DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY

Department of Drug Technology and Biopharmaceutics

APPROVED
Temporary acting vice-rector on
educational and pedagogical work,
assoc.prof. I.I. Solonynko
_____
«_05_» _____07_____ 2022

EDUCATIONAL PROGRAM
on elective discipline

SCIENTIFIC RESEARCH METHODOLOGY ON THE TOPIC OF MASTER'S THESIS (TECHNOLOGY OF DRUGS)

for training specialists of the second (master's) degree of higher education of the branch of study 22 "Health care" of the specialty 226 "Pharmacy, industrial pharmacy" for the 5st year students of Faculty of Pharmacy of the full-time and part-time forms of education

Approved
at the meeting of Department of
Drug Technology and Biopharmaceutics
Minutes No.12
« 8 » June 2022
Head of the Department
_____ assoc.prof. S.B. Bilous

Approved
by the Methodological Committee on
Chemical and Pharmaceutical Disciplines
Minutes No.3
« 21 » June 2022
Head of Committee
_____ assoc.prof. S.B. Bilous

2022

DEVELOPERS OF THE PROGRAM:

Bilous S.B. – head of the Department, DSc, associate professor
Strus O.Ye. – PhD, associate professor
Philipska A.M. – PhD, assistant professor

REVIEWER:

Fedorovska M.I. – Associate Professor, DSci, Department of Organic Chemistry and Pharmacy, Lesya Ukrainka Volyn National University, Lutsk, Ukraine

INTRODUCTION

Elective discipline working program

«Scientific research methodology on the topic of master's thesis»

according to the Standard of Higher Education of the second (master's) level

branch of knowledge - *22 «Health care»*

specialty - *226 "Pharmacy, Industrial pharmacy"*

educational program of *Master of Pharmacy*

Description of the elective discipline (abstract)

Elective discipline "Scientific research methodology on the topic of master's thesis " belongs to the cycle of professionally-oriented training disciplines for specialists in the specialty "Pharmacy, Industrial Pharmacy".

The elective discipline program "Scientific research methodology on the topic of master's thesis" is compiled in accordance with the Standard of Higher Education of Ukraine for the specialty "Pharmacy, Industrial Pharmacy".

The elective discipline "Scientific research methodology on the topic of master's thesis" is designed for graduates of higher full-time education, consolidates and deepens the knowledge gained in the study of "Technology of Drugs", improves practical skills and abilities needed to work in industrial conditions and forms the need for the future specialist to systematically update their knowledge in accordance with modern achievements of the pharmaceutical industry, as well as to apply them in practice.

The structure of the elective discipline	Number of credits, hours, of them				Year of study / semester	Types of control
	Total	Lecture classes		ISW		
		Lectures	Practical classes			
«Scientific research methodology on the topic of master's thesis»	**15 credits /450 h**	**4**	**26**	**420**	**5/X**	**Credit Defense of FQW**

The subject of the study is to provide professional knowledge and skills in the field of pharmacy and training by acquiring general and special competencies for professional activities.

Interdisciplinary links:

The elective course " Scientific research methodology in drug technology on the topic of master's thesis " is based on general knowledge of such disciplines as "Technology of drugs", "Biopharmacy", " Good Pharmacy Practice ", "Technology of medicinal cosmetics", "Pharmaceutical biotechnology" , "World Pharmaceutical Industry", which involves the use of skills acquired during the study of these disciplines in writing a qualification (master's) thesis.

1. The aim and objectives of the elective discipline

1.1. **The aim of the elective course** " Scientific research methodology on the topic of master's thesis " is to deepen professional knowledge, improve practical skills and abilities necessary for independent decision-making during specific work in production conditions and form a motivated need for future specialists to systematically update their knowledge. to modern achievements of the pharmaceutical industry, as well as to apply them in practice.

1.2. **The main task of the elective discipline** is to train a specialist capable of solving complex problems and problems in the field of pharmacy and industrial pharmacy, as well as in planning, writing and defending a dissertation, demonstrating the ability to analyze modern scientific, patent and scientific and technical information in pharmaceuticals. and related fields in order to implement possible scientific innovations, to conduct experimental research in the field of production and quality control of medicines.

1.3. **Competences and learning outcomes**, the formation of which is facilitated by the discipline (relationship with the normative content of training of higher education applicants, formulated in terms of learning outcomes in the Standard of Higher Education).

General competencies

GC 1 Ability to act socially responsible and civic conscious.
GC *2.* Ability to use knowledge in practical situations
GC *3.* Desire of saving the environment
GC 4 Ability for abstract thinking, analysis and synthesis; ability to study and to be modernly trained
GC 5 Atmosphere of entrepreneurship, the ability to be proactive.
GC *6.* The knowing and understanding of subject field and the understanding of profession.
GC 7. The ability to adapt and act in a new situation.
GC 8. The ability to communicate in the mother tongue in both spoken and written ways, the ability to communicate in other language
GC 9. Abilities to use information and communication technologies.
GC 10 Ability to choose communication strategy, ability to work in team.
GC 11 Ability to evaluate and ensure quality of performed work.
GC 12 Ability to conduct investigations in an appropriate level.
GC 13. Ability to exercise their rights and responsibilities as a member of society, to realize the values of civil (free democratic) society and the need for its sustainable development, the rule of law, human and civil rights and freedoms in Ukraine.
GC 14. Ability to save and multiply 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. Use different types and forms of physical activity for active recreation and a healthy lifestyleactive recreation and a healthy lifestyle.

