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



CURRICULUM ON THE OPTIONAL DISCIPLINE MECHANISMS OF PHARMACOLOGICAL ACTIVITY AND DRUG TOXICITY

for students of the third year of the Pharmacy Faculty

training of specialists of the second (master's) level of higher education education sector 22 «Public Healthcare» Specialty 226 "Pharmacy, Industrial Pharmacy"

Discussed and approved

at the methodical meeting of the Department of Toxicological and Analytical Chemistry, protocol No 14 from 13.06.2022 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 Head of the profile methodical commission Assoc. prof. S.B. Bilous.

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INTRODUCTION

Curriculum of the optional discipline <u>"Mechanisms of pharmacological activity and drug toxicity " is</u> <u>made</u> 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 OPTIONAL DISCIPLINE (ABSTRACT)

The optional discipline "Mechanisms of pharmacological activity and drug toxicity" is designed for students of higher educational institutions of pharmaceutical profile of Ukraine and is an integral part of the state standard of education.

The curriculum of the optional discipline "Mechanisms of pharmacological activity and toxicity of drugs" provides: compliance with the content of industry standards of higher education through a direct link between the content of the discipline and the goals of higher education (skills and abilities defined in Educational and Professional Program 2022); compliance with licensing and accreditation conditions and requirements; compliance with "Standards and recommendations for quality assurance in the European Higher Education Area"; the possibility of using disciplinary competencies as an information base for the formation of diagnostic tools; unambiguous criteria for assessing academic achievement.

The developed working curriculum determines: the amount of knowledge of the optional discipline "Mechanisms of pharmacological activity and toxicity of drugs", which must be mastered by the student in accordance with the requirements of the educational and qualification characteristics of the future specialist; algorithm of studying the educational material of the discipline taking into account interdisciplinary connections; necessary methodological support and methodology for assessing students' knowledge.

The curriculum of the optional discipline "Mechanisms of pharmacological activity and toxicity of drugs" lays the ideology of the content of education and the organization of the educational process, determines the educational and methodological principles of the department. This program is the basis for the development of all educational and methodological materials to ensure the educational process, including for independent work of students.

STRUCTURE OF THE COURSE

	Numb	er of credits	(hours)				
The structure of the	Total anadita /	Class	room		Educational	Type of	
discipline	Total credits / hour		Seminars	ISW	level / term	control	
		(hours)	(hours)				
Course title: Mechanisms	3,0 credits / 90	10	20	60	Third year	Credit	
of pharmacological activity	hours				(5-6 term)		
and drug toxicity							
Module 1							

The subject of study of the optional discipline "Mechanisms of pharmacological activity and toxicity of drugs" are:

- the relationship between the structure of substances and their biological activity;
- types and kinds of interactions between the substance and the receptor;
- mechanisms of pharmacological activity and factors influencing them;
- mechanisms of toxic action of xenobiotics;
- quantitative patterns of pharmacological effect;
- toxicometric parameters.

Interdisciplinary links:

a) Optional discipline is based on knowledge of inorganic chemistry, organic chemistry, biological chemistry and integrates with pharmaceutical chemistry, toxicological chemistry and pharmacology;

b) Optional discipline lays the foundations for the study of pharmaceutical chemistry, toxicological chemistry and pharmacotherapy and provides for the formation of skills to apply the acquired knowledge for the study of special disciplines and in professional activities.

1. The purpose and objectives of the discipline

- 1.1. The purpose of teaching the optional discipline "Mechanisms of pharmacological activity and toxicity of drugs" is to prepare students for the development of medical-biological and special disciplines, for which on the basis of modern scientific ideas to form students' necessary knowledge, skills and abilities in toxicological chemistry.
- **1.2.** The main objectives of the study of the discipline of choice "Mechanisms of pharmacological activity and toxicity of drugs" are:

- formation of students' knowledge and skills, practical skills in toxicology, which is a general theoretical discipline in the system of pharmacist training;

- preparation of students for mastering a special and pharmaceutical discipline - toxicological chemistry, as well as obtaining basic toxicological knowledge necessary for understanding and mastering a number of medical, biological and chemical disciplines studied at the Faculty of Pharmacy.

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 seekers, formulated in terms of learning outcomes in the Standard of Higher Education).

