DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY
Department of Toxicological and Analytical Chemistry

APPROVED
The Acting First Vice-Rector for
scientific and pedagogical work
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«30» June 2022

CURRICULUM ON THE PROFILE COURSE «RESEARCH METHODOLOGY ON THE TOPIC OF THE MASTER'S PROJECT»

for fifth-year students of the Pharmacy Faculty

for the training of specialists of the 2nd (master degree) level of higher education
education sector 22 Public Healthcare
specialty 226 «Pharmacy»

Discussed and approved
at the methodical meeting of the Department
of Toxicological and Analytical Chemistry,
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Head of the department
Assoc. prof. I.Y. Halkevych

«Approved»
by profile methodical commission
in chemical and pharmaceutical disciplines
Protocol No. 3 from 21.06.2022
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INTRODUCTION

Curriculum of the optional course **"RESEARCH METHODOLOGY ON THE TOPIC OF THE MASTER'S PROJECT" is made** in accordance with the draft Standard of Higher Education of Ukraine for the training of specialists of *the second (master's) level*
education sector 22 " Public Healthcare"
specialty 226 " *Pharmacy, Industrial Pharmacy* "
educational program of *Master of Pharmacy*

DESCRIPTION OF THE DISCIPLINE (ABSTRACT)

The profile course " Research methodology on the topic of the master's project " is designed for students of higher educational institutions of the pharmaceutical profile of Ukraine and is part of the state standard of education.

The curriculum contains the necessary list of knowledge, skills and abilities, taking into account the international requirements for the credit transfer system, international regulations and standards governing the professional activities and training of masters of pharmacy.

Research methodology is a training profile course, which includes mastering a set of criteria that provide a basis for conducting a patent information search, approaches to the correct evaluation of research results and conclusions and the process of organizing a number of chemical studies, both pure substances and various objects of biological origin for the presence of toxic substances. During the study of the profile course, students get acquainted with the rules and procedures for the final qualification (master's) work.

STRUCTURE OF THE DISCIPLINE

Structure of the discipline	**Number of credits, hours**				**Year of study / semester**	**Type of control**
	Total credits / hours	**Classroom**		**ISW**		
		Lectures (hours)	Practical classes (hours)			
Name of elective discipline: **Research methodology on the topic of the master's project** Content modules 1	**15,0 credits / 450 hours**	**4**	**26**	**420**	**5th year (9-10 semesters)**	**Credit, defense of master's thesis**

The subject of study of the discipline are:

- organizational structure and staff of laboratories of chemical and toxicological analysis;
- setting a task for research;
- conducting a patent information search on the research topic:
- choice of selection method when conducting research;
- use of different methods for sample cleaning;
- detection of toxic substances in biological objects;
- quantification of toxic substances in biological objects;
- interpretation of research results on the presence of drugs and other potentially toxic compounds in tissues and body fluids, so that they can be protected in court;
- tools and their calibration;
- rules for storage of biological samples:

– writing the master's thesis.

Interdisciplinary links

Research methodology on the topic of the master's project as a discipline is based on knowledge of analytical chemistry, biological chemistry, physiology, organic and inorganic chemistry.

1. The purpose and objectives of the discipline

1.1. The purpose of the discipline " Research methodology on the topic of the master's project **"** is the acquisition by students of the necessary theoretical knowledge and practical skills of organizing a patent information search, the work of chemical analytical laboratories; conducting chemical and toxicological research and interpretation of the obtained results, registration of the obtained results in the master's thesis.

1.2. The main objectives of the discipline " Research methodology on the topic of the master's project **"** are to teach students the peculiarities of patent information search, work of chemical and toxicological laboratories, planning and conducting research on biological material for toxicants, developing new and improving existing methods of isolating toxic substances. Relevant facilities, development of effective methods for cleaning extracts obtained from objects of chemical and toxicological analysis, to identify and quantify toxic substances in them, to conduct the correct registration of research results in printed works: articles, abstracts and master's theses.

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

According to the requirements of the standard, the discipline " Research methodology on the topic of the master's project " provides students with the acquisition of competencies:

integral:

– ability to solve typical and complex specialized problems and practical problems in the learning process, which involves research, innovation and is characterized by complexity and uncertainty of conditions and requirements;

general:

- GC 2. Ability to apply knowledge in practical situations.
- GC 3. Efforts to preserve the environment.
- GC 4. Ability to think abstractly, analyze and synthesize, learn and be modernly educated.
- GC 5. The ability to show initiative and entrepreneurship.
- GC 6. Knowledge and understanding of the subject area and understanding of professional activity.
- GC 7. Ability to adapt and act in a new situation.
- GC 9. Skills in using information and communication technologies.
- GC 10. The ability to choose a communication strategy, the ability to work in a team and with experts from other fields of knowledge/types of economic activity.
- GC 11. Ability to evaluate and ensure the quality of performed works
- GC 12. Ability to conduct research at the appropriate level.
- GC 13. The ability to realize one's rights and responsibilities as a member of society, to realize the values of a civil (free democratic) society and the need for its sustainable development, the rule of law, the rights and freedoms of a person and a citizen in Ukraine.
- GC 14. The ability to preserve and multiply moral, cultural, scientific values and achievements of society based on an understanding of 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, to use different types and forms motor activity for active recreation and leading a healthy lifestyle.

special (professional, subject):