Professional competencies:

PC 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
PC 2 Ability to provide advice on prescription and over-the-counter drugs and other pharmaceutical products; pharmaceutical care in 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

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

PC 12 Ability to use in professional activities knowledge of regulations, legislation of Ukraine and recommendations of good pharmaceutical practices.

PC 14 Ability to carry out the production activities of pharmacies for the manufacture of drugs in various dosage forms on prescriptions and orders of medical institutions, including justification of technology and selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).

PC 15 Ability to organize and participate in the production of medicines in the context of pharmaceutical companies, including the selection and justification of the technological process, equipment in accordance with the requirements of Good Manufacturing Practice (GMP) with the appropriate development and design of the necessary documentation. Determine the stability of drugs

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

PC 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 methods.

Detailing of competencies according to NFQ descriptors in the form of "Competence Matrix".

Competence Matrix

№	**Competence**	**Knowledge**	**Abilities**	**Communication**	**Autonomy and responsibility**
Integrative competency					
The ability to solve typical and complex specialized tasks and practical problems 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 reveal clearly and unambiguously conclusions and knowledge, reasoning them, to the professional and non-professional audience..					
General competencies					
CG 1	Ability to act in socially and civil responsible manner	To know social and civil rights and responsibilities	To form civil consciousness and to act according to it	Ability to prove social and civil position.	To be responsible for civil

					position and activity
CG 2	Ability to use knowledge in practical situations	To know methods of knowledge implementation in solving practical issues	To be able to use professional knowledge for solving practical issues	To establish contacts with entities of practical activities	To be responsible for the timely taken decision
CG 3	Desire to preserve the environment	To know the problems of environmental protection, the requirements of the sanitary and hygienic regime and the conditions of labor protection.	To be able to form requirements for environmental protection, compliance with sanitary and hygienic regime and labor protection conditions; interpret the requirements of laws and regulations on labor protection; conclude about the presence of harmful factors during the performance of professional duties; to provide labor protection of pharmaceutical personnel	To develop measures to preserve and protect the environment.	Be responsible for the implementation of environmental protection measures within its competence.
CG 4	Ability for abstract thinking, analysis and synthesis, ability to study and to be modernly trained.	To know current development trends of the branch and to analyze them	To be able to analyze professional information, make reasoned decisions,	To establish appropriate contacts for achieving the goals.	To be responsible for timely acquisition of up-to-date knowledge

			acquire up-to-date knowledge		
CG 5	Ability to show initiative and entrepreneurship	To know the laws and trends of modern economic development	To be able to apply knowledge for modern enterprise development	Interact with relevant structures in solving social problems	To be responsible for the goals of the activity
CG 6	Knowing and understanding of subject field and the understanding of profession.	To know structure and features of professional activities	To be able to carry out professional activities that requires updating and integration of knowledge	To form communication strategy in the professional activities	To be responsible for professional growth with high level of autonomy
CG 7	Ability to adapt and act in a new situation	To know elements of production and social adaptation, factors of successful adaptation to a new environment	To be able to form an effective strategy of personal adaptation for new conditions	To contact with a wide range of the public (colleagues, administration, professionals of other branches) in case of new situations with unpredictable elements	To be responsible for taking decisions
CG 8	Ability to communicate in the state language (speaking, writing), the ability to communicate in a foreign language (mostly English) at a level that ensures effective professional activity.	To have a perfect knowledge of the native language and basic knowledge of a foreign language (English)	To be able to use knowledge of the native language (speaking, writing), be able to communicate in a foreign language (English)	To use the native language in professional and business communication and in the preparation of documents. Use a foreign language in professional activities	To be responsible for fluency in the native language, for the development of professional skills
CG 9	Abilities to use information and	To have a deep knowledge in	To be able to use the	To use the information	To be responsible

	communication technologies	the information and communication technologies, which are used in the professional activities	information and communication technologies in the professional activities that requires updating and integrating the knowledge	and communication technologies in the professional activities	for the development of professional knowledge and skills
CG 10	Ability to choose communication strategies, ability to work in a team.	To know the tactics and strategies of communication, laws and ways of communicative behavior	To be able to choose ways and strategies of communication to ensure effective teamwork	To use communication strategies and interpersonal skills	To be responsible for the choice and tactics of communication
CG 11	Ability to evaluate and ensure quality of performed work	To know methods for evaluation of work quality	To be able to ensure competent performance of professional activities	To establish contacts for assurance of competent performance of activities	To be responsible for competent performance of activities
CG 12	Ability to conduct investigations in an appropriate level	To know elements of the health care system, planning and evaluation of scientific experiment	To search scientific sources of information; to carry out choice of methods of scientific research; to use methods of mathematical analysis and modeling, theoretical and experimental investigations in pharmacy	To use information from scientific sources	To be responsible for the development and implementation of planned projects
CG 13	Ability to exercise their rights and responsibilities as a member of society, to realize the	To know your rights and responsibilities as a member of society	To use your rights and responsibilities into practice, taking into	To be able to communicate with respect for fundamental	To be responsible for your actions in civil society

	values of civil (free democratic) society and the need for its sustainable development, the rule of law, human and civil rights and freedoms in Ukraine		account the values of civil society	human and civil rights and freedoms in Ukraine.	
CG 14	Ability to preserve and multiply 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	To know the history and patterns of pharmacy development, its place in the general system of knowledge about nature and society and in the development of society, technology and engineering	To use an understanding of the history and patterns of pharmacy development in practice	To be able to communicate with moral, cultural and scientific values	To be responsible for the observance of moral, cultural and scientific values.
Specific (professional, objective) competencies					
PC 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	To know: environmental factors and endogenous factors that contribute to the spread of diseases of internal organs, dangerous infectious	To organize scientific and practical seminars for medical staff and lectures for the population on the rational use of drugs, medicinal raw materials, the	To carry out preventive work and take anti-epidemic measures to prevent diseases	To be responsible for the quality and timeliness of preventive and anti-epidemic measures

