

**Danylo Halytsky Lviv National Medical University**  
**Department of Pharmaceutical, Organic and Bioorganic chemistry**

**SYLLABUS FOR ELECTIVE COURSE**  
**“Control Quality of Drugs”**

**Second (master's) educational level**  
**Field: 22 " Healthcare "**  
**Specialty 226 " Pharmacy, industrial pharmacy"**

<b>1. General information</b>	
<b>Faculty</b>	Pharmaceutical
<b>Program</b>	22 Healthcare, 226 Pharmacy, industrial pharmacy the second (master's) level, full-time
<b>Academic year</b>	2021/2022
<b>Subject</b>	Control Quality of Drugs, ББ 1.38, <a href="mailto:Kaf_pharmchemistry@meduniv.lviv.ua">Kaf_pharmchemistry@meduniv.lviv.ua</a>
<b>Department</b>	Department Pharmaceutical, Organic and Bioorganic chemistry Pekarska 69, Lviv, Tel. +38(032)275-59-66, 275-59-77, 278-64-34 <a href="mailto:Kaf_pharmchemistry@meduniv.lviv.ua">Kaf_pharmchemistry@meduniv.lviv.ua</a>
<b>Head of Department</b>	Lesyk Roman, Doctor of Science, Professor <a href="mailto:roman.lesyk@gmail.com">roman.lesyk@gmail.com</a>
<b>Year of study</b>	4
<b>Semester</b>	7
<b>Type of course / module</b>	Compulsory
<b>Academic staff</b>	Andrii Lozynskyi, PhD, Associate Professor, <a href="mailto:lozynskyiandrii@gmail.com">lozynskyiandrii@gmail.com</a> Golota Sergii, PhD, Associate Professor, <a href="mailto:golota.serg@gmail.com">golota.serg@gmail.com</a>
<b>Erasmus yes/no</b>	No
<b>The person responsible for the syllabus</b>	Andrii Lozynskyi, PhD, Associate Professor, <a href="mailto:lozynskyiandrii@gmail.com">lozynskyiandrii@gmail.com</a>
<b>Number of credits ECTS</b>	3
<b>Number of hours</b>	90 (Lectures – 20 hours, Practical classes – 30 hours, Out of class work – 40 hours)
<b>Language of study</b>	English
<b>Information about consultations</b>	On schedule
Address, telephone and regulations of the clinical base, office ... (if necessary)	-
<b>2. Short annotation to the course</b>	
<p>The elective course "Control Quality of Drugs " belongs to the obligatory disciplines of the cycle of professionally-oriented training of specialists in the specialty "Pharmacy". Control Quality of Drugs, as a science based on the general laws of chemical sciences, studies the methods of production and creation, structure, chemical and physical properties of drugs, the relationship between chemical structure and action on the body, methods of quality control and changes occurring in storage. The elective course "Control Quality of Drugs" is the basis for the study of medicines, understanding of their action and practical activities of specialists in pharmaceutical specialties.</p>	
<b>3. The purpose and objectives of the course</b>	
<p><b>1. Objectives of teaching of the " Control Quality of Drugs" course are:</b></p> <ul style="list-style-type: none"> <li>- mastering of regularity of chemical properties of drugs based on their structure; understanding of biochemical processes that occur in biological systems;</li> <li>- be familiar with basic methods of drug synthesis as the basis for new biologically active substances creation;</li> <li>- gaining practical skills that will be helpful to learn the standardization techniques and drug quality control;</li> <li>- disclosure of organic chemistry practical aspects, methods and ways of usage of its achievements in the pharmaceutical practice.</li> </ul> <p><b>2. The purpose of the " Control Quality of Drugs " course are:</b></p>	

- to teach students the general principles of evaluation of the chemical properties of drugs, underlying the synthesis and analysis of pharmaceutical substances;
- to reveal of pharmaceutical chemistry practical aspects, the ways and methods of use its achievements in the pharmaceutical practice.