- PC 2. The ability to consult on prescription and non-prescription drugs and other products of the pharmacy assortment; pharmaceutical care during the selection and sale of an over-the-counter medicinal product by assessing the risk/benefit ratio, compatibility, indications and contraindications guided by data on the health status of a specific patient, taking into account the biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical features of the medicinal product and other products of the pharmacy assortment .
- PC 4. The ability to ensure the rational use of prescription and non-prescription drugs and other products of the pharmacy assortment in accordance with the physicochemical, pharmacological characteristics, biochemical, pathophysiological features of a specific disease and pharmacotherapeutic schemes of its treatment.
- PC 5. The ability to monitor the effectiveness and safety of the use of medicinal products by the population according to the data on their clinical and pharmaceutical characteristics, as well as taking into account subjective signs and objective clinical, laboratory and instrumental criteria for the examination of the patient.
- PC 6. The ability to identify medicinal products, xenobiotics, toxins and their metabolites in biological fluids and body tissues, to conduct chemical and toxicological studies for the purpose of diagnosing acute poisoning, drug and alcohol intoxication.
- PC 7. Ability to ensure proper storage of medicines and other pharmacy products in accordance with their physico-chemical properties and the rules of Good Storage Practice (GSP) in healthcare facilities.
- PC 12. Ability to use knowledge of normative and legal acts of Ukraine and recommendations of proper pharmaceutical practices in professional activity.
- PC 13. The ability to demonstrate and apply in practical activities communicative communication skills, fundamental principles of pharmaceutical ethics and deontology, based on moral obligations and values, ethical standards of professional behavior and responsibility in accordance with the Code of Ethics of Pharmaceutical Workers of Ukraine and WHO guidelines.
- PC 15. The ability to organize and participate in the production of medicinal products in the conditions of pharmaceutical enterprises, 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 preparation of the necessary documentation. Determine the stability of medicines
- PC 19. Ability to organize and carry out quality control of medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and proper practices in pharmacy, to determine sampling methods for medicinal product control and to carry out their standardization in accordance with current requirements, to prevent the distribution of falsified medicinal products.
- PC 20. Ability to develop methods of quality control of medicines, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances using physical, chemical, physico-chemical, biological, microbiological, pharmacotechnological and pharmaco-organoleptic control methods.

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

Competence Matrix

No	Competence	Knowledge	Skills	Communication	Autonomy and responsibility
1	2	3	4	5	6
Integral competence					
Ability to solve typical and complex specialized problems and practical problems in professional activities in the field of health care, or in the learning process, which involves research and / or innovation and is characterized by complexity and uncertainty of conditions and requirements.					
General competencies					

1	GC 2. Ability to apply knowledge in practical situations	Have specialized conceptual knowledge acquired in the learning process	To be able to solve complex tasks and problems that arise in professional activity.	Clear and unambiguous delivery of one's own conclusions, knowledge and explanations, which justify them to specialists and non-specialists.	Be responsible for making decisions in difficult conditions
2	GC 3. Efforts to preserve the environment	To know the problems of environmental preservation and the ways of its preservation	To be able to form requirements for oneself and others regarding the preservation of the environment	Make proposals to relevant bodies and institutions regarding measures to preserve and protect the environment	To bear responsibility for the implementation of environmental protection measures within the framework of one's competence
3	GC 4. Ability to abstract thinking, analysis and synthesis, to study and be modernly educated.	Know methods of analysis, synthesis and further modern education	Be able to analyze information, make informed decisions, be able to acquire modern knowledge	Establish appropriate connections to achieve goals.	To be responsible for the timely acquisition of modern knowledge.
4	GC 5. Ability to show initiative and entrepreneurship	Know the responsibilities and ways of performing assigned tasks	To be able to determine the goal and task, to be persistent and conscientious in the performance of duties	Establish interpersonal relationships for effective performance of tasks and responsibilities	To be responsible for the high-quality performance of assigned tasks
5	GC 6. Knowledge and understanding of the subject area and understanding of the profession	Have in-depth knowledge of the structure of professional activity	To be able to carry out professional activities that require updating and integration of knowledge	The ability to effectively form a communication strategy in professional activities	To be responsible for professional development, the ability for further professional training with a high level of autonomy
6	GC 7. Ability to adapt and act in a new situation	Know the elements of industrial and	To be able to form an effective strategy of personal	Interact with a wide range of people	Be responsible for making

		social adaptation; factors of successful adaptation to a new environment	adaptation to new conditions	(colleagues, management, specialists from other fields) when new situations with elements of unpredictability arise	decisions
7	GC 9. Skills in using information and communication technologies	Have deep knowledge in the field of information and communication technologies used in professional activities	To be able to use information and communication technologies in a professional field that requires updating and integration of knowledge	Use information and communication technologies in professional activities	To be responsible for the development of professional knowledge and skills
8	GC 10. Ability to choose a communication strategy; the ability to work in a team and with experts from other fields of knowledge	To know communication tactics and strategies, laws and methods of communicative behavior	Be able to choose methods and strategies of communication to ensure effective teamwork	Use communication strategies and interpersonal skills	To be responsible for the choice and tactics of the method of communication
9	GC 11. Ability to evaluate and ensure the quality of performed works	Know the methods of evaluating performance quality indicators	Be able to ensure quality performance of work	Establish relationships to ensure quality performance of work	To be responsible for quality performance of works
10	GC 12. The ability to conduct research on the appropriate levels	Know the components of the health care system, planning and evaluation of scientific research	Search for scientific sources of information; to choose methods of conducting scientific research, to use methods of mathematical analysis and modeling, theoretical and experimental research in pharmacy	Use information data from scientific sources	Be responsible for the development and implementation of planned projects
11	GC 13. The ability to realize one's rights and responsibilities as a	Know your rights and responsibilities as	Apply their rights and duties in practice, taking into	Ability to communicate with respect for	To bear responsibility for one's actions