	timely detection and maintenance of adherence to treatment of these diseases in accordance with their medical and biological characteristics and microbiological characteristics	(tuberculosis, HIV, etc.) and parasitic diseases; characteristics and clinical signs of common diseases of internal organs, dangerous infectious (tuberculosis, HIV, etc.) and parasitic diseases; conditions for the rational use of drugs for the treatment of dangerous infectious and parasitic diseases	harmfulness of drug and potent drug abuse, measures to prevent drug addiction;		
PC 2	Ability to provide advice on prescription and OTC medicines and other pharmaceutical products; pharmaceutical care in the selection and implementation of OTC medicines by assessing the risk / benefit, compatibility, indications and contraindications based on data on the health of a particular patient,	To know: pharmacodynamics and pharmacokinetics of OTC drugs; pharmacokinetic and biopharmaceutical factors influencing the choice of dosage form	To provide information on the regime, terms and requirements for storage of drugs of various dosage forms at home using knowledge of chemical, physicochemical, properties; to provide information on the compatibility, indications and contraindications of drugs,	To provide counseling and pharmaceutical care when dispensing OTC drugs	To be responsible for the provision of pharmaceutical care when dispensing OTC drugs

	taking into account biopharmaceutical, pharmaco-kinetic, pharmacodynamic and physicochemical characteristics of the drug and other pharmaceutical products		taking into account their biopharmaceutical, pharmacokinetic and pharmacodynamic properties.		
PC 7	Ability to ensure proper storage of medicines and other pharmaceutical products in accordance with their physicochemical properties and the rules of Good Storage Practice (GSP) in health care facilities.	To know: classification of drugs and dosage forms; orders of the Ministry of Health of Ukraine on receipt, storage and dispensing of poisonous, narcotic and similar drugs; general requirements for storage of medicines in pharmacies; rules of storage of medicinal substances with different physicochemical properties; stability and shelf life of drugs	To ensure appropriate storage conditions for poisonous, narcotic and similar drugs, as well as dosage forms with them; to control the conditions of storage of raw materials at pharmaceutical enterprises; to determine the stability of drugs and other pharmaceutical ptoducts during storage during the established shelf life	To carry out constant monitoring of proper storage of medicines and other pharmaceutical products at pharmaceutical enterprises	To be responsible for the storage of medicines and other pharmaceutical products in accordance with Good Storage Practice (GSP) in healthcare facilities
PC 12	Ability to use in professional activities knowledge of regulations, legislation of Ukraine and	To know: basics of the legal system and pharmaceutical legislation;	To use normative legal acts regulating pharmaceutical activity in Ukraine and abroad;	To form conclusions and professionally use laws and regulations	To be responsible for the quality and timely use of regulations in

	recom-mendations of Good Pharmacy Practice (GPP).	legal and ethical norms of pharmaceutical activity.	to build relationships with patients and physicians in order to meet WHO ethical criteria and principles of good pharmacy practice to promote medicines on the market, minimize abuse and misuse of medicines		professional activities
PC 14	Ability to carry out the production activities of pharmacies for the manufacture of drugs in various dosage forms on prescriptions and orders of medical institutions, including justification of technology and selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).	To know drug technology in pharmacies	To be able to prepare various dosage forms and intrapharmacy preparations from medicinal substances and excipients.	To organize the production activities of the pharmacy	To be responsible compounded preparation of drugs in pharmacies
PC 15	Ability to organize and participate in the manufacture of drugs in the pharmaceutical enterprises, including the selection and justification of the	To know: industrially technology of drugs; GMP requirements and other GPP	To be able: to choose the optimal technology for the manufacture of dosage forms using the necessary equipment;	To choose the optimal technological process of manufacturing drugs in the pharmaceutica l enterprises	To be responsible for compliance with GMP

	technological process, equipment in accordance with the requirements of Good Manufacturing Practice (GMP) with the appropriate development and design of the necessary documentation; to determine the stability of drugs		to select excipients (stabilizers, emulsifiers, prolongators, ointment and suppository bases, fillers for tablets, etc.) for the manufacture of dosage forms.		
PC 19	Ability to organize and control the quality of medicines in accordance with the requirements of the current SPhUand GPP, to determine methods of sampling for control of drugs and standardize them in accordance with current requirements, prevent the spread of counterfeit medicines.	To know: state regulation of the quality of drugs; methods of qualitative and quantitative analysis of drugs; analysis of dosage forms in the production process; quality indicators of parenteral, solid, semi solid and aerosol dosage forms; stability and shelf life of drugs	To determine the main indicators of finished drugs derived obtained from medicinal substances and excipients, visual and instrumental methods: transparency; color; pH; refractive index; angle of rotation and density of injection solutions; yo determine the stability of drugs and other pharmaceutical products during storage during the established shelf life	To carry out quality control of drugs and their certification	To be responsible for certifying and preventing the spread of falsified medicines

PC20	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 methods.	To know: general methods of analysis of inorganic and organic drug compounds	To determine cations and anions of active substances of inorganic nature, functional groups of active substances of organic nature in raw materials, materials, intermediates, finished products	To develop methods of quality control of pharmaceutical products	To be responsible for the validity of the developed quality control methods

Learning outcomes:

LO 1 Identification of future professional activity as socially important for the human health.