### **3. Competences and learning outcomes, the formation of which provides the study of the discipline.**

3K – General competencies, ФК – Special responsibility, ППН – Program learning outcomes

General competencies:

3K 1. The ability to act socially responsible and civic conscious.

3K 2. The ability to apply knowledge in practical situations.

3K 3. The striving to save the environment.

3K 4. The ability to abstract thinking, analysis and synthesis; the ability to study and to be trained up-to date

3K 6. Knowledge and understanding of the subject area and comprehension of the profession.

3K 8. Ability to communicate in the state language both orally and in writing, the ability to communicate in a foreign language (mostly English) at a level that ensures effective professional activity.

3K 9. Skills in the use of information and communication technologies.

3K 10. Ability to choose communication strategies, ability to work in a team and with experts from other fields of knowledge / types of economic activity.

3K 11. Ability to assess and ensure the quality of performed work.

3K 12. Ability to perform research at the appropriate level.

3K 14. Ability to preserve and increase moral, cultural, scientific values and achievements of society based on understanding the history and patterns of development of the subject area, its place in the general system of knowledge about nature and society and in the development of society, techniques and technologies. active recreation and a healthy lifestyle.

Special responsibility:

ФК 1. Ability to conduct health education among the population to prevent common diseases, prevent dangerous infectious, viral and parasitic diseases, as well as to facilitate the timely detection and maintenance of adherence to treatment of these diseases in accordance with their medical and biological characteristics and microbiological characteristics.

ФК 2. Ability to provide advice on prescription and over-the-counter drugs and other pharmaceutical products; pharmaceutical care during the selection and sale of over-the-counter drugs by assessing the risk / benefit, compatibility, indications and contraindications based on data on the health of a particular patient, taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical characteristics of the drug and other pharmaceutical products.

ФК 4. Ability to ensure the rational use of prescription and over-the-counter drugs and other pharmaceutical products in accordance with the physicochemical, pharmacological characteristics, biochemical, pathophysiological features of a particular disease and pharmacotherapeutic regimens for its treatment.

ФК 6. Ability to identify drugs, xenobiotics, toxins and their metabolites in body fluids and tissues, to conduct chemical and toxicological studies to diagnose acute poisoning, drug and alcohol intoxication.

ФК 7. Ability to ensure proper storage of medicines and other products of the pharmacy range in accordance with their physicochemical properties and the rules of Good Storage Practice (GSP) in health care facilities.

ФК 19. Ability to organize and control the quality of medicines in accordance with the requirements of the current State Pharmacopoeia of Ukraine and good practices in pharmacy, determine methods of sampling for control of medicines and standardize them in accordance with current requirements, prevent the spread of counterfeit medicines.

ФК 20. Ability to develop methods for quality control of medicines, including active pharmaceutical ingredients, medicinal plant raw materials and excipients using physical, chemical, physicochemical, biological, microbiological, pharmacotechnological and pharmacoeconomic control methods.

Program learning outcomes:

ППН 2. To apply knowledge of general and professional disciplines in professional activities;

ППН 3. To follow to the rules of sanitary-hygienic regime and safety requirements when carrying out professional activities;

ППН 4. To use the results of independent search, analysis and synthesis of information from various

sources for solving typical tasks of professional activity;

ІІPH 5. Propose their professional activity and personal qualities in the pharmaceutical labor market; to formulate the purposes of own activity taking into account public and industrial interests.

ІІPH 8. Carry out professional communication in the state language, use the skills of oral communication in a foreign language, analyzing texts of professional orientation and translate foreign language information sources.

ІІPH 9. Carry out professional activities using information technology, "Information Databases", navigation systems, Internet resources, software and other information and communication technologies.

ІІPH 10. To follow the norms of communication in professional interaction with colleagues, management, consumers, to work efficiently in a team.

ІІPH 12. Analyze the information obtained as a result of scientific research, summarize, systematize and use it in professional activities.

