Danylo Halytsky Lviv National Medical University

Department of Pharmaceutical, Organic and Bioorganic chemistry

SYLLABUS FOR
“Standardization of drugs”

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

1. General information	
Faculty	Pharmaceutical
Program	22 Healthcare, 226 Pharmacy, industrial pharmacy the second (master's) level, full-time
Academic year	2021/2022
Subject	Standardization of drugs, OK 39, Kaf_pharmchemistry@meduniv.lviv.ua
Department	Department Pharmaceutical, Organic and Bioorganic chemistry Pekarska 69, Lviv, Tel. +38(032)275-59-66, 275-59-77, 278-64-34 Kaf_pharmchemistry@meduniv.lviv.ua
Head of Department	Lesyk Roman, Doctor of Science, Professor roman.lesyk@gmail.com
Year of study	fifth
Semester	9
Type of course / module	Compulsory
Academic staff	Andrii Lozynskyi, PhD, Associate Professor, lozynskyiandrii@gmail.com Golota Sergii, PhD, Associate Professor, golota.serg@gmail.com
Erasmus yes/no	No
The person responsible for the syllabus	Andrii Lozynskyi, PhD, Associate Professor, lozynskyiandrii@gmail.com
Number of credits ECTS	3
Number of hours	90 (Lectures – 8 hours, Practical classes – 30 hours, Out of class work – 52 hours)
Language of study	English
Information about consultations	On schedule
Address, telephone and regulations of the clinical base, office ... (if necessary)	-

2. Short annotation to the course

The discipline "Standardization of drugs" belongs to the obligatory disciplines of the cycle of professionally-oriented training of specialists in the specialty "Pharmacy". Standardization 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 discipline "Standardization of drugs" is the basis for the study of medicines, understanding of their action and practical activities of specialists in pharmaceutical specialties.

3. The purpose and objectives of the course

1. **Objectives of teaching of the "Standartization of drugs" course are:**

- mastering of regularity of chemical properties of drugs based on their structure; understanding of biochemical processes that occur in biological systems;
- be familiar with basic methods of drug synthesis as the basis for new biologically active substances creation;
- gaining practical skills that will be helpful to learn the standardization techniques and grug quality control;
- disclosure of organic chemistry practical aspects, methods and ways of usage of its achievements in the pharmaceutical practice.

2. **The purpose of the "Standartization of drugs" course are:**

- 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.

ЗК – General competencies, ФК – Special responsibility, ПРН – Program learning outcomes

General competencies:

ЗК 1. The ability to act socially responsible and civic conscious.
ЗК 2. The ability to apply knowledge in practical situations.
ЗК 3. The striving to save the environment.
ЗК 4. The ability to abstract thinking, analysis and synthesis; the ability to study and to be trained up-to date
ЗК 6. Knowledge and understanding of the subject area and comprehension of the profession.
ЗК 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.
ЗК 9. Skills in the use of information and communication technologies.
ЗК 10. Ability to choose communication strategies, ability to work in a team and with experts from other fields of knowledge / types of economic activity.
ЗК 11. Ability to assess and ensure the quality of performed work.
ЗК 12. Ability to perform research at the appropriate level.
ЗК 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 pharmacoorganoleptic control methods.

Program learning outcomes:

ПРН 2. To apply knowledge of general and professional disciplines in professional activities;
ПРН 3. To follow to the rules of sanitary-hygienic regime and safety requirements when carrying out professional activities;
ПРЗ 4. To use the results of independent search, analysis and synthesis of information from various

sources for solving typical tasks of professional activity;
ПРН 5. Propose theyr professional activity and personal qualities in the pharmaceutical labor market; to formulate the purposes of own activity taking into account public and industrial interests.
ПРН 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.
ПРН 9. Carry out professional activities using information technology, "Information Databases", navigation systems, Internet resources, software and other information and communication technologies.
ПРН 10. To follow the norms of communication in professional interaction with colleagues, management, consumers, to work efficiently in a team.
ПРН 12. Analyze the information obtained as a result of scientific research, summarize, systematize and use it in professional activities.
ПРН 13. Carry out sanitary-educational work in professional activity in case of outbreaks of infectious, viral and parasitic diseases.
ПРН 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.
ПРН 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.
ПРН 30. Ensure quality control of medicines and document its results. Manage quality risks at all stages of the life cycle of medicines.
ПРН 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
Зн – Knowledges Ум – skills АВ – independence and responsibility К – competence		ПРН – program learning outcomes
Зн-1	basic principles of classification, nomenclature, structural and spatial isomerism of drugs	ПРН 1, ПРН 3, ПРН 5, ПРН 8, ПРН 9
Зн-2	types of chemical bonds, conjugate systems, electronic effects, acidity and basicity of pharmaceutical substances as a basic basis of their reactivity	ПРН 2, ПРН 12
Зн-3	principles of classification of drugs according to the direction, method	ПРН 2, ПРН 12