LO 2. To use knowledge on general and professional disciplines in professional activities.

LO 3 To adhere to the norms of sanitary and hygienic regime and safety requirements when carrying out professional activities.

LO 4 To use the results of independent search, analysis and synthesis of information from various sources for solving typical professional tasks.

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

LO 6 To argue information for decision-making, to be responsible for the decisions in standard and nonstandard professional situations.

LO 7 To carry out professional activities using creative methods and approaches

LO 8 To 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.

LO 9 To carry out professional activities using reference scientific literature, information technologies, information databases, navigation systems, Internet resources, software and other information and communication technologies.

LO 10 To adhere to the norms of communication in professional interaction with colleagues, management, consumers, work effectively in a team.

LO 11 To use methods for evaluating the performance indicators; to identify reserves for improving the labor productivity.

LO 12 To analyze the information obtained in the results of scientific research, to generalize, systematize and use it in the professional activities.

LO 13 To carry out sanitary-educational work in professional activity in case of outbreaks of infectious, viral and parasitic diseases.

LO 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 OTC medicines and other products of the pharmacy range with the provision of counseling and pharmaceutical care.

LO 16 To determine the impact 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.

LO 19 To predict and determine the impact of environmental factors on the quality of drugs and consumer characteristics of other pharmaceutical products during their storage. To study the influence of environmental factors on the stability of medicines.

LO 24 To plan and carry out professional activities based on the normative abd legal acts of Ukraine and recommendations of GPP.

LO 25 To promote health, including disease prevention, rational use and use of drugs. To perform your professional duties in good faith, comply with the law on the promotion and advertising of drugs. To possess psychological communication skills to build trust and understanding with colleagues, doctors, patients, consumers.

LO 26 To choose an optimal technology, to compound medicines in different dosage forms in accordance with the prescriptions of doctors and orders of health care facilities, to prepare them for dispensing. To perform technological operations: to weigh, to measure, to dose different medicines by weight, volume, etc. To develop and complete technological normative documents for the compounding (manufacturing) drug products in pharmacies and pharmaceutical enterprises.

LO 27 To substantiate the technology and organize the production of medicines at pharmaceutical enterprises and draw up technological documentation for the production of medicines at pharmaceutical enterprises. To substantiate the technology and organize the manufacture of drug products at pharmaceutical enterprises.

LO 31 To carry out all types of quality control of drugs; to compose quality certificates for the batch of the medicinal product and the certificate of analysis taking into account the requirements of current regulations, the State Pharmacopoeia of Ukraine and the results of quality control. To develop specifications and methods of quality control in accordance with the requirements of the current State Pharmacopoeia of Ukraine. To perform quality control of drug products.

LO 32 To determine the main organoleptic, physical, chemical, physicochemical and pharmacotechnological indicators 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.

2. Information volume of elective discipline

The elective course " Scientific research methodology on the topic of master's thesis" is studied by 5th year students in the Faculty of Pharmacy, who study in the specialty 226 "Pharmacy, Industrial Pharmacy" in the 10th semester.

15 ECTS credits, 450 hours, are allocated for the study of this elective discipline.

3. The structure of elective discipline

Theme	Lectures (h)	Laboratory classes (h)	ISW (год)	Individual work
Topic 1. Methodology of pharmaceutical development as a basis for creating high-quality, effective and safe drugs. New dosage forms	2	6		-
Topic 2. Modern approaches to the technology of solid, soft, liquid and sterile medicines and cosmetics.	2	16		-
Topic. 3 GMP and GPP requirements for the production of sterile drugs.	-	4		-
Topic 4 ISW on the topic of master's thesis	-	-	420	-
Total 450 h/ 15 credits ECTS	**4**	**26**	**420**	**-**
Final control				**Test Defense of FQW**

4. Thematic lecture plan

No	Lecture topic	Number of hours
1	Pharmaceutical development as a basis for creating high-quality, effective and safe drugs. Prospects for the development of drug technology. Biotechnology. New dosage forms	2
2	Modern approaches to the technology of solid, semi solid, liquid and sterile medicines. The use of new ingredients and the latest technologies in the production of medicines and cosmetics.	2
	Total	**4**

5. Thematic practical classes plan

No	Practical classes topic	Number of hours
1	Requirements for research on pharmaceutical development of different groups of drugs. Excipients, characteristics of the main groups and requirements for them.	4
2	Production of solid drugs, their quality control.	4
3	Production of liquid drugs, their quality control.	4
4	Production of semi solid drugs, their quality control.	4
5	Production of sterile drugs, their quality control.	4
6	Development of composition and technology of cosmetics of various purposes and actions.	4

7	Novel dosage forms. Liposomes. Magnetically controlled drugs. Transdermal therapeutic systems. Characteristic. Manufacturing methods, quality control. **Credit**.	2
	Total	**26**

6. Thematic independent student work plan

No	ISW topic	Number of hours	Type of control
1	**ISW on the topic of master's thesis**	420	Checking for uniqueness and absence of plagiarism Preliminary protection in order to establish the level of readiness and eliminate detected errors
	Total	**420**	

7. Individual tasks

Not provided by the curriculum.

8. Types of educational activities

Types of student educational activities are:

a) lectures; b) practical classes; c) independent student work (ISW).

Individual tasks are not provided by the curriculum.

