Syllabus for discipline

«PHARMACEUTICAL BIOTECHNOLOGY»

1. General information	
Faculty	Pharmacy
Educational program	22 Healthcare, 226 Pharmacy, 2nd (master's) level of higher education, full-time study
Educational discipline, code	Pharmaceutical biotechnology, OK 41 http://new.meduniv.lviv.ua/
Department	Department of Drug Technology and Biopharmaceutics; 79010, Lviv, Pekarska str.,75 (032) 276-85-84, (032) 276-85-98, Kaf_biopharm@ meduniv.lviv.ua
Head of the depratment	Bilous Svitlana Bohdanivna, DSci, assoc. prof. svitlana.bilous@gmail.com
Academic year	5th
Semester	9th
Type of discipline	obligatory
Educators	Bilous S. B., DSci, assoc. prof. svitlana.bilous@gmail.com
Erasmus	No
Person responsible for syllabus	Bilous S. B., DSci, assoc. prof. svitlana.bilous@gmail.com
Number of credits ECTS	3 credits ECTS
Number of hours	Total – 90 h: lectures – 8 h; laboratory classes – 30 h; self-educational work – 52 h
Language of study	English
Information on consultations	Consultations are provided in accordance with schedule of consultations by the responsible educators

2. A brief review of the discipline

The discipline "Pharmaceutical Biotechnology" together with other pharmaceutical disciplines and social sciences plays an important role in providing special technological training for professional activities.

Discipline "Pharmaceutical Biotechnology", designed for higher education, provides theoretical knowledge and develops practical skills in the development and production of drugs by biotechnological methods, general requirements to biotechnological products of different groups, modern trends in pharmaceutical biotechnology.

The subject of the discipline is the main provisions and trends in the development of pharmaceutical biotechnology in Ukraine and the world; modern principles of production of medicines in various dosage forms with the use of biotechnology methods - microbial synthesis, cell technologies, methods of genetic engineering, the main modern types of equipment for biotechnological productions.

3. Purpose and objectives of the disicpline

The aim of discipline "Pharmaceutical Biotechnology" is the assimilation of higher education acquisitions of the main stages of the creation and production of medicinal products by biotechnological methods, general requirements for biotechnological medicines of various groups, modern directions of development of pharmaceutical biotechnology, environmental safety of biotechnology products, vaccines, hormones, immunomodulators, vitamins, vitamins, enzymes, probiotic, antibiotic and many other medical treatment preparations obtained using organisms-producers and other biobjects, which makes it possible to fully implement scientific and creative potential in future specialists.

The main tasks of studying the discipline "Pharmaceutical biotechnology" are:

- mastering the theoretical bases of biotechnological processes, means and methods for obtaining biologically active substances with the help of living objects and their enzyme systems;
- formation of higher education acquisitions for the practical use of biotechnological processes to obtain an industrial method of medicinal products used in various fields of medicine and pharmacy;
- assimilation of the methodology for creation, standardization, quality assessment and safety of medicines received by biotechnological methods based on general patterns of chemical-biological sciences to perform professional tasks of a specialist in pharmacy;
- formation of systematized knowledge on handling, storage, transportation, use of information on biotechnological preparations and providing information on these issues for patients.

According to the requirements of the Standard, discipline provides acquisition by students of competencies: general and professional.

General:

GC 2. Ability to apply knowledge in practical situations.

GC 3. The desire to preserve the environment.

GC 4. Ability to abstract thinking, analysis and synthesis, learn and be modern.

GC 6. Knowledge and understanding of the subject area and understanding of professional activity.

GC 7. Ability to adapt and action in a new situation.

GC 10. The ability to select a communication strategy, the ability to work in a team and experts from other branches of knowledge / types of economic activity.

GC 11. Ability to evaluate and provide quality of work performed.

GC 12. The ability to conduct research at the appropriate level.

Professional:

PC 1. The ability to carry out sanitary and educational work among the population for the purpose of prevention of common diseases, prevention of dangerous infectious, viral and parasitic diseases, as well as for the purpose of promoting timely detection and support of adherence to the treatment of these diseases according to their medico-biological characteristics and microbiological features.