According to the requirements of the Standard, the optional discipline "Mechanisms of pharmacological activity and toxicity of drugs" contributes to the acquisition by students of competencies: *integral*:

- ability to solve typical and complex specialized problems and practical problems in professional pharmaceutical activity with the application of theoretical principles of toxicology, reasonably substantiate research results and unambiguously communicate their conclusions and knowledge to professional and non-professional audience;

general:

- GC 2. Ability to apply knowledge in practical situations.

- GC 4. Ability to think abstractly, analyze and synthesize, learn and be modernly educated.
- 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 8. The ability to communicate in the state language both orally and in writing, the ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity. - GC 9. Skills in using information and communication technologies.

- 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. The ability to evaluate and ensure the quality of performed works.

- GC 12. Ability to conduct research at the appropriate level

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.
- -P4. 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;
- -PC 5. The ability to monitor the effectiveness and safety of the use of medicinal products by the population according to data on their clinical and pharmaceutical characteristics, as well as taking

into account subjective signs and objective clinical, laboratory and instrumental criteria of the patient's examination.;

- -PC 12. Ability to use knowledge of regulatory and legislative 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.

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

Competence Matrix

№	Competence	Knowledge	Skills	Communication	Autonomy and re- sponsibility		
1	2	3	4	5	6		
			tegral competence				
pharr resea	ability to solve typical and complex specialized problems and practical problems in professional pharmaceutical activity with the application of theoretical principles of toxicology, reasonably substantiate research results and unambiguously communicate their conclusions and knowledge to professional and non-professional audience.						
			al competencies (GG				
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 presentation 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 4. Ability to abstract thinking, analysis and synthesis, ability to learn and be modernly trained.	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.		
3	GC 6. Knowledge and understanding of the subject area and understanding of the profession	Have deep 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.		
4	GC 8. The ability to communicate in the state language both orally and in writing, the	Have perfect knowledge of the native language and basic knowledge of a foreign language	To be able to apply knowledge of the native language, both orally and in writing, to be able	Use your native language in professional and business communication and when	To be responsible for fluency in the native language, for		

	ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity.		to communicate in a foreign language	preparing documents.			
5	GC 9. Skills in the use of information and communication technologies	languages	To be able to use information and communication technologies in a professional field that requires updating and integration of knowledge	Use a foreign language in professional activities	development of professional knowledge		
6	GC 11. Ability to evaluate and ensure the quality of performed works	Have deep knowledge in the field of information and communication technologies used in professional activities	Be able to ensure quality performance of work	Use information and communication technologies in professional activities	To be responsible for the development of professional knowledge and skills		
7	GC 12. Ability to conduct research at the appropriate level	Know the methods of evaluating performance quality indicators	Search for scientific sources of information; to choose methods of scientific research, to use methods of mathematical analysis and modeling, theoretical and experimental research in pharmacy	Establish relationships to ensure quality performance of work	To be responsible for quality performance of works		
	Special (professional, subject) competencies (PC)						
1.	PC 2. The ability to provide counseling and pharmaceutical care during the selection and sale of an over-the- counter medicinal product by assessing the risk/benefit ratio, compatibility,	Know the modern requirements for the organization and ensuring the control of the safety of medicinal products.	To be able to choose methods of researching the toxicity of medicinal products.	To justify the selected methods of research of medicinal products.	To be responsible for the organization, provision and control of the safety of medicinal products.		

	indications and contraindications, taking into account the biopharmaceutica l, pharmacokinetic, pharmacodynami c and physicochemical features of the medicinal product and other products of the pharmacy assortment.				
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 physicochemical, pharmacological characteristics, biochemical, pathophysiologic al features of a specific disease and pharmacotherape utic schemes of its treatment;	Know the pharmacological and toxicological properties of xenobiotics	Be able to apply pharmacological and toxicological models to calculate pharmacokinetic parameters	Reasonably evaluate the results of conducted pharmacological, toxicological and biopharmaceutica l studies	Be responsible for decision-making regarding the evaluation of drug safety research results
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,	Know mathematical models for calculating pharmacological and toxicological parameters	Be able to use special software for calculating biopharmaceutica l parameters of drug safety	Reasonably evaluate the results of pharmacological, toxicological and biopharmaceutica l calculations	Be responsible for decision-making regarding the evaluation of drug safety results