	member of society, to realize the values of a civil (free democratic) society and the need for its sustainable development, the rule of law, the rights and freedoms of a person and a citizen in Ukraine.	a member of society	account the values of civil society	fundamental rights and human and civil liberties in Ukraine.	in civil society
12	GC 14. The ability to preserve and multiply moral, cultural, scientific values and achievements of society based on an understanding of 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, technology and technology nology, use different types and forms of physical activity for active recreation and leading a healthy lifestyle	To know the history and regularities of the development of pharmacy, its place in the general system of knowledge about nature and society and in the development of society, technology and technology	Use the understanding of the history and patterns of pharmacy development in practical activities	Ability to communicate in compliance with moral, cultural and scientific values.	To bear responsibility for compliance with moral and cultural and scientific values.
Special (professional, subject) competencies					
1	PC 2. The ability to consult on prescription and non-prescription drugs and other products of the pharmacy assortment; pharmaceutical care during the selection and sale of an over-the-counter medicinal product by assessing the risk/benefit ratio, compatibility, indications and contraindications, guided by data on the	Know the biopharmaceutical , pharmacokinetic, pharmacodynamic , physicochemical features of medicinal products and their therapeutic, toxic and lethal doses. Types of toxic action.	To carry out consultations on prescription and non-prescription drugs by assessing the risk/benefit ratio, compatibility, indications and contraindications guided by data on the health status of a specific patient, taking into account the biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical	Provide advisory assistance when choosing a drug, taking into account compatibility with other groups of drugs that can enhance/or inhibit its effect and cause additional toxic effects.	To be responsible for providing high-quality consulting assistance in choosing a medicinal product

	health status of a specific patient, taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physical - chemical features of the medicinal product and other products of the pharmacy assortment.		features of the drug.		
2	PC 4. The ability to ensure the rational use of prescription and non-prescription drugs and other products of the pharmacy assortment in accordance with the physico-chemical, pharmacological characteristics, biochemical, pathophysiological features of a specific disease and pharmacotherapeutic schemes of its treatment.	To know the chemical structure and physicochemical properties of medicines and poisons of natural origin; the influence of the chemical structure on the toxicity of substances and their biotransformation ; general patterns of behavior of poisonous substances of different groups in the body	Ensure the rational use of prescription and non-prescription drugs and other products of the pharmacy assortment in accordance with the physico-chemical, pharmacological characteristics, biochemical, pathophysiological features of a specific disease, taking into account the physiological features of the patient, the influence of the chemical structure on the toxicity of substances and their metabolism.	Provide information on the influence of the chemical structure on the toxicity of substances and their biotransformatio n for the purpose of rational use of drugs in accordance with the physicochemical, pharmacological characteristics, biochemical, pathophysiologic al features of a specific disease	To be responsible for the rational use of prescription and non-prescription drugs and other products of the pharmacy assortment in accordance with the physico-chemical, pharmacological characteristics, biochemical, pathophysiologic al features of a specific disease, taking into account the physiological features of the patient, the influence of the chemical structure on the toxicity of substances and their metabolism.
3	PC 5. The ability to monitor the effectiveness and safety of the use of medicinal products by the population according to the data on their clinical and pharmaceutical characteristics, as well as taking into account subjective signs and objective clinical, laboratory and	To know the ways of poisons entering the body and removing them from the body, their toxicokinetics	To be able to carry out differential diagnosis and express analysis of acute intoxications for the provision of qualified medical assistance.	Reasonably evaluate the obtained results	The ability to monitor the effectiveness and safety of the use of medicinal products by the population according to the data on their clinical and pharmaceutical characteristics, as well as taking into account subjective signs

	instrumental criteria of the patient's examination.				and objective clinical, laboratory and instrumental criteria for the examination of the patient.
4	PC 6. The ability to identify medicinal products, xenobiotics, toxins and their metabolites in biological fluids and tissues of the body, to conduct chemical and toxicological studies for the purpose of diagnosing acute poisoning, drug and alcohol intoxication.	Know the modern requirements for the organization and provision of chemical-toxicological analysis and forensic toxicological research. Know the methods of extracting poisons from various research objects; methods of their determination, distribution in the body, storage in cadaveric material and the influence of these processes on the results of chemical and toxicological analysis;	Be able to choose research objects for analysis, guided by knowledge about the distribution of poisons in organs, tissues and body fluids. Detect and determine poisons using chemical, spectral and chromatographic methods of analysis.	Justify the correctness of the choice of objects and methods of analysis for forensic toxicological research	Be responsible for making decisions about the selection of objects and methods of analysis for forensic toxicological research
5	PC 7. Ability to ensure proper storage of medicines and other pharmacy products in accordance with their physico-chemical properties and Good Storage Practice (GSP) rules in healthcare facilities.	Know the orders of the Ministry of Health of Ukraine regarding receipt, storage and issuance poisonous, narcotic and similar medicines; general requirements for the storage of medicines in pharmacies; storage rules for medicinal substances with different physical and chemical	Ensure appropriate storage conditions for poisonous, narcotic and similar medicines and substances at pharmaceutical enterprises	Carry out constant monitoring of the proper storage of medicines at pharmaceutical enterprises	Be responsible for the storage of medicines and medical devices in accordance with Good Storage Practices (GSP) in healthcare facilities

