



**INTEGRATED ACADEMIC  
STUDIES OF PHARMACY**

**FOURTH YEAR OF STUDIES**

Academic year 2025/2026

**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.milosavljevic@fmn.kg.ac.rs	Associated Professor
2.	Jovana Novakovic	<a href="mailto:jovana.novakovic@fmn.kg.ac.rs">jovana.novakovic@fmn.kg.ac.rs</a>	Assistant Professor
3.	Maja Jovanovic	maja.savic@fmn.kg.ac.rs	Assistant Professor
4.	Nevena Lazarevic	nevenasdraginic@gmail.com	Assistant Professor
5.	Jelena Terzic	jelena.terzic@fmn.kg.ac.rs	Teaching Assistant

## ASSESSMENT:

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
$\Sigma$		<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.

number of acquired points	grade
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, 6 <sup>th</sup> Edition.	Crommelin DJA, Sindelar RD (Eds)	Taylor & Francis Ltd., London, UK, 2024	Have
Handbook of Pharmaceutical Biotechnology	Rho JP, Louie SG (Eds)	Pharmaceutical Products Press, Binghamton, N. Y., 2003	Have

# PROGRAM:

## FIRST MODULE: PRODUCTION OF BIOPHARMACEUTICALS

### 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.

### TEACHING UNIT 3 (THIRD WEEK):

#### VECTORS IN rDNA TECHNOLOGY

lectures - 3 classes	Practice - 2 classes
Role of Vectors in Gene Transfer. Essential Structural and Functional Elements of Vectors. Types of Vectors Used in Recombinant DNA Technology	Role of Vectors in Gene Transfer. Essential Structural and Functional Elements of Vectors. Types of Vectors Used in Recombinant DNA Technology

### TEACHING UNIT 4 (FOURTH WEEK):

#### EXPRESSION SYSTEMS

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 5 (FIFTH WEEK):

#### PRODUCTION OF THERAPEUTIC PROTEINS

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

### TEACHING UNIT 6 (SIXTH 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 7 (SEVENTH 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 8 (EIGHTH WEEK):

#### PRODUCTION OF MONOCLONAL ANTIBODIES

lectures - 3 classes	Practice - 2 classes
Overview of Monoclonal Antibody Production. Hybridoma Technology and Cell Fusion. Screening and Selection of Antibody-Producing Clones.	Overview of Monoclonal Antibody Production. Hybridoma Technology and Cell Fusion. Screening and Selection of Antibody-Producing Clones.

Purification and Isolation of Monoclonal Antibodies	Purification and Isolation of Monoclonal Antibodies
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TEACHING UNIT 9 (NINTH WEEK):

**PROCESSING AREAS AND GMP PRINCIPLES**

lectures - 3 classes	Practice - 2 classes
Processing Areas: Design and Classification. Documentation and Record Keeping. Principles of Good Manufacturing Practice (GMP)	Processing Areas: Design and Classification. Documentation and Record Keeping. Principles of Good Manufacturing Practice (GMP)

TEACHING UNIT 10 (TENTH WEEK):

**THERAPEUTIC PROTEINS**

lectures - 3 classes	Practice - 2 classes
General properties of proteins. Post-translational modifications of proteins.	General properties of proteins. Post-translational modifications of proteins.

TEACHING UNIT 11 (ELEVENTH WEEK):

**STABILITY CHALLENGES OF PROTEIN PRODUCTS: CHEMICAL AND PHYSICAL MODIFICATIONS**

lectures - 3 classes	Practice - 2 classes
Chemical Modifications Affecting Protein Stability. Physical Modifications Affecting Protein Stability. Strategies to Enhance Protein Stability	Chemical Modifications Affecting Protein Stability. Physical Modifications Affecting Protein Stability. Strategies to Enhance Protein Stability

TEACHING UNIT 12 (TWELFTH WEEK):

**ANALYSIS OF THE FINAL PROTEIN PRODUCT**

lectures - 3 classes	Practice - 2 classes
Analysis of the final protein product. Detection of pyrogens and protein impurities	Analysis of the final protein product. Detection of pyrogens and protein impurities

TEACHING UNIT 13 (THIRTEENTH WEEK):

**PROTEIN THERAPEUTICS: ADMINISTRATION AND TARGETED DELIVERY**

lectures - 3 classes	Practice - 2 classes
Routes of Administration of Protein Products. Targeted Delivery Systems for Protein Drugs	Routes of Administration of Protein Products. Targeted Delivery Systems for Protein Drugs

TEACHING UNIT 14 (FOURTEENTH WEEK):

**PHARMACOKINETICS AND PHARMACODYNAMICS OF PROTEIN PRODUCTS**

lectures - 3 classes	Practice - 2 classes
Absorption of Protein Therapeutics. Distribution and Tissue Targeting. Metabolism and Degradation Pathways. Excretion and Clearance Mechanisms. Mechanisms of Action and Biological Effects. Dose-Response Relationships and Therapeutic Window	Absorption of Protein Therapeutics. Distribution and Tissue Targeting. Metabolism and Degradation Pathways. Excretion and Clearance Mechanisms. Mechanisms of Action and Biological Effects. Dose-Response Relationships and Therapeutic Window

