Syllabus for elective discipline

«World pharmaceutical industry»

1. General information	
Faculty	Pharmacy
Educational program	22 Healthcare, 226 Pharmacy, 2nd (master's) level of higher education, full-time study
Educational discipline, code	World Pharmaceutical Industry, ВБ-1.28 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	3rd
Semester	5th
Type of discipline	elective
Educators	Vashchenko O.O, PhD, assoc.prof., o_vashchenko@ukr.net Strus O.Ye., DSci, assoc.prof., oxana.strus@ukr.net
Erasmus	No
Person responsible for syllabus	Vashchenko K.F., PhD, assoc.prof., vkf.07@ukr.net
Number of credits ECTS	2
Number of hours	Total – 60 h: lections – 10 h; seminars – 20 h; independent work of students – 30 h
Language of instruction	English
Information on consultations	Consultations are provided in accordance with schedule of consultations by the responsible educators

2. A brief review of the disicpline

The elective discipline "World Pharmaceutical Industry" belongs to the cycle of disciplines of the professionally-oriented training of specialists in the specialty "Pharmacy, Industrial Pharmacy" and consists of 1 content module.

The elective discipline «World pharmaceutical industry» is designed for higher full-time education graduates and provides theoretical knowledge about the basic stages of the formation and development of pharmaceutical technology in Ukraine and the world, the current trends of the pharmaceutical industry development, and the general requirements for the manufacturing of various pharmaceutical groups of drugs.

3. Purpose and objectives of the disicpline

The aim of the elective discipline "World pharmaceutical industry" is gaining the theoretical bases of the pharmaceutical industry formation in Ukraine and in the world, the stages of the development of new drug products, organization of medicines production in pharmaceutical enterprises with considerations of the requirements of good manufacturing practice; gaining the knowledge of characteristics, classification and assortment of dosage forms, which gives the opportunity to realize more the scientific and creative potential of futur specialists.

The main objectives of learning the elective discipline "World Pharmaceutical Industry" are:

- familiarization with stages of the pharmaceutical industry development in Ukraine and in the

world;

- gaining the basic knowledge about the characteristics and classification of drug products, main stages of the development and standardization;
- acquisition with the requirements of current normative documents regulating the organization of masnufacturing in pharmaceutical enterprises;
- acquisition with the organization of manufacture of drug products in accordance with the requirements of Good Manufacturing Practice (GMP);
- using laws and other normative documents regulating the manufacture of drug products in the professional activity.

According to the Standard of Higher Education, the discipline provides gaining the following **competencies**: integrative and professional.

Integrative:

- the ability to solve typical and complex specialized tasks and practical issues in the professional pharmaceutical practice using statements, theories and methods of fundamental, chemical, technological, biomedical and social-economic sciences;
- ability to integrate knowledge and solve complex issues, to formulate judgments in case of insufficient or limited information;
- to present clearly and unambiguously conclusions and knowledge, justifying in a wise way to the professional and non-professional audience.

General:

- The ability to act in socially and civil responsible manner.
- The ability to use knowledge in practical situations.
- The desire to maintain the environment.
- The ability for abstract thinking, analysis and synthesis, ability to study and to be modernly trained.
- The ability to show initiative and entrepreneurship.
- The knowing and understanding of subject field and the understanding of profession.
- The ability to adapt and act in a new situation.
- The ability to communicate in the native language in both spoken and written ways. The ability to communicate in other language that provides an effective professional activity.
- The ability to use information and communication technologies.
- The ability to choose communication strategy, to work in team and with experts from other fields of knowledge / types of economic activity.
- The ability to evaluate and ensure quality of performed work.
- The ability to conduct investigations on an appropriate level.
- The ability to realize the rights and responsibilities as a member of society, to understand the value of civil (independent democratic) society and the necessity for its stable growth, to understand the rule of law, civil and human rights and liberties in Ukraine.

Specific (professional, objective):

- The ability to use knowledge of laws and regulations and the recommendations of good pharmaceutical practices in the professional activities.
- The ability to demonstrate and apply communication skills in the professional activities, fundamental principles of pharmaceutical ethics and deontology, which are based on moral obligations and values, ethical standards of professional behavior and responsibility in accordance with the Code of Ethics for Pharmaceutical Workers of Ukraine and WHO guidelines

4. Prerequisites of the disicpline

The elective discipline ***« World pharmaceutical industry»***:

- it is based on the learning the history of pharmacy and medicine, pharmaceutical informatics and statistics;