		properties;			
6	PC 12. Ability to use knowledge of normative and legal acts of Ukraine and recommendations of proper pharmaceutical practices in professional activity.	Know: the basics of the legal system and pharmaceutical legislation; legal and ethical standards of pharmaceutical activity. Know the requirements of Ukrainian and European regulatory documents for the organization and provision of chemical-toxicological analysis and forensic toxicological studies	To use regulatory and legal acts regulating pharmaceutical activity in Ukraine and abroad; form relationships with patients and doctors in order to fulfill the ethical criteria of the WHO and the principles of proper pharmacy practice regarding the promotion of medicinal products on the market, minimizing the abuse and incorrect use of medicinal products. To be able to choose objects and methods of analysis for conducting chemical-toxicological analysis and forensic toxicological research in accordance with the requirements of regulatory documents.	To substantiate the correctness of drawing up a plan of forensic toxicological research.	Be responsible for conducting forensic toxicological and chemical toxicological studies in accordance with regulatory and normative documents
7	PC 13. The ability to demonstrate and apply in practical activities communicative communication skills, fundamental principles of pharmaceutical ethics and deontology based on moral obligations and values, ethical norms of professional behavior and responsibility in accordance with the Code of Ethics of pharmaceutical workers of Ukraine and WHO leadership.	Apply in practical activities communicative communication skills, fundamental principles of pharmaceutical ethics and deontology based on moral obligations and values, ethical norms of professional behavior and responsibility in accordance with	Conduct professional activities in social interaction based on humanistic and ethical principles in accordance with the Code of Ethics of pharmaceutical workers of Ukraine and WHO guidelines	Adhere to the norms of communication in professional interaction with colleagues, management and work effectively in a team	Argue information for decision-making, bear responsibility for them in standard and non-standard professional situations; adhere to the principles of deontology and ethics in professional activity

		the Code of Ethics of pharmaceutical workers of Ukraine and WHO guidelines.			
8	PC 15. The ability to organize and participate in the production of medicinal products in the conditions of pharmaceutical enterprises, 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 preparation of the necessary documentation. Determine the stability of medicines	Know the requirements of regulatory documents for the placement of equipment and for the safe and high-quality correct maintenance of the equipment necessary for each specific analysis.	Be able to prepare the necessary reagents and work with modern equipment of forensic toxicological and chemical toxicological laboratories.	Ensure the operation of the laboratory in accordance with the requirements of regulatory documents	Be responsible for the organization of forensic toxicological and chemical toxicological studies in accordance with regulatory and normative documents
9	PC 19. The ability to organize and carry out quality control of medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and proper practices in pharmacy, to recognize methods of sampling for medicinal product control and to carry out their standardization in accordance with current requirements, to prevent the distribution of falsified	To know the State regulation of the quality of medicinal products; methods of qualitative and quantitative analysis of medicinal substances	Be able to apply chemical and instrumental methods of analysis to control the quality of medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and proper practices in pharmacy	Organize and carry out quality control of medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and proper practices in pharmacy	To be responsible for the quality control of medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and proper practices in pharmacy

	medicinal products.				
10	PC 20. The ability to develop methods of quality control of medicinal products, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances using physical, chemical, physico-chemical, biological, microbiological, pharmacotechnological and pharmaco-organoleptic control methods	To know chemical and modern instrumental methods of analysis, to know the specificity and sensitivity of various research methods. Know the standard procedures of statistical analysis	To be able to choose chemical and instrumental methods of analysis of substances, development of methods of quality control of medicinal products, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances. statistical Be able to justify the size of the sample, apply methods of statistical analysis, and present the results of data processing	Reasonably evaluate and interpret the results of chemical, physico-chemical and physical methods in the development of quality control methods for medicinal products, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances	To be responsible for the validity of the developed methods of quality control of medicinal products

Learning outcomes (PLO):

Integrative final program learning outcomes, the formation of which is facilitated by the profile course:

- PLO 1. To carry out professional activities in social interaction based on humanistic and ethical principles; to identify future professional activity as socially significant for human health.
- PLO 2. Apply knowledge from general and specialized disciplines in professional activity.
- PLO 3. To comply with the norms of the sanitary and hygienic regime and the requirements of safety equipment when carrying out professional activities.
- PLO 4. Demonstrate the ability to independently search, analyze and synthesize information from various sources and use these results to solve typical and complex specialized tasks of professional activity.
- PLO 5. To position one's professional activity and personal qualities on the pharmaceutical labor market; formulate the goals of one's own activity taking into account public and industrial interests.
- PLO 6. Argue information for decision-making, bear responsibility for them in standard and non-standard professional situations; adhere to the principles of deontology and ethics in professional activity.
- PLO 7. Perform professional activities using creative methods and approaches.
- PLO 8. Carry out professional communication in the state language, use oral communication skills in a foreign language, analyzing specialized texts and translating foreign language information sources.
- PLO 9. To carry out professional activities using information technologies, "Information databases", navigation systems, Internet resources, software and other information and communication technologies.
- PLO 10. Adhere to the norms of communication in professional interaction with colleagues, management, consumers, work effectively in a team.
- PLO 11. Use methods of evaluating indicators of the quality of activity; identify reserves for increasing labor efficiency.
- PLO 12. Analyze information obtained as a result of scientific research, summarize, systematize and use it in professional activities.
- PLO 13. To carry out sanitary and educational work in professional activities in the event of outbreaks of infectious, viral and parasitic diseases.