ІІPH 13. Carry out sanitary-educational work in professional activity in case of outbreaks of infectious, viral and parasitic diseases.

ІІPH 14. To determine the advantages and disadvantages of drugs of different pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic and pharmacodynamic features. To recommend to consumers over-the-counter medicines and other products of the pharmacy range with the provision of counseling and pharmaceutical care.

ІІPH 16. To determine the influence of factors influencing the processes of absorption, distribution, deposition, metabolism and excretion of the drug and due to the condition, features of the human body and physicochemical properties of drugs.

PRN 17. Use data from clinical, laboratory and instrumental studies to monitor the effectiveness and safety of drugs.

ІІPH 30. Ensure quality control of medicines and document its results. Manage quality risks at all stages of the life cycle of medicines.

ІІPH 32. To determine the main organoleptic, physical, chemical, physicochemical and pharmacotechnological properties of medicines, to substantiate and choose methods of their standardization, to carry out statistical processing of results in accordance with the requirements of the current State Pharmacopoeia of Ukraine.

#### 4. Pre-details of the course

Basic knowledge and learning outcomes are based on the study of the chemical structure of drugs, their physical and chemical properties; the relationship between chemical structure and action on the body, methods of quality control and changes that occur during storage and metabolism, as well as methods of production and purification of drugs, biologically active compounds and their metabolites.

Interdisciplinary links: general and inorganic chemistry, organic and bioorganic chemistry, analytical chemistry, biophysics, biology, biological chemistry, normal physiology, pathological physiology, pharmacology, toxicological chemistry, pharmacognosy, drug technology, clinical pharmacy, drug standardization.

#### 5. Program learning outcomes

##### List of learning outcomes

Learning outcome code	The content of the learning outcome	Reference to the code of the competence matrix
3H – Knowledges УМ – skills AB – independence and responsibility K – competence		ІІPH – program learning outcomes
3H-1	basic principles of classification, nomenclature, structural and spatial isomerism of drugs	ІІPH 1, ІІPH 3, ІІPH 5, ІІPH 8, ІІPH 9
3H-2	types of chemical bonds, conjugate systems, electronic effects, acidity and basicity of pharmaceutical substances as a basic basis of their reactivity	ІІPH 2, ІІPH 12
3H-3	principles of classification of drugs according to the direction, method	ІІPH 2, ІІPH 12

	of bond disconnection and mechanism of their course	
3H-4	structure, nomenclature, isomerism, chemical properties and biological role of drugs	ППН 4, ППН 12, ППН 13, ППН 14, ППН 16, ППН 17, ППН 30, ППН 32
3H-5	names and purpose of chemical and laboratory equipment	ППН 32
УМ-1	use chemical and reference literature, work with tabular and graphic data	ППН 4, ППН 9
УМ-2	to make separate laboratory installations	ППН 30, ППН 32
УМ-3	purify liquid and solid pharmaceutical compounds, establish their purity	ППН 30, ППН 32
УМ-4	determine the physical constants of drugs	ППН 17, ППН 30, ППН 32
УМ-5	to conduct elemental analysis	ППН 14, ППН 17, ППН 30, ППН 32
УМ-6	use laboratory methods of obtaining individual drugs	ППН 30, ППН 32
УМ-7	to carry out qualitative reactions to multiple bonds and the main functional groups;	ППН 10, ППН 30, ППН 32
УМ-8	independently carry out the synthesis and analysis of the proposed drugs	ППН 10, ППН 30, ППН 32
К-1	have a scientific worldview and creative thinking	ППН 12
К-2	have information management skills	ППН 9
АВ-1	have the ability to critically evaluate the results of their own research	ППН 12
АВ-2	be able to improve their own learning	ППН 4
АВ-3	be able to learn new areas through self-study, using the acquired knowledge of organic chemistry	ППН 4