PC 2. Ability to advise for prescription and non-recipient medicines and other products of pharmacy assortment; Pharmaceutical burns during the choice and implementation of a non-prescription drug by assessing the ratio of risk / benefits, compatibility, indications and contraindications guided by the state of health of a particular patient taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physical and chemical characteristics of the medicinal product and other products of pharmacy assortment.

PC 7. Ability to ensure proper storage of medicines and other products of pharmacy assortment in accordance with their physical and chemical properties and rules of proper storage practice (GSP) in health care facilities.

PC 12. The ability to use in professional activity of knowledge of normative legal, legislative acts of Ukraine and recommendations of proper pharmaceutical practices.

PC 13. The ability to demonstrate and apply in practical activities communicative communication skills, fundamental principles of pharmaceutical ethics and deontology, based on moral obligations and

values, ethical standards of professional behavior and responsibility in accordance with the Code of Ethics of Pharmaceutical Workers of Ukraine and WHO guidelines.
PC 15. The ability to organize and participate in the production of medicines in the conditions of pharmaceutical enterprises, including the choice and substantiation of the technological process, equipment in accordance with the requirements of proper production practices (GMP) with the relevant development and registration of the necessary documentation. To determine the stability of medicines
PC 18. The ability to develop and implement a system of quality management of pharmaceutical enterprises in accordance with the requirements of applicable standards, to audit the quality and risk management for the quality of pharmaceutical products.
PC 19. The ability to organize and monitor the quality of drugs in accordance with the requirements of the current State Pharmacopoeia of Ukraine and proper practices in pharmacy, to determine methods for sampling for drugs and to standardize in accordance with applicable requirements, preventing the propagation of falsified medicines.

4. Prerequisites of the disicpline

«Pharmaceutical biotechnology»:

- the discipline based on the study of biophysics, physical and physico-chemical methods of analysis; inorganic, analytical, biological, physical and colloidal chemistry; normal physiology; human anatomy; pathological physiology with the basics of pathological anatomy;
- summarizes the knowledge gained in the study of disciplines: drug technology, biochemistry, pharmacology, pharmacotherapy, etc;
- the discipline lays the foundations for the training of future specialists, promotes the formation of pharmaceutical and technical thinking;
- together with other pharmaceutical disciplines and social sciences, the discipline plays an important role in providing special training for professional activities.

5. Program learning outcomes

List of learning outcomes

Code of learning outcome	**Content of learning outcome**	**Reference to the code of the competency matrix**
** **Kn** – knowledge, **Ab** – ability, **Sk** – skills, **C** – competence, **AR** – autonomy and responsibility, **LO** – learning outcome*		
Kn-1	To have specialized conceptual knowledge acquired in the learning process	*LO-1, 4, 23*
Kn-2	To have deep knowledge of the structure of professional activity	*LO -2, 14, 15, 17*
Kn-3	To know ways for self-regulation, leading a healthy life	*LO -5, 6, 7*
Kn-4	To know the tactics and strategies of communication, laws and ways of communicative behavior	*LO -8, 9, 12*
Kn-5	To have advanced knowledge of native language and basic knowledge of foreign language	*LO -8*
Kn-6	To have deep knowledge in the field of information and communication technologies used in professional activities	*LO -12*
	To know the methods of analysis, synthesis and further modern learning	*LO -4,6*
Kn-7	To know methods for evaluation of work quality	*LO -9, 12, 17, 31*
Kn -8	To know the responsibilities and ways to accomplish the tasks	*LO -1, 22, 24*
Kn -9	To know the basics of the legal system and pharmaceutical legislation	*LO -3, 5*
Kn-10	To know the conditions in healthcare facilities of proper storage	*LO -24, 25*