- It gives the foundations for learning the industrial technology of drugs, good pharmaceutical practices, management and marketing in pharmacy, which involves the integration of teaching with the mentioned disciplines to develop skills to apply knowledge in further education process and 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*
Kn-7	To know the methods of analysis, synthesis and further modern learning To know methods for evaluation of work quality	*LO -4,6*
Kn -8	To know the responsibilities and ways to accomplish the tasks	*LO -9, 12, 17, 31*
Kn -9	To know the basics of the legal system and pharmaceutical legislation	*LO -1, 22, 24*
Kn-10		*LO -3, 5*
Kn-11	To know the conditions in healthcare facilities of proper storage 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)	*LO -24, 25* *LO -1, 24*
Kn-12	To know the general principles of the organization of pharmaceutical supply of the population; basic mechanisms of state regulation of pharmaceutical activity	*LO -1, 9, 25*
Kn-13	To know basic requirements of normative documents (orders, guidelines etc) regulating the development of medicines, preparation of technological douments	
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	*LO -12*

	of knowledge	
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 skills	*LO -8, 9, 12*
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 *AR-8* *AR-9* *AR-10* *AR-11* *AR-12* *AR-13*	To be responsible for the timely gaining of modern knowledge To be responsible for the quality performance of the work To be responsible for the quality performance of the tasks To be responsible for the personal civil position and activities To be responsible for the quality and timely use of normative documents in the professional activities To be responsible for the analysis of prescription and OTC drug products and other products of the pharmaceutical assorment To be responsible for compliance with Good Manufacturing Practice	*LO -4,6* *LO -9, 12, 17, 31* *LO -1, 22, 24* *LO -3, 5* *LO -24* *LO -14, 17* *LO -27*

6. Mode and scope of the disicpline

Forma of the dicsipline	Full-time study	
Type of activity	Number of hours	Number of hours
lections	10	
practical	-	
seminars	20	
independent	30	

7. Topics and content of the disicpline

Code of activity type	Topic	Learning content	Code of learning outcome
L-1 2 h	Historical aspects of pharmaceutical industry formation	Characteristics of the main stages of development of the industrial production. Factors influenced the development of the pharmaceutical industry at the initial stages in different countries. Characteristics of leading pharmaceutical companies	*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	Current state of the world pharmaceutical industry and factors influencing pharmaceutical industry development	Characteristics of the current world pharmaceutical industry. Factors contributing to the growth of the pharmaceutical market. Biosimilars. Characteristics of the top 10 largest pharmaceutical companies in the world today	*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	Organization of pharmaceutical manufacture, normative and technical documents regulating pharmaceutical production	Characteristics of the pharmaceutical industry. The main objects of the pharmaceutical industry. The objectives of organizing the pharmaceutical production. Structure of pharmaceutical companies. Pharmaceutical regulation and legislation. Basic normative and technical documentation for pharmaceutical production	*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-4 2 h	Classification of drug products. Basic stages in the development of new drug products	Classification of medicial preparations. Classification and characteristics of dosage forms. Characteristics of modern dosage forms - prolonged, modified and controlled released. Basic stages in the development of new drug products	*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-5 2 год	Preclinical and clinical studies of new drug products	The main documents regulating the introduction of drug products into the market. GLP principles. The procedure ofpreclinical studies of medicines, the requirements for the conditions of individual studies. Stages of preclinical research. Clinical studies. Stages of clinical trials	*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, K-4, K-5, K-7, K-10, AR-2, AR-4, AR-5 AR-6, AR-7, AR-10*
S-1 2 h	Pharmaceutical industry. Basic terms and concepts	Development directions of the modern pharmaceutical industry. Characteristics of the initial period of industrial production development. Factors influenced the development of the pharmaceutical industry in the initial stages in different countries. Types of documentation regulating the pharmaceutical production at the state level	*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*
S-2 2 h	Stages of pharmaceutical industry development	Characteristics of the stages of development of the pharmaceutical industry. The effect of certain drugs (thalidomide) uses on requirements to the development of medicines. History of production of the first medicinal "blockbuster". The main trends in the modern pharmaceutical industry. Historical aspects of the development of leading pharmaceutical companies	*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*
S-3 2 h	Current state and development trends of pharmaceutical industry	Pharmaceutical market. Factors influencing the development of the pharmaceutical market. Types of pharmaceutical markets. Globalization as a direction of development of the world pharmaceutical industry. Successes of development of the world pharmaceutical industry. The pharmaceutical industry in Ukraine. The latest diagnostic systems and drugs. Definitions and types	*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*
S-4 2 h	Social and geographic aspects of the development of world pharmaceutical industry	The influence of social and economic factors on the development of the world pharmaceutical industry. Geographical and demographic factors influencing the development of the global pharmaceutical industry. Prospects and directions of development of the world pharmaceutical industry. Prospects and directions of	*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,*