The lecture course task is to cover important sections and topics based on the achievements of domestic and foreign science in the field of pharmaceutical development of medicines and medicinal cosmetics using modern methods and technological equipment, etc.

In the practical lesson, the teacher organizes a detailed review by students of material for theoretical and practical knowledge. Methodical developments for teachers and students have been created for practical classes.

Independent student work is the main way to master the study material in the time free from compulsory education.

Laboratory class tasks are on the basis of technology theoretical provisions, modern requirements for dosage forms, knowledge of the properties of drugs and excipients to deepen students' knowledge of the production (manufacture) of drugs for various purposes; to master the main stages of medical production, drawing up of technological and hardware schemes of production; to acquaint with the main criteria and quality control methods of the intermediate product and finished products. In laboratory classes, students acquire skills and abilities to produce (manufacture) all kinds of dosage forms.

Laboratory classes on specialization are conducted in the department laboratories with using individual tasks (recipes, work recipes, situational tasks). Students in the laboratory are encouraged to draw up protocols in which they indicate the topic and aim of the lesson, indicate the drug composition according to the working prescription, describe the technology with a theoretical basis, make a technological scheme of production, determine quality indicators and solve situational problems.

A number of the program sections are submitted for independent study by textbooks, regulations, reference books.

The basis of laboratory classes is ISW (independent student work). To deepen the theoretical knowledge, an oral consideration of certain issues is planned, which is recommended to be conducted in the form of a discussion.

Master's thesis tasks

Final Qualifying Work (FQW) involves generalized independent research, experimental work in the specialty. Requirements for qualification work are regulated by the «Regulations on preparation and defense of final qualification work by students of the Faculty of Pharmacy of Danylo Halytsky Lviv National Medical University», which specifies requirements for the volume, structure, content and design of qualification work taking into account specifics of knowledge, specialty and future professional activity of higher education applicants.

The master's qualification work is subject to mandatory testing for academic plagiarism.

The defense of the qualification work is carried out openly and publicly.

The main stages of the lesson:

Preparatory stage is topic motivation, control of the initial level of knowledge (basic), the issuance of tasks for independent work.

Control of the initial level of knowledge involves an oral examination and writing a test on the topic.

Main stage is that students receive tasks for independent work, work in groups (4-5 students), draw up protocols.

Final stage is the control of mastering the material by solving problems, oral presentations about the work done. General assessment of each student's work, remarks on the course of the lesson, homework.

In the laboratory classes, it is recommended to fill out a diary in the form of protocols, which record the experimental study results.

9. Control methods

Control methods include current and final control. The final control form in the elective discipline in accordance with the curriculum is a credit and defense of a master's thesis (final qualifying work (**FQW**)

10. Current control is carried out during practical classes and aims to verify the assimilation of students' learning material.

Current control is carried out at each practical lesson in accordance with specific objectives. The assessment form of current educational activity is standardized and includes theoretical training control, which is carried out by means of interrogation, check of protocols with individual practical tasks and situational tasks, and also test written interrogation. Students' independent work is assessed during the current control of the topic in the relevant lesson and involves writing test assignments and oral examination.

For each topic, the student must receive a grade on a 4-point (traditional) scale, taking into account the approved criteria.

Evaluation of current educational activities of students

Rating scale	Evaluation criteria
Criteria for evaluating test control	
2	<50%

3	50-60%
4	70-80%
5	90-100%
Protocol evaluation criteria	
2	The student does not reproduce practical work, does not have a clear idea of the study object and the necessary skills to do practical work
3	The student reproduces the part of the practical work, has a vague idea of the study object, does not have the necessary skills to do practical work
4	The student does the basic provisions and tasks of practical work, shows inappropriateness in doing tasks, works with the help of a teacher with the necessary materials for practical work
5	The student independently correctly does the tasks of practical work, independently uses information sources and necessary materials
Criteria for evaluating the oral response	
2	The student does not reproduce the study material, has a vague idea of the study object.
3	The student has difficulty reproducing the basic educational material, with errors and inaccuracies gives a definition of the basic concepts and definitions of the topic
4	The student shows knowledge and understanding of the main provisions of the study material
5	The student has a systematic, solid knowledge within the requirements of the curriculum, consciously uses them in standard and non-standard situations. Is able to independently analyze, evaluate, summarize the mastered material.

11. **Final control** is carried out in order to assess learning outcomes at a certain educational and qualification level and at some of its completed stages on a national scale and ECTS scale.

Exclusively on the basis of the results of the current control in the amount of educational material determined by the work program and in the terms established by the working curriculum, individual curriculum of the student on a 200-point scale.

The maximum number of points that a student can score for the current academic activity is 200 points.

The minimum number of points that a student must score for the current educational activity is 120.

The calculation of the number of points is based on the grades obtained by the student on the traditional scale during studing the discipline, by calculating the arithmetic mean (AM), rounded to two decimal places. The value obtained is converted into points as follows:

$$X=AM\cdot 200/5$$

Recalculation of the average grade for current activities in a multi-point scale for the discipline, ending with a test.