	of medicines and other products of the pharmacy range in accordance with the physical and chemical properties and the rules of Good Storage Practice (GSP)	
Kn-11	To know the general principles of the organization of pharmaceutical supply of the population; basic mechanisms of state regulation of pharmaceutical activity	*LO -1, 24*
Kn-12	To know basic requirements of normative documents (orders, guidelines etc) regulating the development of medicines, preparation of technological douments	*LO -1, 9, 25*
Kn-13	To know the methods of determining the influence of the nature of excipients on the therapeutic efficacy of drugs by "in vitro" and "in vivo".	*LO -27, 31, 32*
Sk-1	To be able to solve complex issues and issues that arise in the professional activities	*LO -1, 4, 23*
Sk -2	Be able to carry out professional activity that requires updating and integrating of knowledge	*LO -2, 14, 15, 17*
Sk -3	To be able to apply methods of self-regulation, to be able to lead a healthy life and to adapt to new situations of life and activity	*LO -5, 6, 7*
Sk -4	To be able to choose ways and strategies of communication to ensure effective teamwork	*LO -8, 9, 12*
Sk -5	To be able to apply knowledge of the native language, both orally and in writing, to be able to communicate in a foreign language	*LO -8*
Sk -6	To be able to use information and communication technologies in the professional field, which requires updating and integration of knowledge	*LO -12*
Sk -7	To be able to analyze information, to make informed decisions, to be able to acquire modern knowledge	*LO -4,6*
Sk -8	To be able to ensure quality performance of the work	*LO -9, 12, 17, 31*
Sk -9	To be able to set goals and objectives, to be persistent and conscientious in the performance of responsibiliteis	*LO -1, 22, 24*
Sk -10	To be able to use laws and other normative documents that regulate pharmaceutical activity in Ukraine and abroad	*LO -3, 5*
Sk -11	To be able to create conditions in healthcare facilities for proper storage of medicines and other products in accordance with the physical and chemical properties and the rules of Good Storage Practice (GSP)	*LO -12, 24*
Sk -12	To be able to justify the use of prescription and OTC drug products and other products of the pharmaceutical assorment	*LO -14, 17*
Sk -13	To be able to apply the basic requirements of regulatory documents (orders, guidelines, etc.) for the development of drug products and design of technological documentation	*LO - 30,32*
C-1	To give the conclusions and explanations clearly and unambiguously to specialists and non-specialists	*LO -1, 4, 23*
C -2	To form effectively a communication strategy in the professional activities	*LO -2, 14, 15, 17*
C -3	To establish appropriate connections to achieve results	*LO -5, 6, 7*
C -4	To use communication strategies and interpersonal interaction	*LO -8, 9, 12*

	skills	
C -5	To use native language in the professional and business communications and for the preparation of documents	*LO -8*
C -6	To use foreign language in the professional activities	*LO -12*
C -7	To use information and communication technologies in the professional activities	*LO -4,6*
C -8	To establish connections for ensuring the quality work performance	*LO -9, 12, 17, 31*
C -9	To be able to convey one's public and social position	*LO -1, 22, 24*
C -10	To use knowledge of laws and other normative documents which regulate pharmaceutical activity in Ukraine and abroad	*LO -3, 5*
C -11	To carry out a constant monitoring of proper storage of medicines and other products in healthcare facilities in accordance with the physical and chemical properties and the rules of Good Storage Practice (GSP)	*LO -24*
C -12	To analyze use of prescription and OTC drug products and other products of the pharmaceutical assorment	*LO -14, 17*
C -13	To choose an optimal technological process for manufacturing drug products in different dosage forms	*LO -27*
AR-1	To be responsible for making decisions in difficult conditions	*LO -2, 6*
AR-2	To be responsible for professional development, ability to further professional training with a high level of autonomy	*LO -5,7*
AR-3	To be responsible for a healthy lifestyle and timely use of self-regulation methods	*LO -3*
AR-4	To be responsible for the choice and tactics of communication	*LO -8, 9, 12*
AR-5	To be responsible for fluent knowledge of the native language, and the development of professional knowledge	*LO -8, 10*
AR-6	To be responsible for the development of professional knowledge and skills	*LO -12*
AR-7	To be responsible for the timely gaining of modern knowledge	*LO -4,6*
AR-8	To be responsible for the quality performance of the work	*LO -9, 12, 17, 31*
AR-9	To be responsible for the quality performance of the tasks	*LO -1, 22, 24*
AR-10	To be responsible for the personal civil position and activities	*LO -3, 5*
AR-11	To be responsible for the quality and timely use of normative documents in the professional activities	*LO -24*
AR-12	To be responsible for the analysis of prescription and OTC drug products and other products of the pharmaceutical assorment	*LO -14, 17*
AR-13	To be responsible for compliance with Good Manufacturing Practice	*LO -27*

