



**INTEGRATED ACADEMIC
STUDIES OF PHARMACY**

FIFTH YEAR OF STUDIES

academic year 2023/2024

Applied pharmaceutical biotechnology

Course: 19.GE009

Applied pharmaceutical biotechnology

The course is evaluated with 6 ECTS. The course consists of 3 classes of active teaching per week (2 classes of lectures and 1 class of practice and 1 class of project).

TEACHERS AND ASSOCIATES:

RB	Name and surname	E-mail address	vocation
1.	Isidora Milosavljevic	isidora.stojic@medf.kg.ac.rs	Assistant Professor
2.	Slobodan Novokmet	slobodan.novokmet@medf.kg.ac.rs	Full Professor
3.	Jovana Novakovic	jovana.jeremic@medf.kg.ac.rs	Assistant Professor
4.	Nevena Lazarevic	nevena.draginic@medf.kg.ac.rs	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 with reference to Pharmaceutical science	5	2	1	1	asst. prof. Isidora Milosavljevic
2	Application of rDNA technology and genetic engineering in the production of cytokines	5	2	1	1	asst. prof. Isidora Milosavljevic
3	Application of rDNA technology and genetic engineering in the production of hormones and enzymes	5	2	1	1	asst. prof. Isidora Milosavljevic
						$\Sigma 30+15+15=60$

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 50 points:

A. PRESENCE AND ACTIVITY DURING THE CLASS: up to 10 points

B. SEMINAR: The student writes a seminar paper on a given topic and presents it. In this way, the student can gain up to 40 points.

2. FINAL EXAMINATION: The test consists of multiple choice questions. In this way, the student can gain up to 50 points.

MAXIMUM POINTS		
1	STUDENT'S ACTIVITY DURING THE LECTURES	10
2	PROJECT	20
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 point in summary.

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	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 - 2 classes	Practice and project - 2 classes
Introductory lecture, introduction in the pharmaceutical biotechnology. Emergence of Biotechnology Industry. Challenges Facing "Biogenerics". Categories of biopharmaceuticals. Development of biopharmaceuticals.	Introductory lecture, introduction in the pharmaceutical biotechnology. Emergence of Biotechnology Industry. Challenges Facing "Biogenerics". Categories of biopharmaceuticals. Development of biopharmaceuticals.

TEACHING UNIT 2 (SECOND WEEK):

REGULATORY ISSUES IN BIOTECHNOLOGY

lectures - 2 classes	Practice and project - 2 classes
History of biologics regulation in United States. Early Biologics Regulation. Modern Biologics Regulation. Regulatory classification of proteins. Definitions and key terminology. Application of Definitions to proteins: Is it a drug or a biologic? Regulatory Approval Path for Proteins. Intellectual Property Right and Protection.	History of biologics regulation in United States. Early Biologics Regulation. Modern Biologics Regulation. Regulatory classification of proteins. Definitions and key terminology. Application of Definitions to proteins: Is it a drug or a biologic? Regulatory Approval Path for Proteins. Intellectual Property Right and Protection.

TEACHING UNIT 3 (THIRD WEEK):

SAFETY IN BIOTECHNOLOGY

lectures - 2 classes	Practice and project - 2 classes
Biological Precautions. Chemical Precautions. Personal Precautions. Biosafety. Pathogenic Microorganisms and Fungi.	Biological Precautions. Chemical Precautions. Personal Precautions. Biosafety. Pathogenic Microorganisms and Fungi.

TEACHING UNIT 4 (FOURTH WEEK):

RECOMBINANT DNA TECHNOLOGY

lectures - 2 classes	Practice and project - 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 5 (FIFTH WEEK):

PRODUCTION OF THERAPEUTIC PROTEINS

lectures - 2 classes	Practice and project - 2 classes
Sources for the production of biopharmaceuticals (E. Coli, S. Cerevisiae, cell cultures and others). Biosynthesis of biopharmaceuticals (upstream processes). Isolation of therapeutic proteins from cell cultures (downstream processes).	Sources for the production of biopharmaceuticals (E. Coli, S. Cerevisiae, cell cultures and others). Biosynthesis of biopharmaceuticals (upstream processes). Isolation of therapeutic proteins from cell cultures (downstream processes).

SECOND MODULE: APPLICATION OF rDNA TECHNOLOGY AND GENETIC ENGINEERING IN THE PRODUCTION OF CYTOKINES

TEACHING UNIT 6 (SIXTH WEEK):

INTERFERON BIOTECHNOLOGY

lectures - 2 classes	Practice and project - 2 classes
Cytokines. Cytokines receptor. The biochemistry of interferon α , β and γ . Production and medical uses of interferon α , β and γ . Interferon toxicity.	Cytokines. Cytokines receptor. The biochemistry of interferon α , β and γ . Production and medical uses of interferon α , β and γ . Interferon toxicity.