Recalculation of the average grade for current activity in a multi-point scale for elective disciplines ending with test

4-point scale	200-point scale		4-point scale	200-point scale		4-point scale	200-point scale		4-point scale	200-point scale
5	200		4.45	178		3.92	157		3.37	135
4.97	199		4.42	177		3.89	156		3.35	134
4.95	198		4.4	176		3.87	155		3.32	133
4.92	197		4.37	175		3.84	154		3.3	132
4.9	196		4.35	174		3.82	153		3.27	131
4.87	195		4.32	173		3.79	152		3.25	130
4.85	194		4.3	172		3.77	151		3.22	129
4.82	193		4.27	171		3.74	150		3.2	128
4.8	192		4.24	170		3.72	149		3.17	127
4.77	191		4.22	169		3.7	148		3.15	126
4.75	190		4.19	168		3.67	147		3.12	125
4.72	189		4.17	167		3.65	146		3.1	124
4.7	188		4.14	166		3.62	145		3.07	123
4.67	187		4.12	165		3.57	143		3.02	121
4.65	186		4.09	164		3.55	142		3	120
4.62	185		4.07	163		3.52	141		Less than 3	Not enough
4.6	184		4.04	162		3.5	140			
4.57	183		4.02	161		3.47	139			
4.52	181		3.99	160		3.45	138			
4.5	180		3.97	159		3.42	137			
4.47	179		3.94	158		3.4	136			

Points from the discipline are independently converted into both the ECTS scale and the 4-point scale. ECTS scale scores are not converted to a 4-point scale and vice versa.

The points of students studying in one specialty, taking into account the number of points scored in the discipline are ranked on the ECTS scale as follows:

Ranking of students' points in the discipline on the ECTS scale

Score ECTS	Statistical indicator
A	The best 10% of students
B	The next 25% of students
C	The next 30% of students
D	The next 25% of students
E	The last 10% of students

Discipline points for students who have successfully completed the program are converted into a traditional 4-point scale according to absolute criteria.

Conversion of students' points from the discipline into a traditional scale

Points in discipline	Points for 4-point score
From 170 to 200 points	5
From 140 to 169 points	4
From 139 points to the minimum number of points that a student must score	3
Below the minimum number of points that a student must score	2

The ECTS points are not converted to the traditional scale, as the ECTS scale and the 4-point scale are independent.

The objectivity of the assessment of students' learning activities is checked by statistical methods (correlation coefficient between ECTS points and national scale points).

12. Criteria for evaluating the master's thesis

The grade for the master's thesis is based on the assessment of the performance level and the defense level of the master's thesis and is determined by the traditional 4-point scale (5 - "excellent", 4 - "good", 3 - "satisfactory", 2 - "unsatisfactory").

The final grade for the master's thesis is determined by a multi-point (200-point) scale, a traditional 4-point scale and the ECTS grading scale.

The calculation of the number of points on a 200-point system is based on the obtained grades for the performance and defense of the master's thesis by calculating the arithmetic mean (AM). The resulting value is converted into points on a 200-point scale as follows:

$$X=AM\cdot 200/5$$

Criteria for determining the final drade on the FQW on 200-point, 4-point and ECTS scales.

Criteria for determining the final grade for a master's thesis

Estimation limits for 200-point scale	**Grade for 4-point scale**	**Rating ECTS**
200-180	excellent	A
179,9-160	good	B
159,9-140		C
139,9-120	satisfactorily	D
119,9-100,1		E
100-0	unsatisfactorily	FX

13. Methodical support:

Lecture notes and teaching material for practical classes in the discipline.

Regulatory documents governing the production of medicines, Good Practice Standards, SPhU.

Regulations on the preparation and defense of final qualifying work by students of the Faculty of Pharmacy of Danylo Halytsky Lviv National Medical University;

Textbooks and manuals on technology of drugs, biopharmacy, biotechnology, GPP.

List of issues for final (current) control

1. Basic terms of pharmaceutical technology.

2. Dosage forms: requirements and classification.
3. Regulatory and legal documents governing the production (manufacture) of medicines.
4. Production of medicines in accordance with GMP requirements.
5. Technological processes used in the production of solid dosage forms.
6. Novel solid dosage forms, their characteristics.
7. Technological processes used in the production of liquid dosage forms.
8. Suspensions and emulsions as dosage forms, equipment for their production.
9. Stability of heterogeneous liquid dosage forms, methods of ensuring their stability.
10. Technological processes used in the production of semi solid medicines.
11. Aseptic conditions of drug production.
12. Parenteral preparations: classification, requirements and characteristic.
13. Ophthalmic drugs: classification and characteristic.
14. Preparations from medicinal raw materials. Extraction methods of medicinal raw materials; equipment for extraction.
15. Excipients, characteristics of the main groups and requirements for them.
16. Systems with controlled release of drugs, problems of their creation.
17. Mechanisms of drug release from various therapeutic systems.
18. Implantation systems.
19. Characteristic of new dosage forms for oral administration.
20. Liposomes as carriers of drugs. Characteristics of liposomes, their properties. Ways of introducing liposomes into the body.
21. Novel dosage forms with sparingly soluble drugs. Nanosuspension.
22. Immobilization as a method of increasing the stability, prolongation and selectivity of drugs.
23. Microemulsions as carriers of medicinal substances. Characteristic of microemulsions. The mechanism of drug delivery from microemulsion systems.
24. Medicinal cosmetics, characteristics and classification.
25. Classification and characterization of the main groups of cosmetic ingredients, their role in ensuring the cosmetic effect.
26. The most common defects and diseases of the skin, hair and nails.
27. General principles of pharmaceutical care of patients with cosmetic diseases and skin defects.
28. Technology of solid cosmetics.
29. Technology of liquid medicines and cosmetics.
30. Technology of semi solid cosmetics.

Recommended literature

Required

Вимоги до виготовлення нестерильних лікарських засобів в умовах аптек / Під ред. акад. АНТКУ проф. О.І.Тихонова і проф. Т.Г.Ярних // Київ, МОЗ України. – 2005. – 98 с.