6. Mode and scope of the disicpline

Forma of the dicsipline	Full-time study	
Type of activity	Number of hours	Number of groups
lectures	8	
laboratory	30	
seminars	-	
self-educational	52	

work			
7. Topics and content of the disicpline			
Code of activity type	Topic	Learning content	Code of learning outcome
L-1 2 h	Pharmaceutical biotechnology as an integral part of biotechnology. Bioobjects and methods of biotechnology. The main stages of the biotechnological process	Biotechnology as a science, its goals and objectives. The structure of the world market of biotechnological drugs. The largest manufacturers and areas of their specialization in biotechnological drugs. Characteristics of traditional and modern methods of biotechnology. Functions of bioobjects. The concept of producers. The main stages of the biotechnological process. Preparatory operations for biosynthesis. Methods and stages of seed preparation. Methods of sterilization of equipment. Variety and characteristics of preparation of nutrient media for cultivation of producers	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9; C-1, C-2, C-5, C-7, C-9; AR-2, AR-4, AR-6, AR-9*
L-2 2 h	Biotechnological drugs obtained by microbial synthesis. Antibiotics, probiotics, bacteriophages and preparations of metabolites of microorganisms	Methods of obtaining antibiotics: chemical synthesis and biotechnological methods. Scheme of industrial production of antibiotics by microbial synthesis. Features of the process and factors of influence. Organisms are producers of antibiotics. Methods of obtaining active strains of producers. Types of nutrient media and requirements for them. Methods of separation of culture fluid from biomass, isolation of antibiotic from culture medium, purification and drying of the product. Obtaining a finished dosage form of an antibiotic. Quality indicators of antibiotics. Technological process of obtaining probiotic preparations in the form of dry and liquid dosage forms. Requirements for producer strains. Bacteriophages, their species. The mechanism of interaction with the microbial cell. Practical use of bacteriophages	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13; C-1, C-2, C-5, C-7, C-9, C-11; AR-2, AR-4, AR-6, AR-9, AR-11*
L-3 2 h	Immunobiological drugs (vaccines, serums, immunoglobulins) and blood products. General characteristics and technological aspects of obtaining	Subject and tasks of immunobiotechnology. Types of immunobiological drugs. Immunogenic drugs to create artificial active immunity. Classification of vaccines. The main stages of the technological process of making live, killed, antiviral vaccines, toxoids. Examples of vaccines. Immunogenic drugs that form artificial passive immunity. Types of sera. The main stages of the technological process of sera manufacuring. Immunoglobulins. The	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9; C-1, C-2, C-5, C-7, C-9; AR-2, AR-4, AR-6, AR-9*

		essence of immunoglobulin therapy.	
L-4 2 h	Biotechnological drugs obtained by methods of cell technology and genetic engineering	The concept of cell engineering, essence and practical use. Genetic engineering, its essence and practical use. Classification of blood products. Areas of application of blood products. Fractionation of blood into components. Blood plasma proteins. Types of blood components, their functions and application in clinical practice. A method of producing insulin using a recombinant microorganism. Technological scheme of production. Genetically engineered insulin preparations. Somatotropic hormone, characteristics, methods of production. Stages of genetic engineering method of hormone production. Stages of industrial production of somatotropin drug and its quality indicators. Dosage forms of somatotropin.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13; C-1, C-2, C-5, C-7, C-9, C-11; AR-2, AR-4, AR-6, AR-9, AR-11*
Lab-1 2 h	Pharmaceutical biotechnology as an integral part of biotechnology. Basic terms of pharmaceutical biotechnology	Definition of biotechnology. Basic methods of biotechnology. Biotechnology facilities. Types of drugs based on biological objects.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9; C-1, C-2, C-5, C-7, C-9; AR-2, AR-4, AR-6, AR-9*
Lab -2 2 h	Bioobjects and the main stages of the biotechnological process	Functions of bioobjects. The concept of producers. Requirements for producers of biologically active substances. Stages of the biotechnological process. Preparatory operations for biosynthesis. Methods and stages of seed preparation. Methods of sterilization of equipment. Variety and characteristics of nutrient media for cultivation of producers.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9; C-1, C-2, C-5, C-7, C-9; AR-2, AR-4, AR-6, AR-9*
Lab -3 2 h	Regulatory documents regulating the production of medicines by biotechnology methods	Regulatory documents governing the development and production of biotechnological drugs. Pharmacopoeia. Directive 2001/83/EC of November 2001 on the Community code relating to medicinal products for human use. Regulation (EC) No 1394/2007 on advanced therapy medicinal products.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9; C-1, C-2, C-5, C-7, C-9; AR-2, AR-4, AR-6, AR-9*
Lab-4 2 h	Biotechnological production of antibiotics	Methods of obtaining antibiotics: chemical synthesis and biotechnological methods. Scheme of industrial production of antibiotics by microbial synthesis. Features of the process and factors of influence. Organisms - producers of antibiotics. Types of nutrient media and requirements for them. Classification of antibiotics by the	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9; C-1, C-2, C-5, C-7, C-9; AR-2, AR-4, AR-6,*