	laboratory and instrumental criteria for the examination of the patient; PC 12. Ability to	Have specialized	Be able to solve	Clear and	Responsibility for
4	use knowledge of regulatory and legislative acts of Ukraine and recommendations of proper pharmaceutical practices in professional activity.	conceptual knowledge acquired in the process of study and/or professional activity at the level of the latest achievements, which are the basis for original thinking and innovative activity.	complex tasks and problems that require updating and integration of knowledge, often in conditions of incomplete/insuffi cient information and conflicting requirements.	unambiguous presentation of one's own conclusions, as well as the knowledge and explanations that justify them, to specialists and non-specialists, in particular to people who are studying.	the development of professional knowledge and practices.
5	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.	Know the main provisions of the Code of Ethics of pharmaceutical workers of Ukraine, know the moral and deontological principles of a pharmacist	To use in practical activities the principles of the Code of Ethics of pharmaceutical workers of Ukraine, to use communication skills based on moral and deontological values in practical activities.	Observe the regulations when communicating with patients and colleagues	A capacity for further learning that is largely autonomous and self-directed.

Learning outcomes (PLO):

Integrative final program learning outcomes, the formation of which is facilitated by the optional discipline "Mechanisms of pharmacological activity and drug toxicity":

general:

- 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 4. Demonstrate the ability to independently search, analyze and synthesize information from various sources and use these results to solve typical and complex problems specialized tasks of professional activity.

- PLO 6. Argue information for decision-making, bear responsibility for them in standard and nonstandard 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. To 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 activity quality indicators; identify reserves for improving labor efficiency.

– PLO 12. Analyze information obtained as a result of scientific research, generalize, systematize and use it in professional activities.

professional:

- 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 16. To determine the influence of factors affecting the processes of absorption, distribution, deposition, metabolism and excretion of the medicinal product and are caused by the condition, features of the human body and physico-chemical 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 32. To determine the main organoleptic, physical, chemical, physico-chemical 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 outcomes for the optional discipline "Mechanisms of pharmacological activity and drug toxicity":

To know:

- subject, tasks and main sections of toxicology, areas of its application;
- mechanisms of pharmacological activity of drugs;
- relationship between the structure of the substance and its pharmacological action and toxicity;
- mechanisms of toxic action of drugs;
- basic parameters of toxicometry;
- basic regulations governing preclinical trials of drugs;
- theoretical bases of methods for determining toxicity and other safety parameters of substances;
- basics of mathematical processing of results of pharmacological and toxicological researches;
- main literature sources and reference literature on toxicology.

To be able to:

- analyze data from educational and special literature in solving professional problems related to toxicological research;
- predict the main mechanisms of pharmacological activity of substances based on their chemical structure;
- anticipate possible types of toxicity of substances based on their chemical structure;
- perform appropriate calculations, final calculations using statistical processing of analysis results;
- use specialized software in toxicological research;
- work independently with educational and reference literature on toxicology;
- apply the theoretical foundations of toxicology and acquired experimental skills in the study of specialized disciplines.

2. Information volume of the discipline of choice

3 ECTS credits / 90 hours are allocated for the study of the academic discipline.

Topic 1. Benefits and risks when prescribing drugs. Grounds for the use of drugs.

The basic concepts of pharmacology - pharmacological activity, pharmacological action, pharmacological effect of chemicals. Factors that provide the therapeutic effect of drugs - pharmacodynamic action, placebo effects. Drug substance, drug, drug, dosage form. Dose. See dosage. Dosage units of drugs. The purpose of drug dosing. Therapeutic and toxic ranges (intervals) of drug concentrations in the blood. The concept of adequate mode of administration of discrete doses.

Topic 2. Physico-chemical and chemical mechanisms of action of pharmacological substances.

Ferguson's principle. The value of non-covalent and covalent interactions in the effect of drugs. The concept of receptors in pharmacology: the molecular nature of receptors, signaling mechanisms of action of drugs. Types of transmembrane signaling and secondary mediators involved in the implementation of the drug.

Topic 3. Quantitative patterns of pharmacological effect.

Clark-Ariens model and its consequences. General type of concentration - effect in normal and lognormal coordinates. The concept of quantitative pharmacology: effect, efficacy, activity, agonist (complete, partial), antagonist (competitive, non-competitive).

Topic 4. The concept of types of antagonism of drugs: pharmacological, physiological, chemical.

Pharmacological antagonism: competitive, non-competitive. The nature of changes in the activity and effectiveness of drugs depending on the types of pharmacological antagonism.

Topic 5. The concept of additivity, synergy and potentiation during drug interaction.

Clinical difference between the concepts of activity and effectiveness of drugs. Gradual and alternative (quantum) quantitative assessment of the pharmacological effect: essence, clinical application.