<b>6. Format and scope of the course</b>				
<b>Format of the course</b>		Full-time course		
Type of lessons		Number of hours	Number of groups	
lectures		20	2	
practical		30	1	
seminars		-	-	
out of class work		40	2	
<b>7. Topics and content of the course</b>				
Class type code	Topic	Content of training	Code of result of training	Academic staff
Л – lecture, П – practical class, CPC – out of class work				
Л-1	Modern methods of pharmaceutical	To acquaint students with the modern methods of pharmaceutical analysis and tasks	3H-1 3H-2 УМ-1	Andrii Lozynskyi, PhD, Associate Professor, Golota

	analysis, its specific features and main criteria. Ways to establish the quality of medicines. Testing for the maximum content of impurities by HFC.	of control quality of medicines, the system of quality assessment of medicines.	K-1 K-2	Sergii, PhD, Associate Professor
Л-2	Reactions for identification of multicomponent drugs by cations and anions.	To acquaint students with reactions for identification of multicomponent drugs by cations and anions s.	ЗН-1 ЗН-3 ЗН-5 УМ-2 УМ-3 УМ-4 УМ-5 УМ-8	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
Л-3	Identification reactions of multicomponent drugs by analytical-functional groups.	To acquaint students with the identification reactions of multicomponent drugs by analytical-functional groups.	ЗН-1 ЗН-4 УМ-6 УМ-7	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
Л-4	Quality control of unstable drugs and dosage forms and perishable drugs.	To acquaint students with the quality control of unstable drugs and dosage forms and perishable drugs.	ЗН-1 ЗН-4 УМ-6	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
Л-5	Quality control of medicines in pharmacies. Regulatory documentation governing the quality control of medicines. Express analysis of dosage forms. Quality control of drugs of intrapharmacy production. Quality control of concentrated solutions, powder dosage mixtures, liquid dosage forms,	To acquaint students with the quality control of medicines in pharmacies and regulatory documentation governing the quality control of medicines.	ЗН-1 ЗН-4 УМ-6	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor

	eye drops containing inorganic and organic drugs, injectable solutions of pharmacy production, drugs of ointment consistency, determination of homogeneity of ointments, their qualitative and quantitative quality control			
ЛІ-6	Control of industrial drugs. Quality control of tablet forms of drugs. Quality control of injectable drugs of industrial production.	To acquaint students with the control of industrial drugs.	ЗН-1 ЗН-4 УМ-6	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
ЛІ-7	Physical, physicochemical methods of quality control of medicines. Physico-chemical methods of control of multicomponent drug mixtures without prior and with preliminary separation of components.	To acquaint students with the physical, physicochemical methods of quality control of medicines.	ЗН-1 ЗН-4 УМ-6	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
ЛІ-8	Chromatographic methods of research of medicines. Quality control of medicines by physical properties, refractometric and titrometric,	To acquaint students with the chromatographic methods of research of medicines.	ЗН-1 ЗН-4 УМ-6	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor

	titrometric and refractometric, chromatographic, photolorimetric, spectrophotometric methods			
Л-9	Pharmaceutical analysis in biopharmacy and pharmacokinetics. General information on biopharmacy and pharmacokinetics. The concept of biopharmaceutical factors. Ways to establish the bioavailability of drugs. The main tasks and features of biopharmaceutical analysis.	To acquaint students with the pharmaceutical analysis in biopharmacy and pharmacokinetics.	ЗН-1 ЗН-4 УМ-6	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
Л-10	Drug metabolism. Test methods used in biopharmaceutical analysis.	To acquaint students with the drug metabolism and test methods used in biopharmaceutical analysis	ЗН-1 ЗН-4 УМ-6	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-1 (практичне заняття 1)	Modern methods of pharmaceutical analysis, its specific features and main criteria. Ways to establish the quality of medicines. Testing for the maximum content of impurities by HFC.	To acquaint students with the modern methods of pharmaceutical analysis.	ЗН-1 УМ-1 К-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-2	Reactions for identification of multicomponent	To acquaint students with reactions for identification of multicomponent drugs by cations and anions.	ЗН-2 ЗН-5	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD,