		action on the bacterial cell. The main features that determine the specificity of antibiotics in comparison with some other products of organism's metabolites.	*AR-9*
Lab-5 4 h	Technology of probiotics and bacteriophages	Species composition of normal intestinal microflora in different periods of human life and its functions. Intestinal dysbacteriosis and conditions that contribute to its development. Fermented milk products and drugs based on live cultures of bifidobacteria and lactic acid bacteria (lactobacterin, bifidumbacterin, colibacterin and bificol). Types of probiotics. Prebiotics. Technological process of obtaining probiotic preparations in the form of dry and liquid dosage forms. General quality indicators of probiotics. Bacteriophages, their types. The mechanism of interaction with the microbial cell. Practical use of bacteriophages.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9;* *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk-11;* *C-1, C-2, K-5, K-7, K-9, K-11;* *AR-2, AR-4, AR-6, AR-7, AR-9, AR-11*
Lab-6 2 h	Biotechnological production of preparations of metabolites of microorganisms - amino acids and vitamins	Metabolites of microorganisms. Biological role of amino acids and their application in the pharmaceutical industry and as medicines. Microbiological synthesis of amino acids. Biological role of vitamins. Classification of vitamins. Vitamin B2 (riboflavin), the main producers. Vitamin B12, its producers, scheme and features of biosynthesis. Vitamin A, sources and producers of carotenoids. Scheme and features of β-carotene biosynthesis. Biotechnological production of ascorbic acid (vitamin C). Vitamins of group D. Obtaining of ergosterol - provitamin D2 in the cells of yeast and molds. Scheme and features of the technological process.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13;* *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13;* *C-1, C-2, C-5, C-7, C-9, C-11;* *AR-2, AR-4, AR-6, AR-9, AR-11*
Lab-7 2 h	Biotechnological production of enzymes	Classification of enzymes. Sources of enzymes. Areas of enzymes application in medicine. Production of enzymes by microbial synthesis. Advantages of microorganisms as enzyme producers. Technological process of obtaining enzymes by microbial synthesis.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9;* *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk-11;* *C-1, C-2, C-5, C-7, C-9, C-11;* *AR-2, AR-4, AR-6, AR-9, AR-11*
Lab-8 2 h	Biotechnological production of hormones	Hormones: definitions, properties, types of classifications. Methods of obtaining hormones. Hormones obtained by biotechnological methods. A method of producing human insulin using a recombinant microorganism. Technological scheme of production. Genetically	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13;* *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13;* *C-1, C-2, C-5, C-7, C-9, C-11;*