Вимоги до виготовлення стерильних та асептичних лікарських засобів в умовах аптек / Під ред. акад. АНТКУ проф. О.І.Тихонова і проф. Т.Г.Ярних // Київ, МОЗ України. – 2005. – 76 с.

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.

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», 2014. – Т.2. – 724 с.

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.3. – 732 с.

Закон України «Про лікарські засоби» № 123/96-ВР від 4.04.96// Відомості Верховної Ради України. – 1996. – № 123.

Практикум з промислової технології лікарських засобів / Під ред. О.А. Рубан. – Х.: НФаУ, 2011. – 342с.

Практикум з промислової технології лікарських засобів / Під ред. О.А. Рубан. – Х.: НФаУ, 2014. – 374с.

Технологія лікарських препаратів промислового виробництва: навч. посіб./ за ред. проф. Д.І. Дмитрієвського. – Вінниця: Нова книга, 2008. – 280 с.

Технологія ліків промислового виробництва: підруч. для студентів вищ. навч. закл. : в 2-х ч. / В.І. Чуєшов, Є.В. Гладух, І.В. Сайко та ін. – 2-е вид., перероб. і допоп. – Х. : НФаУ : Оригінал, 2012. – Ч. 1. – 694 с.

Технологія ліків промислового виробництва : підруч. для студентів вищ. навч. закл. : в 2-х ч. / В.І. Чуєшов, Є.В. Гладух, І.В. Сайко та ін. – 2-е вид., перероб. і допоп. – Х. : НФаУ : Оригінал, 2013. – Ч. 2. – 638 с.

Тихонов 0.І. Аптечна технологія ліків / 0.І.Тихонов, Т.Г.Ярних. - Вінниця: "Нова книга", 2007. – 640 с.

Технология лекарственных препаратов промышленного производства: Учебное пособие / Д.И. Дмитриевский. Л.И. Богуславская, Л.М. Хохлова и др. – Часть 1. Основные процессы и аппараты в фармацевтическом производстве. Экстракционные препараты. – Х.: Изд-во НФаУ, 2005. – 128 с.

Технология лекарственных препаратов промышленного производства: Учебное пособие / Д.И. Дмитриевский. Л.И. Богуславская, Л.М. Хохлова и др. – Часть 2. Препараты для парентерального применения. Твердые и мягкие лекарственные формы. – Х.: Изд-во НФаУ, 2006. – 164 с.

Технологія лікарських препаратів промислового виробництва: Навчальний посібник / Д.І. Дмитрієвський. Л.І. Богуславська, Л.М. Хохлова та ін.; Ред. Д.І. Дмитрієвський. – Вид. 2-е. - Вінниця: Нова книга, 2008. – 280 с.

Additional

Асептичні лікарські форми: Екстемпоральна рецептура: Методичні рекомендації / О.І. Тихонов, Л.В.Бондарева, Т.Г.Ярних та ін.; За ред. О.І.Тихонова і Т.Г.Ярних. – Х.: Вид-во НФаУ; Оригінал, 2005. – 184 с.

Білоус С.Б. Від нанорозмірних речовин до інноваційних лікарських засобів / С.Б.Білоус, Т.Г.Калинюк, Н.І.Гудзь // Нанотехнології у фармації та медицині: Матер. міжн. наук. – практ. конфер. – Харків, 2011. – С. 35-36.

Гвозденко Н.А. Справочник по терапевтической косметологии / Н.А. Гвозденко. – Ростов н/Д.: «Фенікс», 2004. – 256 с.

Дерматология: Учеб. пособие для студентов спец. «Технология парфюмерно-косметических средств» / А.Г.Башура, С.Г.Ткаченко, Е.С.Шмелькова, В.А.Савоськина. – Х.: Изд-во НФаУ; Золотые страницы, 2006. – 200 с.