	drugs by cations and anions.			Associate Professor
П-3	Identification reactions of multicomponent drugs by analytical-functional groups.	To acquaint students with the identification reactions of multicomponent drugs by analytical-functional groups/	ЗН-5 УМ-1 УМ-2 УМ-3 УМ-4 К-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-4	Quality control of unstable drugs and dosage forms and perishable drugs.	To acquaint students with the quality control of unstable drugs and dosage forms and perishable drugs.	ЗН-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-5	Quality control of medicines in pharmacies. Regulatory documentation governing the quality control of medicines. Express analysis of dosage forms. Quality control of drugs of intrapharmacy production. Quality control of concentrated solutions, powder dosage mixtures, liquid dosage forms, eye drops containing inorganic and organic drugs, injectable solutions of pharmacy production, drugs of ointment consistency, determination of homogeneity of ointments, their qualitative and quantitative quality control	To acquaint students with the Quality control of medicines in pharmacies.	ЗН-3 ЗН-4 УМ-1 УМ-2 УМ-5 УМ-7 К-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-6	Control of medicines of industrial production. Quality control of tablet forms of drugs. Quality control of	To acquaint students with the Control of medicines of industrial production.	ЗН-4 УМ-6	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor

	injectable drugs for industrial production.			
П-7	Physical, physicochemical methods of quality control of medicines. Physico-chemical methods of control of multicomponent drug mixtures without prior and with preliminary separation of components. Chromatographic methods of research of medicines. Quality control of medicines by physical properties, refractometric and titrimetric, titrimetric and refractometric, chromatographic, photocolometric, spectrophotometric methods	To acquaint students with the physical, physicochemical methods of quality control of medicines.	ЗН-4 УМ-6 УМ-7	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-8	Pharmaceutical analysis in biopharmacy and pharmacokinetics. General information on biopharmacy and pharmacokinetics. The concept of biopharmaceutical factors. Ways to establish the bioavailability of drugs. The main tasks and features of biopharmaceutical analysis. Drug metabolism. Test methods used in biopharmaceutical analysis.	To acquaint students with the pharmaceutical analysis in biopharmacy and pharmacokinetics.	ЗН-4 УМ-6 УМ-7	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
CPC-1 (самості)	Modern methods of pharmaceutical	To acquaint students with the modern methods of pharmaceutical analysis.	ЗН-2 ЗН-5	Andrii Lozynskyi, PhD, Associate

йна робота 1)	analysis, its specific features and main criteria. Ways to establish the quality of medicines. Testing for the maximum content of impurities by HFC.			Professor, Golota Sergii, PhD, Associate Professor
CPC-2	Reactions for identification of multicomponent drugs by cations and anions.	To acquaint students with reactions for identification of multicomponent drugs by cations and anions.	ЗН-5 УМ-2 УМ-3	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
CPC-3	Identification reactions of multicomponent drugs by analytical-functional groups.	To acquaint students with the identification reactions of multicomponent drugs by analytical-functional groups/	ЗН-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
CPC-4	Quality control of unstable drugs and dosage forms and perishable drugs.	To acquaint students with the quality control of unstable drugs and dosage forms and perishable drugs.	ЗН-5 УМ-1 УМ-2 УМ-4 К-2 АВ-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
CPC-5	Quality control of medicines in pharmacies. Regulatory documentation governing the quality control of medicines. Express analysis of dosage forms. Quality control of drugs of intrapharmacy production. Quality control of concentrated solutions, powder dosage mixtures, liquid dosage forms, eye drops containing inorganic and organic drugs, injectable solutions of pharmacy production, drugs of ointment consistency, determination of	To acquaint students with the Quality control of medicines in pharmacies.	ЗН-3 К-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor

	homogeneity of ointments, their qualitative and quantitative quality control			
CPC-6	Control of medicines of industrial production. Quality control of tablet forms of drugs. Quality control of injectable drugs of industrial production.	To acquaint students with the Control of medicines of industrial production.	3H-3 3H-4 Y <sub>M</sub> -1 AB-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
CPC-7	Physical, physicochemical methods of quality control of medicines. Physico-chemical methods of control of multicomponent drug mixtures without prior and with preliminary separation of components. Chromatographic methods of research of medicines. Quality control of medicines by physical properties, refractometric and titrometric, titrometric and refractometric, chromatographic, photocolometric, spectrophotometric methods	To acquaint students with the physical, physicochemical methods of quality control of medicines.	3H-2 3H-4 Y <sub>M</sub> -1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
CPC-8	Pharmaceutical analysis in biopharmacy and pharmacokinetics. General information on biopharmacy and pharmacokinetics. The concept of biopharmaceutical factors. Ways to	To acquaint students with the pharmaceutical analysis in biopharmacy and pharmacokinetics.	3H-4 Y <sub>M</sub> -1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor

	<p>establish the bioavailability of drugs. The main tasks and features of biopharmaceutical analysis. Drug metabolism. Test methods used in biopharmaceutical analysis.</p>			
<p>Teaching methods are explanatory-illustrative, problem-solving, partial-search. When studying standardization of drugs, students use textbooks, lecture notes, guidelines, chemical computer programs, models of molecules, laboratory equipment and utensils needed to perform experiments, appropriate reagents.</p> <p>According to the curriculum, the methods of organization and implementation of educational activities are:</p> <p>a) lectures b) practical classes c) out of class work of students.</p> <p>The topics of the lecture course reveal the problematic issues of the relevant sections of pharmaceutical chemistry.</p> <p>Lecture material is presented using multimedia equipment, computer, video clips, graph projector, models of organic molecules and demonstration experiments.</p> <p>Practical classes according to the methods of their organizations are laboratory because they include: laboratory research on synthesis and detection of certain classes of drugs by the properties of their functional groups, qualitative reactions, synthesis of organic compounds, their isolation and purification, the establishment of physicochemical constants.</p> <p>It is recommended that students in laboratory classes briefly record research protocols, indicating the purpose of the study and conclusions.</p> <p>Students also use exercises and solve situational problems. The practical classes use computer programs ISIS DRAW, HyperChem, Chemistry in motion, video clips developed by the department, models of molecules.</p> <p>The structure of the organization of practical classes includes:</p> <ol style="list-style-type: none"> <li>1. Discussion and explanation of the most difficult issues of the topic;</li> <li>2. Written test;</li> <li>3. Performance of practical (laboratory) works.</li> <li>4. Registration of the protocol of practical employment.</li> <li>5. The result of the lesson</li> </ol> <p>Independent work of students includes:</p> <ol style="list-style-type: none"> <li>1. Elaboration of literature on this topic.</li> <li>2. Solving training exercises and tests.</li> </ol>				
<p><b>8. Verification of learning outcomes</b></p>				
<p>Carried out in each lesson according to specific goals, as well as during the individual work of the teacher with the student for those topics that the student develops independently and they are not part of the structure of the practical lesson. A standardized form of control of theoretical and practical training of students is used.</p> <p>The standardized form of control of the theoretical part includes 10 tasks. Five of them of the first level are test (1 point each), and five tasks of the second level, to which in addition to the test answer you need to give a written answer (2 points each).</p> <p>Assessment of practical training of students - as a result of the practical part - is made in the form of a protocol.</p> <p>At the end, the student writes a final test, which includes 50 tests of A format (1 point).</p> <p>The final grade for the current educational activity is set on a 4-point (national) scale.</p>				
<p><b>Criteria for evaluating current learning activities:</b></p> <p>A grade of "5" (excellent) is given to a student who actively participated in the discussion of the most difficult questions on the topic of the lesson, gave at least 90% correct answers to standardized test tasks, answered written tasks without errors, did practical work and drew up a protocol.</p>				

Grade "4" (good) is given to the student who participated in the discussion of the most difficult questions on the topic, gave at least 75% correct answers to standardized test tasks, made some minor mistakes in answering written tasks, did practical work and drew up a protocol.