- PLO 14. Determine the advantages and disadvantages of drugs of various pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic and pharmacodynamic features. Recommend to consumers over-the-counter medicines and other products of the pharmacy assortment with the provision of advisory assistance and pharmaceutical care.
- PLO 15. Provide pre-medical assistance to patients in emergency situations and victims in extreme situations.
- PLO 16. Determine the influence of factors that affect the processes of absorption, distribution, deposition, metabolism and excretion of a medicinal product and are determined by the condition, features of the human body and the physicochemical properties of medicinal products.
- PLO 17. To use the data of clinical, laboratory and instrumental studies to monitor the effectiveness and safety of the use of medicinal products.
- PLO 18. Choose biological objects of analysis, determine xenobiotics and their metabolites in biological environments and evaluate the results obtained taking into account their distribution in the body.
- PLO 19. Predict and determine the influence of environmental factors on the quality of medicines and consumer characteristics of other products of the pharmacy assortment during their storage.
- PLO 20. Implement a complex of organizational and management measures to provide the population and health care institutions with medicines and other products of the pharmacy assortment. Carry out all types of accounting in pharmacies, administrative records, product analysis processes of pharmaceutical personnel in relation to strategic planning of enterprise activities.
- PLO 23. To take into account data on socio-economic processes in society for the pharmaceutical supply of the population, to determine the effectiveness and availability of pharmaceutical care in terms of medical insurance and reimbursement of the cost of drugs.
- PLO 24. Plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of proper pharmaceutical practices.
- PLO 25. Contribute to the preservation of health, in particular the prevention of diseases, the rational prescription and use of medicinal products. To faithfully fulfill one's professional duties, to comply with the legislation on the promotion and advertising of medicinal products. Possess psychological communication skills to achieve trust and mutual understanding with colleagues, doctors, patients, consumers.
- PLO 27. To justify the technology and organize the production of medicinal products at pharmaceutical enterprises and draw up technological documentation for the production of medicinal products at pharmaceutical enterprises.
- PLO 28. Organize and carry out rational procurement of medicinal plant raw materials. Develop and implement measures for the protection, reproduction and rational use of wild species of medicinal plants.
- PLO 29. To ensure competitive positions and effective development of pharmaceutical organizations based on the conducted research work on all elements of the marketing complex.
- PLO 30. Ensure quality control of medicines and document its results. To carry out quality risk management at all stages of the life cycle of medicinal products.
- PLO 31. Carry out all types of quality control of medicinal products; draw up quality certificates of a series of medicinal products and a certificate of analysis, taking into account the requirements of current regulatory documents, the State Pharmacopoeia of Ukraine and the results of quality control. Develop specifications and quality control methods in accordance with the requirements of the current State Pharmacopoeia of Ukraine.
- PLO 32. Determine the main organoleptic, physical, chemical, physicochemical and pharmacotechnological indicators of medicinal products, justify and choose methods of their standardization, carry out statistical processing of the results in accordance with the requirements of the current State Pharmacopoeia of Ukraine.

Learning results for the profile course

" Research methodology on the topic of the master's project "

Know:

- subject and tasks of chemical and toxicological analysis;
- conducting a patent information search;

- organization of chemical and toxicological analysis;
- methods of qualitative and quantitative analysis;
- methods of sample cleaning;
- methods of isolating substances from biological samples;
- main validation characteristics of analysis methods;
- features of interpretation of research results.

Be able:
- - work with regulations on chemical and toxicological analysis;
- - take and prepare samples for analysis;
- - use standard compounds in the development of methods of analysis;
- - to carry out validation of analytical methods.

2. Information volume of the discipline

15 ECTS credits / 450 hours are allocated for the study of the academic discipline.

Semantic module 1. "Principles and methods of patent information search, planning of research on chemical and toxicological analysis, processing of the results and methods of their registration in the master's thesis"

Topic 1. Scientific knowledge and its methodology. The main tasks and methods of research in chemical and toxicological analysis. The procedure for conducting a patent information search.
Classification of methods of scientific knowledge and their characteristics. Synthesis and analysis as the main ways of cognition. Theoretical and experimental research methods. The concept of types of observations and experiments. Basic approaches to experiment planning and observations. The main tasks facing chemical and toxicological analysis. Basic concepts of poisoning and poisons. Objects of chemical and toxicological analysis. Search for information in the patent databases of the EU, USA, Japan and China. Use of general search engines and search of information in specialized databases.

Topic 2. Objects of analysis, their main types and influence on the choice of methodology and method of analysis.
Selection methods, their review and stages. Factors to consider when choosing a method of isolation: physicochemical properties of substances, method of identification and quantification, and others. Determining the cause of unsatisfactory allocation results. Methods of protein denaturation, the process of their implementation and main characteristics. Using freezing. Liquid-liquid and solid-phase extractions, features of their carrying out and calculations. Classification of sorption and chromatographic methods, their use for cleaning extracts. Characteristics of distillation methods and their use. Review of other methods.

Topic 3. Methods of preliminary detection of substances.
Preliminary tests and screening, their purposes and use in chemical and toxicological analysis. Classification of immunochemical methods, their principle and characteristics. Method of chromatography in thin layers of sorbent, its use in rapid analysis, the main approaches to the development of methods for identification of substances by chromatography in a thin layer of sorbent. Classification and main types of immunochemical methods, their use for preliminary detection of substances. Automated systems for the diagnosis of poisoning by certain substances.