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

6. Format and scope of the course		
Format of the course	Full-time course	
Type of lessons	Number of hours	Number of groups
lectures	8	1
practical	30	1
seminars	-	-
out of class work	52	1

7. Topics and content of the course

Class type code	Topic	Content of training	Code of result of training	Academic staff
Л – lecture, П – practical class, СРС – out of class work				
Л-1	Standardization of medicines. Decree of the Cabinet of	To acquaint students with the subject and tasks of standardization of medicines, the system of quality assessment of medicines.	Зн-1 Зн-2 Ум-1	Andrii Lozynskyi, PhD, Associate Professor, Golota

	Ministers of Ukraine "On standardization and certification". WHO strategy in the system of ensuring (guaranteeing) the quality of medicines. Compilation of mandatory principles, norms and rules, called "GMP" - "Good manufacturing practice". Quality certification system Medicines for International Trade developed by the World Health Organization (WHO) European Community (EU) Commission Directives of 1991. EU GMP and GMP WHO principles and rules and GMP RIS and GMP WHO rules EU Commission Directives 91/356 / EEC and 91/412 / EEC Functions performing GMP rules, Ukrainian quality assurance system for medicines, Law of Ukraine "On Medicinal Products" Competent management bodies in the field of creation, production, quality control and sale of medicines in Ukraine.		К-1 К-2	Sergii, PhD, Associate Professor
Л-2	Strategy of Ukraine in the system of quality	To acquaint students with the strategy of Ukraine in the system of quality assurance of medicines.	Зн-1 Зн-3 Зн-5	Andrii Lozynskyi, PhD, Associate Professor, Golota

	assurance of medicines. Guidelines "Manufacture of medicines. Appropriate rules and quality control" are developed in accordance with the legislation of Ukraine, the State Standardization System of Ukraine, the rules of GMP WHO and the EU, their characteristics, objectives, scope and significance. State Pharmacopoeia of Ukraine - concept, content, construction. The main principles on which the State Pharmacopoeia of Ukraine is based. Terms. Format of general and separate articles of the State Pharmacopoeia of Ukraine. Monographs of the State Pharmacopoeia of Ukraine on medicinal substances.		Ум-2 Ум-3 Ум-4 Ум-5 Ум-8	Sergii, PhD, Associate Professor
Л-3	Requirements for quality management, principles of quality assurance, good manufacturing practice, quality control. Requirements for quality control: principles, general requirements. Good laboratory practice in quality control. Requirements for	To acquaint students with the requirements for quality management of medicines.	Зн-1 Зн-4 Ум-6 Ум-7	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor

	premises, equipment, personnel, documentation, sampling. Requirements for testing, control of raw materials, intermediates and materials, finished products. Control of medicines in Ukraine in modern conditions. Current state and prospects of development of biological methods of drug control.			
Л-4	Validation of analytical methods and tests. Standard samples. Basic provisions, procedure for development, certification, approval, registration and application. System of Pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine. Regulatory and technical documentation governing the quality of medicines. Temporary Pharmacopoeial Article (TFS), Pharmacopoeial Article (FS), their requirements for the quality of substances, injectable drugs, eye drops, tablet drugs, capsules, suppositories, ointments, aerosols,	To acquaint students with the validation of analytical methods.	Зн-1 Зн-4 Ум-6	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor

	granules, oily solutions, tinctures and liquid extracts and sorbents. Requirements for documentation, principles, general requirements, required documentation. Specifications, specifications for raw materials and semi-finished products, for packaging materials. Regulatory documentation for intermediate products, semi-finished products and "angro" products. Specifications for finished products. Technological regulations, their categories. Contents of technological regulations. Production and technological instructions. Production requirements: principles, general requirements. Prevention of cross-contamination during production. Validation. Requirements for raw materials, for technological processes of manufacturing intermediate products, for packaging materials, for packaging and labeling processes.			