		development of the pharmaceutical industry in Ukraine. The influence of the country on the development of the pharmaceutical industry	*AR-9*
S-5-6 4 h	Pharmacopoeia as a main legislative document of the manufacture and quality control of drug products	State Pharmacopoeia of Ukraine (SPhU) as a legal document, definitions, basic requirements. Historical aspects of the SPhU development. The basic principles in the SPhU. The structure of the first and second editions of the SPhU. Characteristics of general monographs on drug products. Analysis of the structure of the pharmacopoeial article	*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*
S-7 2 h	Pharmaceutical development. Regulatory documents	Stages of the medicine life cycle. Pharmaceutical development, definitions and approaches. The main objects of pharmaceutical development. Normative documents regulating the pharmaceutical development. Purpose and stages of pharmaceutical development. Types of excipients. General requirements for the selection of excipients	*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-8 2 h	Preclinical and clinical studies of new drug products	The main documents regulating the introduction of drug products into the market. Good laboratory practice. Basic principles of good laboratory practice. The procedure of preclinical studies, the requirements for the conditions of individual studies. Stages of the preclinical studies. Clinical studies. Stages of clinical trials	*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*
S-9 2 h	Development of new drug products	Modern technologies in the development of new drug products. The main stages and methodological approaches to the discovery of medicinal substances. Preliminary stage of the pharmaceutical development. Therapeutic target Definition, properties. Characteristics of the stages of identification and validation of target. Development of medicines. Search for a leader compound. Preliminary tests for drug safety. Optimization of the leader compound. Preliminary clinical trials. Registration of new medicines and production.	*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-10 2 h	The European vector for the Ukrainian pharmaceutical industry	Characteristics of the European pharmaceutical market. Leaders of the European pharmaceutical market. The main directions of development of the pharmaceutical industry of European countries. Requirements for the development of medicines in the countries	*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;*

		of the European Union. State registration of medicines in the countries of the European Union. State registration of medicines in Ukraine. The main stages of the process of European integration of the Ukrainian pharmaceutical industry.	*AR-2, AR-4, AR-6, AR-9, AR-11*
IW-1 6 h	Common principles of organization of pharmaceutical manufacture		*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*
IW-2 6 h	Concepts of good practices in pharmaceutical industry		*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*
IW-3 6 h	Normative regulation of quality assurance of drug products		*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*
IW-4 6 h	Role and functions of the International Pharmacopoeia		*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*
IW-5 6 h	Brand and generic drugs. Characteristics and registration features		*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*

IW-6 6 h	Biosimilars – clinical and regulatory aspects	*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*
IW-7 6 h	Postmarket studies of medicines	*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*
IW-8 6 h	Specific features of the world market of pharmaceutical products	*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*
IW-9 6 h	Trends in the development of pharmaceutical industry in the world	*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*
IW-10 6 h	The influence of epidemics on the pharmaceutical industry	*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 materiali are used on seminars, a list of literature sources for independent 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. Independent work of students is assessed during the current control of the topic in the relevant class.	*Evaluation criteria for current control.* 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. *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 evaluation	Form of final control is a credit		
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. Биофармация: Учеб. для студ. фармац. вузов и фак. / Тихонов А.И., Ярных Т.Г., Зупанец И.А. и др. / Под ред. Тихонова А.И. – Х.: Изд-во НФаУ; Золотые страницы, 2003. – 240 с.
2. Богатирьова Є.В. Історія фармації України / Є.В. Богатирьова, Ю.П. Сніжанко, В.П. Черних та ін. – Х., 1999. – 322 с.
3. Державна Фармакопея України. – Х.: РІРЕГ, 2001. – 556 с.; Доповнення 1, 2004. – 520 с.; Доповнення 2, 2008. – 617 с.; Доповнення 3, 2009. – 280 с.; Доповнення 4, 2011. – 540 с.
4. Державна Фармакопея України / Державне підприємство «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.; Т.2 , 2015. - 724 с.; Т.3, 2015. – 732 с.
5. Про лікарські засоби: закон України від 4.04.96 № 123/96 // Відомості Верховної Ради України. – 1996. – № 123.
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4. Компендиум: лекарственные препараты: − [Електроний ресурс]. – Режим доступу: http://compendium.com.ua/.

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

Computer and multimedia projector; educational materials and guides

12. Additional information

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