Topic 4. Use of gas chromatography, high performance liquid chromatography (HPLC) and electrophoretic methods for detection and quantification of substances.

The structure of the gas chromatograph. The main sorbents used to separate substances. Principles of identification and quantification of compounds. The main groups of substances that can be detected and quantified by gas chromatography. The structure of the chrome agraph for HPLC. Basic sorbents and solvent systems used for separation of substances. Principles of identification and quantification of compounds. The main groups of substances that can be detected and quantified by HPLC. The basic principles underlying the separation of electrophoretic methods. Use of electrophoresis on paper, gel electrophoresis, capillary electrophoresis for identification of substances.

Topic 5. The use of atomic emission and atomic adsorption analyzes for the detection of quantitative metals. Use of UV-, IR- and mass-spectrophotometry in chemical toxicological analysis.
Basic principles and use of atomic emission and atomic adsorption methods in chemical and toxicological analysis. Structure of devices. Principles of identification and quantification of substances by UV spectrophotometry. Review of basic techniques of mass spectrometry. Methodical approaches to the use of this method to establish the structure of substances, their identification and confirmation of identity. Basic libraries of mass spectra, programs of work with them and principles of work of these programs.

Topic 6. Evaluation and interpretation of research results obtained by different methods.
Methodical approaches to assessing the adequacy of the obtained results and establishing the need for clarifying research. The main methodological approaches to the generalization of the obtained research results. The procedure and features of statistical processing of experimental data, calculations of metrological characteristics of analysis methods for their validation and formulation on the basis of these characteristics of conclusions about the suitability of analytical methods, features of their use, etc. Use of specialized programs for statistical and other calculations.

Topic 7. Basic rules and procedure for registration of the results of scientific work.
Regulations on final qualifying work, basic rules and procedures for registration of the results of scientific work. Types and systems of bibliographic references, UDC, the basic documents regulating them and programs and services of the Internet for their registration. Registration of results of scientific work by means of word processors, specialized graphic editors and other programs. Basic requirements for the presentation and the order of their creation.

3. Structure of the discipline

Theme	Number of hours			
	Lectures	Practical classes	ISW	Individual work
1	2	3	4	5
Content module 1. **"Principles and methods of patent information search, planning of research on chemical and toxicological analysis, processing of the results and methods of their registration in the master's thesis"**				
Topic 1. Scientific knowledge and its methodology. The main tasks and methods of research in chemical and toxicological analysis. The procedure for conducting a patent information search.	**2**	4	10	-
Topic 2. Objects of analysis, their main types and influence on the choice of methodology and method of analysis.	-	2	10	-

Topic 3. Methods of preliminary detection of substances.	-	4	10	-
Topic 4. Use of gas chromatography, high performance liquid chromatography (HPLC) and electrophoretic methods for detection and quantification of substances.	-	4	10	-
Topic 5. The use of atomic emission and atomic adsorption analyzes for the detection of quantitative metals. Use of UV-, IR- and mass-spectrophotometry in chemical toxicological analysis.	-	4	10	-
Topic 6. Evaluation and interpretation of research results obtained by different methods.	1	4	3	-
Topic 7. Basic rules and procedure for registration of research results.	1	4	350	-
Total	4	26	420	-

4. Thematic plan of lectures

No	Theme	Hours
Content module 1. **"Principles and methods of patent information search, planning of research on chemical and toxicological analysis, processing of the results and methods of their registration in the master's thesis"**		
1	Scientific knowledge and its methodology. Classification of methods of scientific knowledge and their characteristics. Synthesis and analysis as the main ways of cognition. Theoretical and experimental methods of research. The concept of types of observations and experiments. Basic approaches to experiment planning and observations. Ways to find patterns based on the obtained empirical data.	**2**
2	Planning and procedure for conducting research. Basic approaches to patent information search in scientific research. Search for information in the patent databases of the EU, USA, Japan and China. Use of general search engines and search of information in specialized databases. Approaches to the processing of information obtained in the process of search and experiment, its impact on the further implementation of research, evaluation and processing of information obtained.	**2**
	Total	**4**

5. Thematic plan of practical classes

No	Theme	Hours
Content module 1. **"Principles and methods of patent information search, planning of research on chemical and toxicological analysis, processing of the results and methods of their registration in the master's thesis"**		
1.	The main factors to consider when planning a research. Structure and procedure of scientific research. Methodological approaches to assessing the relevance of the topic and setting tasks for scientific work. Search for general information on the use, pharmacological and toxicological properties of substances on the Internet.	2
2.	Search for information on the topic of scientific work in patent databases, reports on side effects, prohibitions on use and search for sources with reports of poisoning, non-medical use, etc.	2
3.	Search for information on the topic of scientific work in scientific journals. Ukrainian journals and information resources where you can find information on	2