Grade "3" (satisfactory) is given to a student who did not participate in the discussion of the most difficult questions on the topic, gave at least 60% correct answers to standardized test tasks, made significant mistakes in answering written tasks, did practical work and drew up a protocol.

Grade "2" (unsatisfactory) is given to a student who did not participate in the discussion of the most difficult questions on the topic, gave less than 60% of correct answers to standardized test tasks, made gross mistakes in answering written tasks or did not answer them at all, performed practical work and did not draw up a protocol.

Learning outcome code	Code of the type of classes	Method of verification of learning outcomes	Enrollment criteria
3H-1 Y <sub>M</sub> -1 K-2	II-1	1. Acquaintance with the organization and procedure of practical classes in standardization of drugs. 2. Acquaintance with safety precautions and rules of work in a chemical laboratory. 3. Consideration of the basic principles of classification and nomenclature of drugs and types of structural isomerism. 4. Acquaintance with the equipment used in the chemical laboratory. 5. Performing training exercises and tests.	evaluation according to the established criteria on a traditional 4-point scale
3H-2 3H-5	II-2 CPC-1	1. Control of home self-preparation. 2. Solving training exercises. 3. Control of knowledge of theoretical material. 4. Work with chemical utensils and laboratory equipment, assembly of equipment for various distillation methods, etc.	evaluation according to the established criteria on a traditional 4-point scale
3H-5 Y <sub>M</sub> -1 Y <sub>M</sub> -2 Y <sub>M</sub> -3 Y <sub>M</sub> -4 K-2	II-3 CPC-2	1. Checking the preparation of students for classes. 2. Demonstration of methods for identification and assay of drugs 3. Familiarity with the methods of establishing physical constants of drugs. 4. Performance by students of a practical part of the class.	evaluation according to the established criteria on a traditional 4-point scale
3H-1	II-4 CPC-3	1. Control of homework. 2. Consideration on models, computer programs and tables of the spatial structure of drugs, conformations and configuration states of molecules and methods of their representation. 3. Solving training exercises and monitoring their implementation. 4. Practical part: - a compilation of models of chiral molecules of drugs;	evaluation according to the established criteria on a traditional 4-point scale
3H-3 3H-4 Y <sub>M</sub> -1 Y <sub>M</sub> -2 Y <sub>M</sub> -5 Y <sub>M</sub> -7 K-2	II-5 CPC-4 CPC-5	1. Control of home self-preparation. 2. Solving training exercises. Monitoring their implementation. 3. Performing of experiments. 4. Control of mastering the topic from theoretical material and from performed experiments.	evaluation according to the established criteria on a traditional 4-point scale
3H-4 Y <sub>M</sub> -6	II-6	1. Control of home self-preparation. 2. Solving training exercises. Monitoring their implementation. 3. Performing of experiments.	evaluation according to the established criteria on a

		4. Control of mastering the topic from theoretical material and from performed experiments.	traditional 4-point scale
3 <sub>H</sub> -4 У <sub>M</sub> -6 У <sub>M</sub> -7	П-7 CPC-6	1. Control of home self-preparation. 2. Solving training exercises. Monitoring their implementation. 3. Performing of experiments. 4. Control of mastering the topic from theoretical material and from performed experiments.	evaluation according to the established criteria on a traditional 4-point scale
3 <sub>H</sub> -4 У <sub>M</sub> -6 У <sub>M</sub> -7	П-8 CPC-7	1. Control of home self-preparation. 2. Solving training exercises. Monitoring their implementation. 3. Performing of experiments. 4. Control of mastering the topic from theoretical material and from performed experiments.	evaluation according to the established criteria on a traditional 4-point scale

#### Final control

General evaluation system	Credit
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Rating scales	Traditional 4-point scale, multi-point (200-point) scale, ECTS rating scale
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Type of final control	Methods of final control	Enrollment criteria
Credit	Credit is a form of final control of mastering by the student of theoretical and practical material on academic discipline. The final control is carried out in writing, using the Misa training platform, according to the schedule. Lasts 2 academic hours	<b>The maximum number of points</b> that a student can score is 200. <b>The minimum number of points</b> not less than 120.