		engineered insulin preparations. Somatotropic hormone, characteristics, methods of production. Stages of genetic engineering method of hormone production. Stages of industrial production of somatotropic drug and its quality indicators. Dosage forms of somatotropin. Hormones produced by microbiological transformation: progestins, sex hormones and adrenal cortex hormones (corticosteroids).	*AR-2, AR-4, AR-6, AR-9, AR-11*
Lab 9-11 2 h	Immunobiological medicines. Vaccines. Serums. Immunoglobulins and diagnostics based on them	Types of immunity. Definitions of "antigens", "antibodies". Immunogenic drugs to create artificial active immunity. Classification of vaccines. The main stages of the technological process of production of live, killed, antiviral vaccines, toxoids. Examples of vaccines. Immunogenic drugs that form artificial passive immunity. Types of sera. The main stages of the technological process of serum production. Immunoglobulins. The essence of immunoglobulin therapy. Mechanisms of anti-infective action of immunoglobulins. Types of immunoglobulins.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13;* *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13;* *C-1, C-2, C-5, C-7, C-9, C-11;* *AR-2, AR-4, AR-6, AR-9, AR-11*
Lab 12-13 2 h	Production of blood products. Blood plasma. Blood plasma proteins	Liquids of the internal environment of the body. The concept of homeostasis. Blood composition. Fractionation of blood into components. Blood plasma proteins. Types of blood components, their functions and application in clinical practice. Classification of blood products. Areas of application of blood products. Methods of obtaining plasma. Types and properties of plasma preparations. Albumin, raw materials and production technology. Quality indicators. γ – Globulin: raw materials and production technology. Drugs of hemostatic action (blood clotting correctors), representatives, application. Fibrinolysin: raw materials, the essence of the method of production, stages of the technological process of production. Hemostatic agents for topical use. Raw materials, features of production technologies, the principle of hemostatic action. Technology of "Hematogen"obtaining, indications for use.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13;* *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13;* *C-1, C-2, C-5, C-7, C-9, C-11;* *AR-2, AR-4, AR-6, AR-9, AR-11*
Lab 14 2 h	Excipients obtained by biotechnological methods.	Excipients, main groups of excipients in drugs, their functions. Preservatives and surfactants, safety of their use. Excipients obtained by microbial synthesis.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13;* *Sk -1, Sk -2, Sk -6,*

	Antimicrobial preservatives and surfactants		*Sk -7, Sk -9, Sk -13; C-1, C-2, C-5, C-7, C-9, C-11; AR-2, AR-4, AR-6, AR-9, AR-11*
Lab 15 2 h	Biosimilars. Features of quality control methods of biotechnological medicines	Active substances of similar biological drugs, profiles of their efficiency and safety. Biosimilars. Immunogenicity of biotechnological drugs. Clinical studies of biosimilars as the only way to prove the similarity of two drugs by their effects.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13; C-1, C-2, C-5, C-7, C-9, C-11; AR-2, AR-4, AR-6, AR-9, AR-11*
S-E-1 5 h	Producers of biologically active substances, requirements for producers		*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13; C-1, C-2, C-5, C-7, C-9, C-11; AR-2, AR-4, AR-6, AR-9, AR-11*
S-E-2 6 h	Regulatory documents of pharmaceutical biotechnology		*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13; C-1, C-2, C-5, C-7, C-9, C-11; AR-2, AR-4, AR-6, AR-9, AR-11*
S-E-3 5 h	Cellular and genetic engineering, their essence and practical use		*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13; C-1, C-2, C-5, C-7, C-9, C-11; AR-2, AR-4, AR-6, AR-9, AR-11*
S-E-4 5 h	Classification of antibiotics by the nature of the action on the bacterial cell		*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13; Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13; C-1, C-2, C-5, C-7, C-9, C-11; AR-2, AR-4, AR-6, AR-9, AR-11*
S-E-5 5 h	Obtaining finished dosage forms of antibiotics. Quality parameters of antibiotics		*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9;*