Topic 6. Resorptive, systemic and local action of drugs.

Change in the effect of the drug with repeated administration. Dependence of action of drugs on age, sex, individual features of an organism. The value of circadian rhythms in the action of drugs.

Topic 7. Variability and variability of drugs.

Hypo- and hyperreactivity, tolerance and tachyphylaxis, hypersensitivity and idiosyncrasy. Causes of drug variability. Specificity and selectivity of drugs. Therapeutic, side and toxic effects of drugs, their nature in terms of the concept of receptors.

Topic 8. Basics of toxicometry. Drug safety assessment.

Toxicometry, its tasks and main parameters (Limac - threshold of single (acute) toxic action; DL50 (DL100); CL50 (CL100); MPC; DL50 / Limac. Therapeutic index and standard safety margins. Teratogenic, embryotoxic, fetotoxic, mu carcinogenic effect of drugs.

3. The structure of the discipline

Topio	Nu	mber of hour	rs
Торіс	Lectures	Tutorials	ISW
Topic 1. Basic concepts of pharmacology.	1	2	4
Topic 2. Physico-chemical and chemical mechanisms of action of	1	2	8
pharmacological substances.	1	2	0
Topic 3. Quantitative patterns of pharmacological effect.	1	2	8
Topic 4. The concept of types of drug antagonism.	1	2	8
Topic 5. The concept of additivity, synergy and potentiation during	1	2	8
drug interaction.	1	2	0
Topic 6. Resorptive, systemic and local action of drugs.	1	2	8
Topic 7. Variability and variability of drugs.	2	2	8
Topic 8. Basics of toxicometry. Drug safety assessment.	2	2	8
Final lesson of the practical course.		2	

Enrollment of independent student work. Credit lesson.		2	
Together for the module	10	20	60

4. Thematic plan of lectures

N⁰	Торіс	Number of hours
1.	The basic concepts of pharmacology - pharmacological activity, pharmacological action, pharmacological effect of chemicals.	2
2.	Physico-chemical and chemical mechanisms of action of pharmacological substances.	2
3.	Quantitative patterns of pharmacological effect.	2
4.	The concept of types of drug antagonism: pharmacological, physiological, chemical	2
5.	The concept of additivity, synergism and potentiation during drug interaction.	2
	Total	10

5. Thematic plan of practical classes

N⁰	Торіс	Number of
		hours
1.	Basic concepts of pharmacology.	2
2.	Physico-chemical and chemical mechanisms of action of pharmacological substances.	2
3.	Quantitative patterns of pharmacological effect.	2
4.	The concept of types of drug antagonism: pharmacological, physiological, chemical.	2
5.	The concept of additivity, synergism and potentiation during drug interaction.	2
6.	Resorptive, systemic and local action of drugs.	2
7.	Variability and variability of drug action.	2
8.	Basics of toxicometry. Drug safety assessment.	2
9	Final lesson of the practical course.	2
10.	Credit lesson.	2
	Total	20

6. Thematic plan of individual work of students

20		NT 1	TT A
Nº	Горіс	Number	Type of
		of hours	control

	Total	60		
	Teratogenic, embryotoxic, fetotoxic, mutagenic, carcinogenic effects of drugs.	8		
7.	 Hypo- and hyperreactivity, tolerance and tachyphylaxis, hypersensitivity and idiosyncrasy. Causes of drug variability. Specificity and selectivity of drugs. Therapeutic, side and toxic effects of drugs, their nature in terms of the concept of receptors. Toxicometry. Therapeutic index and standard safety margins. 	8		
6.	Change in the effect of the drug with repeated administration. Dependence of action of drugs on age, sex, individual features of an organism. The value of circadian rhythms in the action of drugs.	8		
5.	Clinical difference between the concepts of activity and effectiveness of drugs. Gradual and alternative (quantum) quantitative assessment of the pharmacological effect: essence, clinical application.	8		
4.	Pharmacological antagonism: competitive, non-competitive. The nature of changes in the activity and effectiveness of drugs depending on the types of pharmacological antagonism.	8		
3.	Clark-Ariens model and its consequences. General type of concentration - effect in normal and lognormal coordinates. The concept of quantitative pharmacology: effect, efficacy, activity, agonist (complete, partial), antagonist (competitive, non-competitive).	8		
2.	Ferguson's principle. The value of non-covalent and covalent interactions in the effect of drugs. The concept of receptors in pharmacology: the molecular nature of receptors, signaling mechanisms of action of drugs. Types of transmembrane signaling and secondary mediators involved in the implementation of the drug.	8		
1.	Factors that provide the therapeutic effect of drugs - pharmacodynamic action, placebo effects. Drug substance, drug, drug, dosage form. Dose. See dosage. Dosage units of drugs. The purpose of drug dosing. Therapeutic and toxic ranges (intervals) of drug concentrations in the blood. The concept of adequate mode of administration of discrete doses.	4	Current control practical classes	in