TEACHING UNIT 15 (FIFTEENTH WEEK):

**IMMUNOGENICITY OF BIOPHARMACEUTICALS**

lectures - 3 classes	Practice - 2 classes
Factors Influencing Immunogenicity. Clinical Consequences of Immune Responses. Strategies to Minimize Immunogenicity	Factors Influencing Immunogenicity. Clinical Consequences of Immune Responses. Strategies to Minimize Immunogenicity

**LECTURES AND PRACTICE**

**LECTURE SCHEDULE**

**MONDAY**  
**YELLOW ROOM 35 (R35)**  
**08.00-10.25**

**EXERCISE SCHEDULE**

**Wednesday**  
**YELLOW ROOM 39 (R39)**  
**12.45-14.15**

[Schedule of lectures, practical classes and tests – academic calendar](#)

## 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.	Assoc. Prof. Isidora Milosavljevic
		<b>P</b>	Introduction to Pharmaceutical Biotechnology.	asst. prof. Isidora Milosavljevic TA Jelena Terzic
	<b>2</b>	<b>L</b>	Recombinant DNA technology	Asst. Prof. Jovana Novakovic
		<b>P</b>	Recombinant DNA technology	Asst. Prof. Jovana Novakovic TA Jelena Terzic
	<b>3</b>	<b>L</b>	Vectors in rDNA technology	Asst. Prof. Nevena Lazarevic
		<b>P</b>	Vectors in rDNA technology	Asst. Prof. Nevena Lazarevic
	<b>4</b>	<b>L</b>	Expression systems	asst. prof. Isidora Milosavljevic
		<b>P</b>	Expression systems	asst. prof. Isidora Milosavljevic TA Jelena Terzic

## LESSON SCHEDULE FOR THE SUBJECT PHARMACEUTICAL BIOTECHNOLOGY

module	Sunday	type	method unit name	a teacher
<b>1</b>	<b>5</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 TA Jelena Terzic
	<b>6</b>	<b>L</b>	Isolation of therapeutic proteins from cell cultures (downstream processes).	Asst. Prof. Jovana Novakovic
		<b>P</b>	Isolation of therapeutic proteins from cell cultures (downstream processes).	Asst. Prof. Jovana Novakovic TA Jelena Terzic
	<b>7</b>	<b>L</b>	Formulation of therapeutic proteins (downstream processes).	Asst. Prof. Jovana Novakovic
		<b>P</b>	Formulation of therapeutic proteins (downstream processes).	Asst. Prof. Jovana Novakovic TA Jelena Terzic
	<b>8</b>	<b>L</b>	Production of monoclonal antibodies	asst. prof. Isidora Milosavljevic
		<b>P</b>	Production of monoclonal antibodies	asst. prof. Isidora Milosavljevic TA Jelena Terzic

## LESSON SCHEDULE FOR THE SUBJECT PHARMACEUTICAL BIOTECHNOLOGY

module	Sunday	type	method unit name	a teacher
<b>1</b>	<b>9</b>	<b>L</b>	Processing Areas and GMP Principles	Asst. Prof. Jovana Novakovic
		<b>P</b>	Processing Areas and GMP Principles	Asst. Prof. Jovana Novakovic TA Jelena Terzic
	<b>10</b>	<b>L</b>	General properties of therapeutic proteins. Post-translational modification of protein	asst. prof. Isidora Milosavljevic
		<b>P</b>	General properties of therapeutic proteins. Post-translational modification of protein	asst. prof. Isidora Milosavljevic TA Jelena Terzic
	<b>11</b>	<b>L</b>	Stability Challenges of Protein Products: Chemical and Physical Modifications	Asst. Prof. Jovana Novakovic
		<b>P</b>	Stability Challenges of Protein Products: Chemical and Physical Modifications	Asst. Prof. Jovana Novakovic TA Jelena Terzic
	<b>12</b>	<b>L</b>	Analysis of the final protein product	asst. prof. Isidora Milosavljevic
		<b>P</b>	Analysis of the final protein product	asst. prof. Isidora Milosavljevic TA Jelena Terzic

## LESSON SCHEDULE FOR THE SUBJECT PHARMACEUTICAL BIOTECHNOLOGY

module	Sunday	type	method unit name	a teacher
<b>1</b>	<b>13</b>	<b>L</b>	Protein Therapeutics: Administration and Targeted Delivery	Asst. Prof. Jovana Novakovic
		<b>P</b>	Protein Therapeutics: Administration and Targeted Delivery	Asst. Prof. Jovana Novakovic TA Jelena Terzic
	<b>14</b>	<b>L</b>	Pharmacokinetics and Pharmacodynamics of Protein Products	Asst. Prof. Maja Savic
		<b>P</b>	Pharmacokinetics and Pharmacodynamics of Protein Products	Asst. Prof. Maja Savic
	<b>15</b>	<b>L</b>	Immunogenicity of Biopharmaceuticals	Asst. Prof. Maja Savic
		<b>P</b>	Immunogenicity of Biopharmaceuticals	Asst. Prof. Maja Savic