		Kn-13; *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13;* *C-1, C-2, C-5, C-7, C-9, C-11;* *AR-2, AR-4, AR-6, AR-9, AR-11*
S-E-6 5 h	Species composition of normal intestinal microflora in different periods of human life and its functions	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13;* *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13;* *C-1, C-2, C-5, C-7, C-9, C-11;* *AR-2, AR-4, AR-6, AR-9, AR-11*
S-E-7 5 h	Biological role of vitamins, their classification and function	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13;* *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13;* *C-1, C-2, C-5, C-7, C-9, C-11;* *AR-2, AR-4, AR-6, AR-9, AR-11*
S-E-8 5 h	Hormones, types of their classifications and functions	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13;* *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13;* *C-1, C-2, C-5, C-7, C-9, C-11;* *AR-2, AR-4, AR-6, AR-9, AR-11*
S-E-9 5 h	Types of immunity. Immunogenic drugs for creation artificial active and passive immunity	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13;* *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13;* *C-1, C-2, C-5, C-7, C-9, C-11;* *AR-2, AR-4, AR-6, AR-9, AR-11*
S-E-10 6 h	Fluids of the internal environment of the body. Homeostasis. Blood composition.	*Kn -1, Kn -2, Kn -6, Kn -5, Kn -7, Kn -9; Kn-13;* *Sk -1, Sk -2, Sk -6, Sk -7, Sk -9, Sk -13;* *C-1, C-2, C-5, C-7, C-9, C-11;* *AR-2, AR-4, AR-6, AR-9, AR-11*

A multimedia presentation is used during lectures; guides with informtative material are used on laboratory classes, a list of literature sources for self-educational work is given.

8. Verification of learning outcomes			
Current control			
Code of learning outcome	Code of activity type	Method of the verification of learning outcomes	Evaluation criteria
Kn-1– Kn-13; Sk-1- Sk-13; C-1 – C-13; AR-1 –AR-13	*L-1 – L-5; S-1 – S-10; IW-1 – IW- 7*	Current control is carried out during the classes and it is aimed to check the comprehension of educational material by students. The form of the assessment of current educational activity is standardized and includes control of the theoretical preparation. The control of theoretical preparation is performed by the oral assessment and by the assessment of the abilities to solve situational tasks, while practical skills – by the assessment of the abilities to interpret the obtained results. Self-educational work of students is assessed during the current control of the topic in the relevant class.	The degree of student's knowledge is assessed during every class using a 4-point (national) scale. All types of activities provided by the discipline program are taken into consideration. A student receives a grade for each topic. Then this 4-point grade is converted into points using a multi-point (200-point) scale. *Evaluation criteria for current control.* *Excellent* ("5") – student gives correct, logical and full answers on the standardized questions on the topic, including the material from lectures and independent work. Student can solve situational tasks. *Good* ("4") – student gives correct and logical answers on the standardized questions on the topic, including the material from lectures and independent work. Student can solve situational tasks with simple and moderate degree of complexity. *Satisfactory* ("3") – student gives incomplete answers on standardized questions on the topic, required additional questions to complete the answer. Student cannot give a clear and logical answer, makes mistakes. Student has only the required minimum of theoretical knowledge. *Fail* ("2") – student does not know material on the topic, cannot give logical answer, doesnot understand the topic.
Final control			
General system of	Form of final control is a credit		

evaluation		
Evaluation scales	Traditional 4-graded scale, multipoint (200-point) scale, rating ECTS scale	
Criteria to be allowed for final control	Students who have completed the all types of activities provided by the program and scored for current educational activity not less than minimum.	
Type of final control	Procedure of final control	Evaluation criteria
Credit	Student is required to pass all topics of the current control. Grades from the 4-point scale are converted into points on a multi-point (200-point) scale in accordance with the Regulation "Criteria, rules and procedures for evaluating the results of students' learning activities."	*Maximum score* that student can get is 200 points, m*inimum score* – 120. Points for discipline are then converted in traditional 4-graded scale using absolute criteria.

9. Policy of the dicipline

To organize the educational process, students, educators and administration act in accordance with:

- Regulations on the organization of the educational process (https://cutt.ly/3ySk64r);
- Regulations on the criteria and rules for evaluation (https://cutt.ly/lySlyw0);
- Regulations on academic integrity (https://cutt.ly/EySkNHu)