Дрибноход Ю.Ю. Косметология Изд. 2-е доп. и перераб. / Ю.Ю.Дрибноход. – Ростов н/Д: Феникс, 2008. – 538 с.
Калинюк Т.Г. Фізичні величини у фармації / Т.Г. Калинюк, Я.Й.Лопушанський. – Львів: Ліга-Прес, 2002. – 248 с.
М'які лікарські форми: Екстемпоральна рецептура: Методичні рекомендації /О.І. Тихонов, Т.Г. Ярних, О.В.Лукієнко та ін.; За ред. О.І. Тихонова – Х.: Вид-во НФаУ; Золоті сторінки, 2003. – 127 с.
Наказ МОЗ № 944 від 14.12.2009 р. Про затвердження Порядку проведення до клінічного вивчення лікарських засобів та експертизи матеріалів доклінічного вивчення лікарських засобів.
Належні практики у фармації: практикум для студ. вищих мед. навч. закладів / Н.І. Гудзь, С.Б. Білоус, Т.Г. Калинюк, К.І. Сметаніна; за ред. Т.Г. Калинюка.- Вінниця: Нова книга, 2013.– 368 с.
Нанонаука, нанобіологія, нанофармація. Монографія / І.С.Чекман, З.Р.Ульберг, В.О.Маланчук [та ін.]. – Київ: Поліграф плюс, 2012. – 328 с.
Настанова 42-01-2003. Лікарські засоби. Технологічний процес. Документація. – Київ, 2003. – 48 с.
Настанова 42-3.1:2004 «Настанови з якості. Лікарські засоби. Фармацевтична розробка».- Київ, МОЗ України, 2004. – 15 с.
Настанова 42-3.4:2004. Настанови з якості. Лікарські засоби. Виробництво готових лікарських засобів. – Київ, 2004. – 18 с.
Настанова 42-7.1:2005. Настанови з клінічних досліджень. Лікарські засоби. Дослідження біодоступності та біоеквівалентності. - Київ, 2005. – 18 с.
Настанова «Лікарські засоби. Фармацевтична розробка (ICH Q8). СТ-Н МОЗУ 42-3.0:2011». - Київ, МОЗ України, 2011. – 33 с.
Настанова «Лікарські засоби. Належна виробнича практика СТ-Н МОЗУ 42-4.0:2015». Режим доступу від 27 серпня 2015 р. http://www.diklz.gov.ua/control/main/uk/publish/article/746296.
Основы практической косметологии. Ч.1. Гигиенический косметический уход: Практ. Руководство: учеб.пособие для студентов вузов /А.Г.Башура, Н.П.Половко, Т.Н.Ковалева, Т.Д.Губченко – Х.: Изд-во НФаУ; Золотые страницы, 2004. – 152 с.
Папий Н.А. Медицинская косметология: Руководство для врачей / Н.А.Папий, Т.Н. Папий. – М.: ООО «Медицинское информационное агенство», 2008. – 512с.
Рідкі лікарські форми: Екстемпоральна рецептура: Методичні рекомендації / О.І. Тихонов, Т.Г.Ярних, Н.Ф.Орловецька та ін.; За ред. О.І.Тихонова і Т.Г.Ярних. – Х.: Вид-во НФаУ; Оригінал, 2005. – 160 с.
Сидоров Ю.І. Процеси і апарати мікробіологічної та фармацевтичної промисловості. Технологічні розрахунки. Приклади і задачі. Основи проектування: Навч.посібник / Ю.І. Сидоров, Р.Й.Влязло, В.П. Новіков. – Львів: Інтелект-Захід, 2008. – 736 с.
Сидоров Ю.І. Процеси і апарати хіміко-фармацевтичної промисловості / Ю.І. Сидоров, В.І.Чуєшов, В.П. Новіков. – Вінниця: НОВА КНИГА, 2009. – 816 с.
Сикорская С. Космецевтика в салоне красоты / С.Сикорская, А. Сикорская. – Москва, 2005. – 192 с.
Справочник экстемпоральной рецептуры / Под ред. А.И.Тихонова. – К.: МОРИОН, 1999. – 496 с.
Тверді лікарські форми: Екстемпоральна рецептура: Методичні рекомендації /О.І. Тихонов, Т.Г. Ярних, С.В. Гриценко та ін.; За ред. О.І. Тихонова – Х.: Вид-во НФаУ; Золоті сторінки, 2003. – 176 с.
Фармацевтична енциклопедія / Голова ред. ради В.П.Черних. – 2-е вид. – К.: Моріон, 2010. – 1632 с.
Фармацевтична енциклопедія / Голова ред. ради та автор передмови В. П. Черних. – 3-тє вид., переробл. і доповн. – К.: «МОРІОН», 2016. – 1952 с.
Фармацевтичне законодавство: Нормативні акти з організації роботи аптечних підприємств // Під ред. проф. Т.А.Грошового. – Тернопіль: Укрмедкнига, 2012. – 569 с.

Фармацевтичні та медико-біологічні аспекти ліків. Навчальний посібник / За ред. І.М.Перцева. – Вінниця: Нова книга, 2007. – 728 с.
Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labeling of cosmetic products.
Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.
Dermatologic, cosmeceutic and cosmetic development / Edit. Y.Walters. – 2008. – 644 p.
Dermatological and transdermal formulations / Edited by Kenneth A.Walters. – NewYork-London. – 2007. – 565 p.
Janicki S. Dostempnosc farmaceutyczna i dostempnosc biologiczna lekow / S. Janicki, M.Sznitowska, W.Zielinsli. - Warszawa: Osrodek informacji naukowej "POLFA" Sp.z o., 2001. - 256 s.
Novel drug formulation sistem and delivery devices /L.A.Chaica, V.V.Libina, T.V.Andrianova et al. – Riga, 1992. – P. 52-93.
Oral Extended (Controlled) Release Dosage Form: In Vivo Bioequivalence and In Vitro Dissolution Testing. Food and Drug Administration Center for Drug and Research (CDER) September 1993. http.//www.fda.gov./cder/guidance/index.htm.
Technologia nowoczesnych postaci lekow / pod red. R.N.Mullera et G.E.Hildebrand. - Warszawa: Wydawnictwo Lekarskie PZWL. – 1998. –356 s.

Information sources

Всесвітня організація охорони здоров'я www.who.int
Державний експертний центр МОЗ України www.pharma-center.kiev.ua
Державний реєстр лікарських засобів України. − [Електронний ресурс]. – Режим доступу: http://www.drlz.com.ua/.
Журнал «Фармацевт практик»: fp.com.ua.
Журнал «Провізор»: www.provisor.com.ua
Компендиум: лекарственные препараты: − [Електроний ресурс]. – Режим доступу: http://compendium.com.ua/.
Офіційний сайт Міністерства охорони здоров'я України: www.moz.gov.ua.
Спеціалізоване медичне інтернет-видання ля лікарів, провізорів, фармацевтів, студентів медичних та фармацевтичних вузів www.morion.ua
Фармацевтична енциклопедія www.pharmencyclopedia.com.ua
Щотижневик Аптека: https://www.apteka.ua/.