	Requirements for finished products. Product complaints and recalls: principles, cases in which mandatory product recalls are required, procedure for recalling defective or potentially defective products.			
П-1 (практичне заняття 1)	Law of Ukraine "On Medicinal Products"	To acquaint students with the law of Ukraine "About medicines"	Зн-1 Ум-1 К-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-2	Production of medicines. State quality control of medicines. Implementation of drugs	To acquaint students with the State quality control of medicines	Зн-2 Зн-5	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-3	Decree of the Cabinet of Ministers of Ukraine "On standardization and certification". Study of pharmaco-technological indicators, purity, identity and quantitative content of the medicinal substance "Angro" "Calcii gluconas pro injectionibus" and its compliance with the Pharmacopoeial article of SPU 1 ed.	To acquaint students with the Decree of the Cabinet of Ministers of Ukraine "On standardization and certification".	Зн-5 Ум-1 Ум-2 Ум-3 Ум-4 К-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-4	WHO strategy in the system of ensuring	To acquaint students with the WHO strategy in the system of ensuring (guaranteeing) the quality of medicines	Зн-1	Andrii Lozynskyi, PhD, Associate Professor, Golota

	(guaranteeing) the quality of medicines. Principles and rules of GMP EU and GMP WHO and rules of GMP RIS and GMP WHO. Study of pharmaco-technological indicators, purity, identity and quantitative content of the drug substance "Angro" "Acidum ascorbinicum" and "Thiamini hydrobromidum aut hydrochloridum " and its compliance with the Pharmacopoeial article of the SPU 1 ed.			Sergii, PhD, Associate Professor
П-5	Strategy of Ukraine in the system of quality assurance of medicines. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Analgini 0.5" and its compliance with the Pharmacopoeial article developed by	To acquaint students with the strategy of Ukraine in the system of quality assurance of medicines.	Зн-3 Зн-4 Ум-1 Ум-2 Ум-5 Ум-7 К-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor

	the manufacturer			
П-6	State Pharmacopoeia of Ukraine. Terms. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Streptocidi 0.3" and its compliance with the Pharmacopoeial article developed by the manufacturer	To acquaint students with the State Pharmacopoeia of Ukraine.	Зн-4 Ум-6	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-7	Requirements for quality management, principles of quality assurance, good manufacturing practice, quality control. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Furacilini 0.02 ad usum externum" and its compliance with analytical regulatory documentation (AND)	To acquaint students with the requirements for drug quality management.	Зн-4 Ум-6 Ум-7	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-8	Requirements for quality control:	To acquaint students with the requirements for quality control of drugs.	Зн-4 Ум-6 Ум-7	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD,

	principles, general requirements. Study of pharmaco-technological parameters, purity, identity and quantitative content of the drug "Sol. Calcii chloridi 10% pro injectionibus ”and its compliance with the Pharmacopoeial article developed by the manufacturer			Associate Professor
П-9	Requirements for premises, equipment, personnel, documentation, sampling. Control of medicines in Ukraine in modern conditions. Study of pharmaco-technological parameters, purity, identity and quantitative content of drugs "Sol. Novocaini 0.5% per injection bus ”and“ Sol. Acidi nicotinici 1% pro injectionibus "and compliance with its analytical regulatory documentation (AND)	To acquaint students with the requirements for the premises.	Зн-4 Ум-6 Ум-7	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-10	Validation of analytical	To acquaint students with the validation of analytical methods.	Зн-4 Зн-5 Ум-1	Andrii Lozynskyi, PhD, Associate Professor, Golota

	methods and tests. System of Pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine. Study of pharmaco-technological parameters, purity, identity and quantitative content of drugs "Sol. Euphylylini 2.4% per injection bus ”and“ Sol. Papaverini hydrochloridi 2% pro injectionibus ”and its temporary Pharmacopoeial article developed by the manufacturer		Ум-2 Ум-3 Ум-6 Ум-7 Ум-8 АВ-1	Sergii, PhD, Associate Professor
П-11	Regulatory and technical documentation governing the quality of medicines. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions	To acquaint students with the normative and technical documentation regulating the quality of medicines.	Зн-4 Зн-5 Ум-1 Ум-2 Ум-3 Ум-6 Ум-7 Ум-8 АВ-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-12	Documentation requirements. Principles, general	To acquaint students with the requirements for documentation for the creation of drugs.	Зн-4 Ум-6 Ум-7	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD,

	requirements. Regulatory documentation for intermediate products, semi-finished products and Angro products. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions			Associate Professor
П-13	Production requirements: principles, general requirements. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in pharmacies according to doctors' prescriptions	To acquaint students with the requirements for production in the creation of drugs.	Зн-2 Зн-4 Ум-6 Ум-7	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
П-14	Validation. Requirements for finished products. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in pharmacies according to doctors' prescriptions	To acquaint students with the requirements of finished products in the creation of drugs.	Зн-4 Зн-5 Ум-1 Ум-2 Ум-3 Ум-6 Ум-7 Ум-8 АВ-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor

П-15	Final control.	Final control.	Зн-4 Зн-5 Ум-1 Ум-2 Ум-3 Ум-6 Ум-7 Ум-8 АВ-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
СРС-1 (самостійна робота 1)	Law of Ukraine "On Medicinal Products"	To acquaint students with the law of Ukraine "About medicines"	Зн-2 Зн-5	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
СРС-2	Production of medicines. State quality control of medicines. Implementation of drugs	To acquaint students with the State quality control of medicines	Зн-5 Ум-2 Ум-3	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
СРС-3	Decree of the Cabinet of Ministers of Ukraine "On standardization and certification".	To acquaint students with the Decree of the Cabinet of Ministers of Ukraine "On standardization and certification".	Зн-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
СРС-4	WHO strategy in the system of ensuring (guaranteeing) the quality of medicines. Principles and rules of GMP EU and GMP WHO and rules of GMP RIS and GMP WHO.	To acquaint students with the WHO strategy in the system of ensuring (guaranteeing) the quality of medicines	Зн-5 Ум-1 Ум-2 Ум-4 К-2 АВ-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
СРС-5	Strategy of Ukraine in the system of quality assurance of medicines.	To acquaint students with the strategy of Ukraine in the system of quality assurance of medicines.	Зн-3 К-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
СРС-6	State Pharmacopoeia of Ukraine. Terms.	To acquaint students with the State Pharmacopoeia of Ukraine.	Зн-3 Зн-4 Ум-1 АВ-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
СРС-7	Requirements for quality management,	To acquaint students with the requirements for drug quality management.	Зн-2 Зн-4 Ум-1	Andrii Lozynskyi, PhD, Associate Professor, Golota

	principles of quality assurance, good manufacturing practice, quality control.			Sergii, PhD, Associate Professor
CPC-8	Requirements for quality control: principles, general requirements.	To acquaint students with the requirements for quality control of drugs.	Зн-4 Ум-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
CPC-9	Requirements for premises, equipment, personnel, documentation, sampling. Control of medicines in Ukraine in modern conditions.	To acquaint students with the requirements for the premises.	Зн-4 Ум-1 Ум-7 К-1 АВ-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
CPC-10	Validation of analytical methods and tests. System of Pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine.	To acquaint students with the validation of analytical methods.	Зн-4 Ум-1 Ум-7 К-1 АВ-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
CPC-11	Regulatory and technical documentation governing the quality of medicines. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions	To acquaint students with the normative and technical documentation regulating the quality of medicines.	Зн-4 Ум-1 Ум-7 К-1 АВ-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
CPC-12	Documentation requirements.	To acquaint students with the requirements for documentation for the creation of drugs.	Зн-4 Ум-1 Ум-7	Andrii Lozynskyi, PhD, Associate Professor, Golota

	Principles, general requirements. Regulatory documentation for intermediate products, semi-finished products and Angro products. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions		К-1 АВ-2	Sergii, PhD, Associate Professor
CPC-13	Production requirements: principles, general requirements. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in pharmacies according to doctors' prescriptions	To acquaint students with the requirements for production in the creation of drugs.	Зн-2 Ум-1 К-1 АВ-2	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor
CPC-14	Validation. Requirements for finished products. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in pharmacies according to	To acquaint students with the requirements of finished products in the creation of drugs.	Зн-2 Зн-4 Ум-1 К-1	Andrii Lozynskyi, PhD, Associate Professor, Golota Sergii, PhD, Associate Professor

	doctors' prescriptions			

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.

According to the curriculum, the methods of organization and implementation of educational activities are:

a) lectures
b) practical classes
c) out of class work of students.

The topics of the lecture course reveal the problematic issues of the relevant sections of pharmaceutical chemistry.

Lecture material is presented using multimedia equipment, computer, video clips, graph projector, models of organic molecules and demonstration experiments.

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.

It is recommended that students in laboratory classes briefly record research protocols, indicating the purpose of the study and conclusions.

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.

The structure of the organization of practical classes includes:

1. Discussion and explanation of the most difficult issues of the topic;
2. Written test;
3. Performance of practical (laboratory) works.
4. Registration of the protocol of practical employment.
5. The result of the lesson

Independent work of students includes:

1. Elaboration of literature on this topic.
2. Solving training exercises and tests.

8. Verification of learning outcomes

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.

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).

Assessment of practical training of students - as a result of the practical part - is made in the form of a protocol.

At the end, the student writes a final test, which includes 50 tests of A format (1 point).