10. Literature

Required

1. Державна фармакопея України : в 3 т. / ДП “Український науковий фармакопейний центр якості лікарських засобів”. – 2-е вид. – Харків : Державне підприємство “ Український науковий фармакопейний центр якості лікарських засобів ”, 2015. – Т.1. – 1128 с.
2. Доклінічне вивчення безпеки лікарських засобів біотехнологічного походження (методичні рекомендації), схвалені на засіданні Науково-експертної ради Державного експертного центру МОЗ. – К., 2011. – 32 с.
3. Особливості біологічних/біотехнологічних продуктів та біосимілярів (методичні рекомендації), схвалені на засіданні Науково-експертної ради Державного експертного центру МОЗ (протокол N 03 від 29.03.2013 р.). – К., 2013. - 38 с.;
4. Подібні біологічні препарати, що містять як активні речовини протеїни, отримані біотехнологічним шляхом. СТ-Н МОЗУ 42-8.0:2013. – Київ, 2013. – 27 с.
5. Про лікарські засоби: закон України № 123/96-ВР від 04.04.1996 р. – К., 1996. – 37 с. – Режим доступу : http://zakon0.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80
6. Сидоров Ю.І. Процеси і апарати мікробіологічної та фармацевтичної промисловості: навчальний посібник. / Ю.І.Сидоров, Р.Й. Влязло. В.П.Новіков. – Львів: Інтелект-Захід, 2008. – 736 с.
7. Технологія ліків промислового виробництва: підручник для студ. вищ. навч. закл.: в 2-х ч. / В.І. Чуєшов, Є.В. Гладух, І.В. Сайко та ін. - 2-е вид., перероб і доп. - Х.: НФАУ. - 2 ч. - 638 с.
8. Фармацевтическая биотехнология: Аспекты фармацевтической химии: учеб. Пособие / Ю.М.Красновольский, О. В. Звягинцева. – Харьков : НТУ «ХПИ», 2018. – 248 с.
9. Фармацевтична розробка біотехнологічних та біологічних продуктів. СТ-Н МОЗУ 42-8.1:2013. – Київ, 2013. – 20 с.
10. Regulation (EC) No 1394/2007 of the Europian parliament and of the counsil of 13 November

2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004. Available at: http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2007_1394/reg_2007_1394_en.pdf

Additional

11. Біотехнологія: Підручник / В.Г. Герасименко, М.О. Герасименко, М.І. Цвіліховський та ін.; Під ред. В.Г. Герасименка. — К.: «ІНКОС», 2006. — 647 с.
12. Физико-химические основы биотехнологии. Биокинетика: учеб. пособие / А. Н. Огурцов, О. Н. Близнюк. – Харьков : НТУ «ХПИ», 2017. – 368 с.
13. Актуальные проблемы биотехнологии и биоинженерии / под ред. А. Н. Огурцова. – Харьков : «Типография Мадрид», 2019. – 240 с.
14. Фармацевтична енциклопедія / Голова ред. ради та автор передмови В.П.Черних. – 3-тє вид. – К.: «МОРІОН», 2016. – 1952 с.
15. Фармацевтичні та медико-біологічні аспекти ліків. Навчальний посібник / За ред. І.М.Перцева . - Видання друге. – Вінниця: НОВА КНИГА, 2007. – 728 с.
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18. Encyclopedia of pharmaceutical technology. Third Edition. / Edited by J. Swarbick. - New York, London: Informa healthcare, 2007 – 1171 p.
19. Guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins, EMEA/CHMP/BMWP/14327/2006. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline

Information sources

20. Офіційний сайт Міністерства охорони здоров'я України: www.moz.gov.ua.
21. Компендиум: лекарственные препараты: − [Електроний ресурс]. – Режим доступу: http://compendium.com.ua/.
22. Державний реєстр лікарських засобів України. − [Електроний ресурс]. – Режим доступу: http://www.drlz.com.ua/.
23. Щотижневик Аптека: https://www.apteka.ua/

11. Equipment, material, technical, and software support of the dicipline

Computer and multimedia projector; educational materials and guides

12. Additional information

Responsible person for the educational process at the Department – Yakymiv O.V., PhD, assoc.prof., e-mail: olga_yakymiv@ukr.net.

It is organized a student scientific group at the Department (scientific advisor - Vashchenko O.O., PhD, assoc.prof., e-mail: o_vashchenko@ukr.net) that is focused on the development of medicinal and cosmetic products.

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