7. Individual tasks for full-time students are not provided.

Tasks for individual work

- 1. Pharmacological (biological) activity of xenobiotics.
- 2. Placebo; placebo effect, nocebo effect.
- 3. Types of doses of drugs.
- 4. The purpose of dosing drugs.
- 5. Mechanisms of action of pharmacological substances.
- 6. The main pharmacological effects.
- 7. The main types of chemical interaction with the biosubstrate.
- 8. Molecular targets.
- 9. Ferguson's principle.
- 10. The concept of receptors in pharmacology and toxicology.
- 11. Molecular nature of receptors.
- 12. Signal mechanisms of action of drugs.
- 13. Clark-Ariens model and its consequences.

14. Dependence concentration - effect in normal and logarithmic coordinates.

15. Effect, effectiveness, activity of the drug.

16. Types of drug antagonism.

17. Pharmacological antagonism: competitive, non-competitive.

18. The nature of changes in the activity and effectiveness of drugs depending on the types of pharmacological antagonism.

19. Additivity, synergism and potentiation in the interaction of drugs.

20. Clinical difference between the concepts of activity and effectiveness of drugs.

21. Gradual and quantum quantitative assessment of the pharmacological effect.

22. Quantitative assessment of drug activity and efficacy in experimental and clinical practice.

- 23. Resorptive, systemic and local action of drugs.
- 24. Changing the effect of drugs on repeated administration.
- 25. Dependence of action of drugs on age, sex, individual features of an organism.
- 26. Variability and variability of drug action.
- 27. Causes of drug variability and rational therapy strategy.

28. Specificity and selectivity of drugs. Therapeutic, side and toxic effects of drugs, their nature from the standpoint of the concept of receptors.

29. Drug safety assessment. Therapeutic index and standard safety margins.

30. Teratogenic, embryotoxic, fetotoxic, mutagenic, carcinogenic effects of drugs.

8. Teaching methods

In the process of studying the optional discipline "Mechanisms of pharmacological activity and toxicity of drugs" the following methods of teaching students are used:

by sources of knowledge:

- verbal lecture, explanation, instruction;
- visual demonstration, illustration;
- practical practical work, situational tasks.

by the nature of the logic of cognition:

- analytical,
- synthetic,
- analytical-synthetic,
- inductive, deductive.

by the level of independent mental activity:

- problematic,
- partial search,
- research.

according to the main stages of the process:

- knowledge formation,
- formation of skills and abilities,
- application of knowledge,
- generalization,
- fixing,
- audition

to the system approach:

- stimulation and motivation,
- control and self-control

9. Control methods

Current control is carried out at each practical lesson in accordance with the specific objectives of the topic. All practical classes use objective control over the performance of independent work, theoretical training and the acquisition of practical skills.

The following means of diagnosing the level of preparation of students are used: testing, solving situational problems, conducting laboratory research, interpretation and evaluation of their results, control of practical skills.

At each practical lesson the student answers test tasks (on the topic of practical lesson, standardized questions, knowledge of which is necessary to understand the current topic, lecture course and independent work related to the current lesson; demonstrates knowledge and skills of practical skills according to the practical lesson).

The form of final control in the study of the discipline of choice "Mechanisms of pharmacological activity and toxicity of drugs" is a test. Students who have completed all types of work provided for in the curriculum, completed all classes and scored the number of points above the minimum level are allowed to take the final control.

Methods and means of standardized assessment in the preparation of the final control

Regulations for the test

The form of final control is standardized, includes control of theoretical and practical training.

The final control consists of a written answer to the test tasks of format A (blank). The student answers 40 test tasks of format A on each topic of the module and is evaluated with 2 points for each correct answer.

The credit score is determined by the sum of points for answers to test tasks.

The maximum number of points when taking the test is 80. The minimum number of points is 50.