TEACHING UNIT 7 (SEVENTH WEEK):

INTERLEUKIN BIOTECHNOLOGY

lectures - 2 classes	Practice and project - 2 classes
Interleukin 2 production. Interleukin 2 and cancer treatment. Interleukin 2 and infectious diseases. Inhibition of interleukin 2 activity. Biochemistry of interleukin 1. Interleukin 1 biotechnology.	Interleukin 2 production. Interleukin 2 and cancer treatment. Interleukin 2 and infectious diseases. Inhibition of interleukin 2 activity. Biochemistry of interleukin 1. Interleukin 1 biotechnology.

TEACHING UNIT 8 (EIGHTH WEEK):

TUMOR NECROSIS FACTORS BIOTECHNOLOGY

lectures - 2 classes	Practice and project - 2 classes
Tumor necrosis factors biochemistry. Biological activities of tumor necrosis factor α . Tumor necrosis factors receptors. Biotechnology of tumor necrosis factors.	Tumor necrosis factors biochemistry. Biological activities of tumor necrosis factor α . Tumor necrosis factors receptors. Biotechnology of tumor necrosis factors.

TEACHING UNIT 9 (NINTH WEEK):

HEMATOPOIETIC GROWTH FACTORS BIOTECHNOLOGY

lectures - 2 classes	Practice and project - 2 classes
The interleukins as hematopoietic growth factors. Granulocyte colony-stimulating factor. Macrophage colony-stimulating factor. Granulocyte macrophage colony-stimulating factor. Erythropoietin. Trombopoietin.	The interleukins as hematopoietic growth factors. Granulocyte colony-stimulating factor. Macrophage colony-stimulating factor. Granulocyte macrophage colony-stimulating factor. Erythropoietin. Trombopoietin.

TEACHING UNIT 10 (TENTH WEEK):

GROWTH FACTORS AND WOUND HEALING

lectures - 2 classes	Practice and project - 2 classes
Insulin-like growth factors. Insulin-like growth factor biological effect. Epidermal growth factor. Platelet-derived growth factor. Fibroblast growth factor. Transforming growth factors. Neurotrophic factors.	Insulin-like growth factors. Insulin-like growth factor biological effect. Epidermal growth factor. Platelet-derived growth factor. Fibroblast growth factor. Transforming growth factors. Neurotrophic factors.

THIRD MODULE: APPLICATION OF rDNA TECHNOLOGY AND GENETIC ENGINEERING IN THE PRODUCTION OF HORMONES AND ENZYMES

TEACHING UNIT 11 (ELEVENTH WEEK):

INSULIN AND GLUCAGON BIOTECHNOLOGY

lectures - 2 classes	Practice and project - 2 classes
The insulin molecule. Insulin production. Production of human insulin by recombinant DNA technology. Formulation of insulin products. Engineered insulins. Glucagon biotechnology.	The insulin molecule. Insulin production. Production of human insulin by recombinant DNA technology. Formulation of insulin products. Engineered insulins. Glucagon biotechnology.

TEACHING UNIT 12 (TWELFTH WEEK):

HUMAN GROWTH HORMONES BIOTECHNOLOGY

lectures - 2 classes	Practice and project - 2 classes
Growth hormone receptor. Biological effect of growth hormone. Therapeutic uses of growth hormone. The gonadotrophins (follicle-stimulating hormone, luteinizing hormone and human chorionic gonadotrophin). Medical application of gonadotrophins.	Growth hormone receptor. Biological effect of growth hormone. Therapeutic uses of growth hormone. The gonadotrophins (follicle-stimulating hormone, luteinizing hormone and human chorionic gonadotrophin). Medical application of gonadotrophins.

TEACHING UNIT 13 (THIRTEENTH WEEK):

RECOMBINANT BLOOD PRODUCTS

lectures - 2 classes	Practice and project - 2 classes
Factor VIII and haemophilia. Production of factor VIII. Factors IX, VIIa and XIII.	Metabolism of water and bioelements. Metabolism of water and bioelements, inorganic substances - minerals. Tissues. Liver.

