof. Isidora Milosavljevic
		<b>P</b>	Antisense oligonucleotides	asst. prof. Isidora Milosavljevic
	<b>15</b>	<b>L</b>	Stem cells	asst. prof. Jovana Novakovic
		<b>P</b>	Stem cells	asst. prof. Jovana Novakovic