10. The current control is carried out during the training sessions and aims to verify the assimilation of educational material by students. Forms of assessment of current educational activities are standardized and include control of theoretical and practical training.

10.1 Evaluation of current educational activities. Current control during training is carried out by standardized control methods, including control of theoretical and practical training. At each practical lesson, the student answers 10 tests, 5 questions on the topic of the practical lesson, knowledge of which is necessary to understand the current topic, lecture course questions and independent work related to the current lesson.

Evaluation criteria

I. Current control. At each lesson, the level of students' knowledge is assessed on a 4-point (national) scale. This takes into account all types of work provided by the discipline program. The student receives a grade from each topic for further conversion of grades into points on a multi-point (200-point) scale.

"Excellent" mark receives a student who correctly, clearly, logically and completely answered the standardized questions of the current topic, including the questions of the lecture course and independent work, gave at least 90% of correct answers to standardized tests, responded to written tasks without any mistake, performed practical work and filled in the protocol.

"Good" mark gets a student who answered the standardized questions of the current topic, lecture course and independent work, gave at least 70% of correct answers to standardized tests, responded to written tasks with some insignificant mistakes, performed practical work and filled in the protocol.

"Satisfactory" mark receives a student who gave with additional questions incomplete answer, could not independently build a clear, logical answer; gave at least 50% of correct answers to standardized tests, responded to written tasks with a lot of mistakes, made mistakes while demonstrating practical skills but performed practical work and made the protocol.

"Unsatisfactory" mark receives a student who can not answer on question on the current topic with additional questions, can not construct a logical answer, did not understand the content of the material; gave less than 50% of correct answers to standardized tests, responded to written tasks with gross mistakes or did not give answer, didn't perform practical work and didn't make the protocol.

At each practical lesson, the student's knowledge is assessed on a four-point system ("5", "4", "3", "2") according to the criteria for assessing the current activities of the student.

The control of laboratory researches and mastering of practical skills is carried out after performance of laboratory work, by an estimation of quality and completeness of its performance, ability to interpret the received results. For the practical part of the lesson the student can type:

4 points, if the laboratory work is performed in full and the student freely and correctly explains the research and gives them an assessment;

2 points, if the laboratory work is performed with some errors, the student can not fully explain the research and give them an assessment;

0 points, if the laboratory work is not performed or the student can not explain the research and give them an assessment.

The final grade for the lesson is determined by the sum of the results of test control and laboratory work as follows:

It is recommended to evaluate the test control according to the following criteria:

Proportion of correct answers (minimum)	Score on a four-point scale
90% - 100%	5
70%	4
55%	3
Less than 55%	2

The final grade for the lesson is determined by the sum of the results of test control and laboratory work as follows:

The sum of points	Score on a four-point scale					
30 - 34	5					
22 - 29	4					
15 - 21	3					
<9 points for test control	2					

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 independent study and are not included in the topics of classroom training, are controlled during the final tests and tests.

11. The form of final control of academic performance in the study of the optional discipline "Mechanisms of pharmacological activity and toxicity of drugs" is a credit. The final control consists of a written answer to the test tasks of format A (blank). The student answers 40 test tasks of format A on each topic of the module and is evaluated with 2 points for each correct answer.

The credit score is determined by the sum of points for answers to test tasks. The maximum number of points in the test is 80. The minimum number of points is 50.

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

The maximum number of points that a student can get for current educational activity during study is 200 points. **The minimum number of points** that a student must get to pass the test on the discipline is 120 points.

Calculating the number of points made on the basis of the student's scores on the traditional 4point scale during the study of the discipline, by calculating the arithmetic mean (CA), rounded to two decimal places. The received value is converted into points by multi-point rate as follows:

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

The average score for the current activity is converted into a multi-scale scale using the table below:

Recalculation of the average score on "Mechanisms of pharmacological activity and toxicity of drugs" for the current activity into a multi-scale scale:

4-	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
points													
scale													