TEACHING UNIT 14 (FOURTEENTH WEEK):

BIOTECHNOLOGY OF ANTICOAGULANTS AND THROMBOLYTIC AGENTS

lectures - 2 classes	Practice and project - 2 classes
Hirudin. Antithrombin. First-generation tissue plasminogen activator. Engineered tissue plasminogen activator. Streptokinase. Urokinase. Staphylokinase. α_1 -antitrypsin.	Hirudin. Antithrombin. First-generation tissue plasminogen activator. Engineered tissue plasminogen activator. Streptokinase. Urokinase. Staphylokinase. α_1 -antitrypsin.

TEACHING UNIT 15 (FIFTEENTH WEEK):

BIOTECHNOLOGY OF ENZYMES WITH THERAPEUTICALLY VALUES

lectures - 2 classes	Practice and project - 2 classes
Asparaginase. DNase. Glucocerebrosidase. A-galactosidase. Urate-oxidase. Laronidase. Superoxide dismutase. Debriding agents. Digestive aids.	Asparaginase. DNase. Glucocerebrosidase. A-galactosidase. Urate-oxidase. Laronidase. Superoxide dismutase. Debriding agents. Digestive aids.

LESSON SCHEDULE FOR THE SUBJECT FUNDAMENTALS OF HUMAN BIOCHEMISTRY

module	Sunday	type	method unit name	a teacher
1	1	L	Introduction to Pharmaceutical Biotechnology.	asst. prof. Isidora Milosavljevic
		P&P	Introduction to Pharmaceutical Biotechnology.	asst. prof. Isidora Milosavljevic
	2	L	Regulatory Issues in Biotechnology	asst. prof. Isidora Milosavljevic
		P&P	Regulatory Issues in Biotechnology	asst. prof. Isidora Milosavljevic
	3	L	Safety in Biotechnology	asst. prof. Isidora Milosavljevic
		P&P	Safety in Biotechnology	asst. prof. Isidora Milosavljevic
	4	L	Recombinant DNA technology	asst. prof. Isidora Milosavljevic
		P&P	Recombinant DNA technology	asst. prof. Isidora Milosavljevic

LESSON SCHEDULE FOR THE SUBJECT FUNDAMENTALS OF HUMAN BIOCHEMISTRY

module	Sunday	type	method unit name	a teacher
1	5	L	Production of therapeutic proteins	asst. prof. Isidora Milosavljevic
		P&P	Production of therapeutic proteins	asst. prof. Isidora Milosavljevic
2	6	L	Interferon biotechnology	asst. prof. Isidora Milosavljevic
		P&P	Interferon biotechnology	asst. prof. Isidora Milosavljevic
	7	L	Interleukin biotechnology	asst. prof. Isidora Milosavljevic
		P&P	Interleukin biotechnology	asst. prof. Isidora Milosavljevic
	8	L	Tumor necrosis factors biotechnology	asst. prof. Isidora Milosavljevic
		P&P	Tumor necrosis factors biotechnology	asst. prof. Isidora Milosavljevic

LESSON SCHEDULE FOR THE SUBJECT FUNDAMENTALS OF HUMAN BIOCHEMISTRY

module	Sunday	type	method unit name	a teacher
2	9	L	Hematopoietic growth factors biotechnology	asst. prof. Isidora Milosavljevic
		P&P	Hematopoietic growth factors biotechnology	asst. prof. Isidora Milosavljevic
	10	L	Growth factors biotechnology and wound healing	asst. prof. Isidora Milosavljevic
		P&P	Growth factors biotechnology and wound healing	asst. prof. Isidora Milosavljevic
3	11	L	Insulin and glucagon biotechnology	asst. prof. Isidora Milosavljevic
		P&P	Insulin and glucagon biotechnology	asst. prof. Isidora Milosavljevic
	12	L	Human growth hormones biotechnology	asst. prof. Isidora Milosavljevic
		P&P	Human growth hormones biotechnology	asst. prof. Isidora Milosavljevic

LESSON SCHEDULE FOR THE SUBJECT FUNDAMENTALS OF HUMAN BIOCHEMISTRY

module	Sunday	type	method unit name	a teacher
3	13	L	Recombinant blood products	asst. prof. Isidora Milosavljevic
		P&P	Recombinant blood products	asst. prof. Isidora Milosavljevic
	14	L	Biotechnology of anticoagulants and thrombolytic agents	asst. prof. Isidora Milosavljevic
		P&P	Biotechnology of anticoagulants and thrombolytic agents	asst. prof. Isidora Milosavljevic
	15	L	Biotechnology of enzymes with therapeutically values	asst. prof. Isidora Milosavljevic
		P&P	Biotechnology of enzymes with therapeutically values	asst. prof. Isidora Milosavljevic