**The maximum number of points** that a student can score for the current academic activity for admission to the exam is 120 points.

**The minimum number of points** that a student must score for the current academic activity for admission to the exam is 72 points.

**The calculation of the number of points** is based on the grades received by the student on a 4-point (national) scale during the study of the discipline, by calculating the arithmetic mean (CA), rounded to two decimal places. The resulting value is converted into points on a multi-point scale as follows:

$$x = \frac{CA \times 120}{5}$$

#### 9. Course policy

The student must independently complete homework, training exercises and tests, tasks of current and final control. It is not allowed to spy on another student's work, write off, use a textbook, notebook or mobile phone while writing a test, final or exam paper, use cheat sheets, copy your work by other students. Omissions of practical classes are not allowed. If a student misses classes for good reasons, which are documented, he has the right to practice them.

#### 10. Literature

##### The main literature

1. Kaufman, B., & Novack, G. D. (2003). Compliance issues in manufacturing of drugs. The ocular surface, 1(2), 80-85.
2. Ahuja, S., & Scypinski, S. (Eds.). (2001). Handbook of modern pharmaceutical analysis (Vol. 3). Academic press.
3. Schirmer, R. E. (1990). Modern methods of pharmaceutical analysis (Vol. 2). CRC press.
4. Siddiqui, M. R., AlOthman, Z. A., & Rahman, N. (2017). Analytical techniques in pharmaceutical analysis: A review. Arabian Journal of chemistry, 10, S1409-S1421.

##### The additional literature

1. Lyman, M. D. (2013). Drugs in society: Causes, concepts, and control. Routledge.
2. Vankeirsbilck, T., Vercauteren, A., Baeyens, W., Van der Weken, G., Verpoort, F., Vergote, G., & Remon, J. P. (2002). Applications of Raman spectroscopy in pharmaceutical analysis. TrAC trends in analytical chemistry, 21(12), 869-877.

3. Ermer, J., & Miller, J. H. M. (Eds.). (2006). Method validation in pharmaceutical analysis: A guide to best practice. John Wiley & Sons.
4. Lim, C. K., & Lord, G. (2002). Current developments in LC-MS for pharmaceutical analysis. *Biological and Pharmaceutical Bulletin*, 25(5), 547-557.
5. David C. Eaton. Laboratory investigation in Organic Chemistry. – McGRAW-HILL BOOK COMPANY. – New York – Toronto. – 893 p.

#### Information resources

1. [www.ncbi.nlm.nih.gov/PubMed](http://www.ncbi.nlm.nih.gov/PubMed) – free access to the database of scientific research in the field of biomedical sciences.
2. <https://pubchem.ncbi.nlm.nih.gov/> free access to the database of scientific data in the field of biomedical sciences.
3. <http://www.orgsyn.org> - has provided the chemistry community with detailed, reliable, and carefully checked procedures for the synthesis of organic compounds.
4. <http://www.organic-chemistry.org> - offers an overview of recent topics, interesting reactions, and information on important chemicals for organic chemists.
6. [www.bioorganica.org.ua](http://www.bioorganica.org.ua) - a scientific publication that presents works on bioorganic and medical chemistry.

### **11. Equipment, logistics and software of the discipline**

Equipment for laboratory work in the discipline, chemical utensils, reagents, multimedia projector for classes, overhead projector, computers, Internet for individual tasks, platform for distance learning MISA; thematic tables, molecule models, methodical instructions for practical and independent work are posted on the MISA distance learning service and are freely available to students.

### **12. Additional information**

The department has a permanent student research group.

The Syllabus was developed by:  
Andrii Lozynskyi, PhD, Associate Professor