The final grade for the current educational activity is set on a 4-point (national) scale.

Criteria for evaluating current learning activities:

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.

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
Зн-1 Ум-1 К-2	П-1	1. Acquaintance with the organization and procedure of practical classes in standartixation 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
Зн-2 Зн-5	П-2 СРС-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
Зн-5 Ум-1 Ум-2 Ум-3 Ум-4 К-2	П-3 СРС-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
Зн-1	П-4 СРС-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
Зн-3 Зн-4 Ум-1 Ум-2 Ум-5 Ум-7 К-2	П-5 СРС-4 СРС-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
Зн-4 Ум-6	П-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
Зн-4 Ум-6 Ум-7	П-7 СРС-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
Зн-4 Ум-6	П-8 СРС-7	1. Control of home self-preparation.	evaluation according to

Ум-7		2. Solving training exercises. Monitoring their implementation. 3. Performing of experiments. 4. Control of mastering the topic from theoretical material and from performed experiments.	the established criteria on a traditional 4-point scale
Зн-4 Ум-6 Ум-7	П-9 СРС-8	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. 5. Writing the final test.	evaluation according to the established criteria on a traditional 4-point scale
Зн-4 Зн-5 Ум-1 Ум-2 Ум-3 Ум-6 Ум-7 Ум-8 АВ-1	П-10 СРС-9	1. Discussion of the main points of the topic. 2. Test control of knowledge. 3. Solving training exercises and monitoring their implementation. 4. Performing of experiments. 5. Verification of theoretical preparation of students for synthesis. 6. Performing of syntheses. 7. Control of mastering of theoretical material and practical part (performed experiments and syntheses) of the topic.	evaluation according to the established criteria on a traditional 4-point scale
Зн-4 Зн-5 Ум-1 Ум-2 Ум-3 Ум-6 Ум-7 Ум-8 АВ-1	П-11 СРС-14	1. Continuation of synthesis and calculation of product yield. 2. Homework control. 3. Solving training exercises and monitoring their implementation. 4. Execution of experiments. 5. Control of mastering the topic from theoretical material and from performed experiments.	evaluation according to the established criteria on a traditional 4-point scale
Зн-4 Ум-6 Ум-7	П-12 СРС-10	1. Control of home self-preparation. 2. Solving training exercises. Monitoring their completion. 3. Execution 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
Зн-2 Зн-4 Ум-6 Ум-7	П-13 СРС-11 СРС-13 СРС-15	1. Control of home self-preparation. 2. Solving training exercises. Monitoring their completion. 3. Execution 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
Зн-4 Зн-5 Ум-1 Ум-2 Ум-3 Ум-6 Ум-7 Ум-8 АВ-1	П-14	1. Consideration of the main points of the topic. 2. Execution of training exercises and control of their completion. 3. Checking the synthesis plan and the correctness of the assembly of equipment. 4. Execution of experiments and syntheses. 5. Control of theoretical knowledge and acquired practical skills.	evaluation according to the established criteria on a traditional 4-point scale
Зн-4 Зн-5 Ум-1 Ум-2 Ум-3	П-15	1. Consideration of the main points of the topic. 2. Execution of training exercises and control of their completion. 3. Checking the synthesis plan and the correctness of the assembly of equipment.	evaluation according to the established criteria on a

Ум-6 Ум-7 Ум-8 АВ-1		4. Execution of experiments and syntheses. 5. Control of theoretical knowledge and acquired practical skills.	traditional 4-point scale

Final control

General evaluation system	Credit
Rating scales	Traditional 4-point scale, multi-point (200-point) scale, ECTS rating scale

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	**The maximum number of points** that a student can score is 200. **The minimum number of points** 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:

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

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. Ahuja, S., & Scypinski, S. (Eds.). (2001). Handbook of modern pharmaceutical analysis (Vol. 3). Academic press.
2. Schirmer, R. E. (1990). Modern methods of pharmaceutical analysis (Vol. 2). CRC press.
3. Siddiqui, M. R., AlOthman, Z. A., & Rahman, N. (2017). Analytical techniques in pharmaceutical analysis: A review. Arabian Journal of chemistry, 10, S1409-S1421.

The additionary literature

1. 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.
2. Ermer, J., & Miller, J. H. M. (Eds.). (2006). Method validation in pharmaceutical analysis: A guide to best practice. John Wiley & Sons.
3. Lim, C. K., & Lord, G. (2002). Current developments in LC-MS for pharmaceutical analysis. Biological and Pharmaceutical Bulletin, 25(5), 547-557.
4. 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 – 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 - 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