	methods of analysis and toxic properties of various substances. The procedure for searching for information in the databases of abstract articles in foreign journals. Resources for access to the full text of articles in foreign journals and other scientific and reference materials.	
4.	Objects of analysis, their main types and influence on the choice of methodology and method of analysis. The concept of matrix effect and methods of taking into account, reducing and / or eliminating the errors of analysis caused by it. Features of analysis of substances in biological matrices. Methodical approaches for choosing a method of isolating toxicologically important substances from biological material and evaluating its effectiveness.	2
5.	The main methods of separation and concentration, widely used in chemical analysis for cleaning and preparation of samples, their main characteristics and features of use. Approaches to the selection of optimal methods and conditions for cleaning samples depending on the properties of the test substances, the method of isolation, the method of analysis and other factors.	2
6.	Use of optical methods for identification and quantification of substances. The procedure for developing methods of identification and confirmation of identity by UV and IR spectroscopy. Approaches for the development of methods for quantitative determination of substances in samples by UV spectrophotometry, spectrometry in the visible region and photocolorimetry.	2
7.	Review and characteristics of chromatographic methods used in chemical analysis. The main approaches to the development of methods for the identification of substances by chromatography in a thin layer of sorbent. The main stages of development of gas chromatography techniques to confirm the identity, identification and quantification of substances.	2
8.	Basic approaches to the development of methods for identification, identification and quantification of substances by high performance liquid chromatography. Features of using high performance liquid chromatography for enantiomer analysis.	2
9.	Basic electromigration methods used in chemical analysis. Procedure for developing methods for substance identification by paper electrophoresis and gel electrophoresis. Review of methods of using capillary band electrophoresis in the analysis. Methodical approaches to the development of methods for identification, identification and quantification of substances by capillary band electrophoresis, features of the use of enantioselective additives to the electrolyte.	2
10.	Review of basic techniques of mass spectrometry. Methodical approaches to the use of this method to establish the structure of substances, their identification and confirmation of identity. Basic libraries of mass spectra, programs of work with them and principles of work of these programs.	2
11.	Evaluation and interpretation of research results obtained by different methods. Analysis of their compliance with the objectives of the study. The value of negative results. Methodical approaches to assessing the adequacy of the obtained results and establishing the need for clarifying research.	2
12.	The main methodological approaches to the generalization of the obtained research results. The procedure and features of statistical processing of experimental data, calculations of metrological characteristics of analysis methods for their validation and formulation on the basis of these characteristics of conclusions about the suitability of analytical methods, features of their use, etc. Use of specialized programs for statistical and other calculations.	2
13.	Regulations on the final qualification work, the basic rules and the order of registration of results of scientific work. Types and systems of bibliographic references, UDC, the basic documents regulating them and programs and services of the Internet for their registration. Registration of results of scientific	2

	work by means of word processors, specialized graphic editors and other programs. Basic requirements for the presentation and the order of their creation.	
	Total	26

6. Thematic plan of independent work

No	Topic	Hours
1	Scientific knowledge and its methodology. Basic methods of cognition.	10
2	Content and organization of research in toxicological chemistry, the concept of the plan of chemical and toxicological analysis.	20
3	Information support of scientific research. The main sources of scientific information.	20
4	The main methodological approaches to the generalization of the obtained research results. The order of registration and presentation of results of scientific researches.	20
5.	Qualification (master's) work: preparation, writing, design, defense.	350
	Total	**420**

7. Individual tasks are not required

8. Teaching methods

In the course of the profile course " Research methodology on the topic of the master's project " the following teaching methods are used:

- explanatory-illustrative - (verbal and visual - lectures, theoretical part of the seminar);
- partial search method - preparation for a seminar, testing, control of independent work;
- research method - performing experimental work.

Preference is given to active and interactive methods and multimedia learning (multimedia lectures, educational films).

9. Control methods

Assimilation of the topic is controlled in practical classes in accordance with specific goals, mastering the content module (intermediate control) - in the final lesson. The following means of control of level of preparation of students are applied:

- oral examination and written assignments;
- solving situational problems;
- testing the ability to interpret and evaluate the results of various methods of identification and quantification of substances, control of practical skills.

Forms of current control:

theoretical knowledge - individual surveys, interviews;

practical skills and abilities - solving typical and situational problems and control of practical actions.

Final control is carried out on the basis of control of theoretical knowledge, practical skills and abilities.

At each lesson, the level of students' knowledge is assessed on a 4-point scale ("5", "4", "3", "2") in accordance with the criteria for assessing the current activities of the student. The obtained scores are converted into appropriate points.

Distribution of points received by students.

10. Current control is carried out at each seminar. In each lesson, the student answers 10 tests and 5 questions on the topic of the seminar, the knowledge of which is necessary to understand the current topic, the issues of the lecture course and independent work related to the current lesson;

demonstrates knowledge and skills of practical skills in accordance with the topic of practical training.

10.1 Evaluation criteria

I. Current control. At each lesson, the level of students' knowledge is assessed on a 4-point scale.

Excellent ("5"). The student correctly, clearly, logically and fully answers the standardized questions of the current topic, including questions of independent work. Closely connects theory with practice and correctly demonstrates the performance (knowledge) of practical skills. Freely solves situational problems of increased complexity, is able to summarize the material.

Good ("4"). The student correctly and essentially answers the standardized questions of the current topic, independent work. Demonstrates performance (knowledge) of practical skills. Correctly uses theoretical knowledge in solving practical problems. Is able to solve easy and medium situational problems. Has the necessary practical skills and techniques to perform them in excess of the required minimum.

Satisfactory ("3"). The student incompletely, with the help of additional questions, answers the standardized questions of the current topic, lecture course and independent work. Cannot build a clear, logical answer on their own. During the answer and demonstration of practical skills the student makes mistakes. The student solves only the easiest problems, has only a mandatory minimum of research methods.

Unsatisfactory ("2"). The student does not know the material of the current topic, can not build a logical answer, does not answer additional questions, does not understand the content of the material. Makes significant, gross mistakes when answering and demonstrating practical skills.

The student's independent work is assessed during the current control of the topic in the relevant classroom. Assessment of topics that are submitted for self-study and are not included in the topics of classroom training, are controlled during the final tests.

11. The form of final control is a credit. The course ends with the implementation of master's work, which is assessed by passing an objective structured practical exam

The credit lesson is held at the last practical lesson in the form of a test control. Students who have completed all types of work provided for in the curriculum, completed all practical classes and scored at least the minimum number of points while studying the module are admitted to the test.
The grade for the discipline is defined as the sum of grades for the current educational activity and is expressed on a 200-point scale.

12. Scheme of accrual and distribution of points received by students:

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

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

The calculation of the number of points is based on the grades obtained by the student on the traditional 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:

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

Recalculation of the average score for current activities in a multi-point scale is based on the table:

Table

Recalculation of the average grade for current activities in a multi-point scale

4-point scale	**5**	**4.97**	**4.95**	**4.92**	**4.9**	**4.87**	**4.85**	**4.82**	**4.8**	**4.77**	**4.75**	**4.72**	**4.7**

200-point scale	200	199	198	197	196	195	194	193	192	191	190	189	188
4-point scale	**4.67**	**4.65**	**4.62**	**4.6**	**4.57**	**4.52**	**4.47**	**4.45**	**4.42**	**4.4**	**4.37**	**4.35**	**4.32**
200-point scale	187	186	185	184	183	181	180	178	177	176	175	174	173
4-point scale	**4.3**	**4.27**	**4.24**	**4.22**	**4.19**	**4.17**	**4.14**	**4.12**	**4.09**	**4.07**	**4.04**	**4.02**	**3.99**
200-point scale	172	171	170	169	168	167	166	165	164	163	162	161	160
4-point scale	**3.97**	**3.94**	**3.92**	**3.89**	**3.87**	**3.84**	**3.82**	**3.79**	**3.77**	**3.74**	3.**72**	3.**7**	3.**67**
200-point scale	159	158	157	156	155	154	153	152	151	150	149	148	147
4-point scale	**3.65**	**3.62**	**3.57**	**3.55**	**3.52**	**3.5**	**3.47**	**3.45**	**3.42**	**3.4**	3.**37**	3.**35**	3.**32**
200-point scale	146	145	143	142	141	140	139	138	137	136	135	134	133
4-point scale	**3.3**	**3.27**	**3.25**	**3.22**	**3.2**	**3.17**	**3.15**	**3.12**	**3.1**	**3.07**	3.**02**	3	**Less than 3**
200-point scale	132	131	130	129	128	127	126	125	124	123	121	120	Not enought

13. Methodical support

Multimedia texts of lectures
Computers
A set of situational tasks for classes.
Recommended literature.

14. Recommended literature

Basic

1. Harding S. Objectivity and Diversity: Another Logic of Scientific Research. – University of Chicago Press, 2015. – 232 p.
2. Deetjen T.Published: a guide to literature review, outlining, experimenting, visualization, writing, editing, and peer review for your first scientific journal article. – Productive Academic, 2020. – 276 p.
3. Kelly M. A., Haddix P. L. The Fundamentals of Scientific Research. An Introductory Laboratory Manual. – Wiley-Blackwell, 2015. – 208 p.
4. Food, Drug Administration Centre for Drug Evaluation and Research (FDA). Guidance for industry-bioanalytical method validation, center for drug evaluation and research. US Department for Health and Human Services, 2013, Silver Spring, MD, 2001.
5. Guideline on bioanalytical method validation. European Medicines Agency (EMEA/CHMP/EWP/192217/2009), 2011.
6. Handbook of Toxicology. 2 ed. / Edited by Derelanko M.J., Hollinger M.A. - N.W.: CRC Press LLC, 2002. 1380 p.
7. Moffat A. C., Osselton M. D., Widdop B. Clarke's analysis of drugs and poisons. London: Pharmaceutical Press, 2011. 2609 p

8. Poisoning and Drug Overdose. Fifth Edition / Edited by Kent R. Olson. - San Francisco: The McGraw-Hill Companies, 2007. 1132 p.
9. Randall C. Baselt. Dispositionof Toxic Drugsand Chemicals in Man. – California, Foster City; Chemical Toxicology Institute, 2000. 920 p.

Auxiliary literature

1. Foong May Yeong. How To Read And Critique A Scientific Research Article Notes To Guide Students Reading Primary Literature. – Wspc, 2014. – 116 p.
2. Mamishev A. Creating Research and Scientific Documents with Microsoft Word. – Microsoft Press, 2013. – 284 p.
3. Wilson E. B. An Introduction to Scientific Research. – Dover Publications, Inc., 2003. – 400 p.
4. Koepsell D. Scientific Integrity and Research Ethics: An Approach from the Ethos of Science. – Springer, 2017. – 129 p.
5. Flanagan R.J., Taylor A.A., Watson I.D., Whelpton R. Fundamentals of Analytical Toxicology. – New York: WileyBlackwell, 2008. – 544 p.
6. Moffat A.C., Osselton M.D., Widdop B. Clarke's analysis of drugs and poisons in pharmaceuticals, body fluids and postmortem material. – London: Pharmaceutical Press, 2011. – 2609 p.
7. Flanagan R.J. Developing an Analytical Toxicology Service: Principles and Guidance / Flanagan R.J. // Toxicological Reviews. – 2004. – Vol. 23, №4. – P. 251-263.