200-	200	199	198	197	196	195	194	193	192	119	190	189	188
points	200	177	170	1,7,	170	170	17.	175	172		190	105	100
scale													
4-	4.67	4.65	4.62	4.6	4.57	4.52	4.5	4.47	4.45	4.42	4.4	4.37	4.35
points													
scale													
200-	187	186	185	184	183	181	180	179	178	177	176	175	174
points													
scale													
4-	4.32	4.3	4.27	4.24	4.22	4.19	4.17	4.14	4.12	4.09	4.07	4.04	4.02
points													
scale													
200-	173	172	171	170	169	168	167	166	165	164	163	162	161
points													
scale													
4-	3.99	3.97	3.94	3.92	3.89	3.87	3.84	3.82	3.79	3.77	3.74	3.72	3.7
points													
scale	1.60	1.50	1.50	17	1	1.5.5	1.5.4	1.50	1.50	1.51	1.50	1.40	1.40
200-	160	159	158	17	156	155	154	153	152	151	150	149	148
points													
scale 4-	3.67	2 (5	2 (2	3.57	3.55	3.52	3.5	3.47	3.45	3.42	3.4	3.37	3.35
points	3.07	3.65	3.62	3.57	3.55	3.52	3.5	3.47	3.45	3.42	3.4	3.37	3.35
scale													
200-	147	146	145	144	143	142	141	140	139	138	137	136	135
points	17/	140	175	177	175	172	171	140	157	150	157	150	155
scale													
4-	3.32	3.3	3.27	3.25	3.22	3.2	3.17	3.15	3.12	3.1	3.07	3.02	3
points													
scale													
200-	133	132	131	130	129	128	127	126	125	124	123	121	120
points													
scale													
4-	Less than 3												
points													
scale													
200-	Not e	nough											
points													
scale													

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 classes, are controlled during the final tests and exam.

The maximum number of points that a student can score when taking the test is 80.

The minimum number of points in the test - not less than 50.

Ranking with grades "A", "B", "C", "D", "E" is conducted for students of this course who study in one specialty and have successfully completed the study of the optional discipline. Students who receive grades FX, F ("2") are not included in the list of ranked students. Students with an FX grade automatically receive an E score after retaking.

Discipline scores for students who have successfully completed the program are converted into a traditional 4-point scale according to the absolute criteria, which are given in the table below::

Score from discipline	Score on 4-point rate
From 170 to 200 points	5
From 140 to 169 points	4

From 139 to the minimum	
number of points which student must get	3
Below the minimum number of points which student must get	2

The ECTS score is not converted to the traditional scale, as the ECTS scale and the four-point scale are independent.

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

13. Methodical support

The list and content of educational and methodological support for the study of the discipline of choice "Mechanisms of pharmacological activity and toxicity of drugs" includes:

- synopsis or extended plan of lectures;

- thematic plans of lectures, practical classes, independent work of students;

- tasks for laboratory work and independent work of students;

- questions, tasks, tasks for current and final control of students' knowledge and skills, complex control work, post-certification monitoring of acquired knowledge and skills in the discipline.

14. Recommended Literature

Basic

1. Law of Ukraine "On Medicinal Products".

2. Order of the Ministry of Health N_{2} 944 "On approval of the Procedure for conducting pre-clinical studies of medicinal products, the Procedure for determining institutions that conduct pre-clinical studies of medicinal products".

3. Order of the Ministry of Health N_{2} 426 "On approval of the Procedure for examination of registration materials for medicinal products submitted for state registration (re-registration), as well as examination of materials on changes to registration materials during the registration certificate".

4. Bidnychenko Y. Toxicological chemistry: Handbook for students. - Lviv, 2009. - 175 p.

5. Bondar VS Toxicological chemistry. Schemes and tables: Handbook for students of higher school / B.C. Bondar, S.A. Karpushina - Kharkiv: NUPh: Golden Pages, 2009. - 120 p.

6. Hodgson E. A Textbook of Modern Toxicology, 4th Edition - John Wiley & Sons, 2004. - 672 p.

7. Belousov Yu.B., Gurevich KG Clinical pharmacokinetics. Drug dosing practice. - M .: Litterra, 2005. - 288 p.

8. Derimedved LV Interaction of drugs and effectiveness of pharmacotherapy / L.V. Derimedved, IM Peppers [etc.]. - H.: Megapolis, 2001. - 784 s.

9. Medical interaction and drug safety: a manual / L.L. Davtyan, GV Zagoriy, Yu.V. Voronenko and others. - K .: PE "Prodigal MI", 2011. - 744 p.

Auxiliary

- Handbook of Toxicology. 2 ed. / Edited by Derelanko M.J., Hollinger_M.A. N.W.: CRC Press LLC, 2002 – 1380 p.
- 2. Poisoning and Drug Overdose. Fifth Edition / Edited by Kent R. Olson. San Francisco: The Mc-Graw-Hill Companies, 2007. – 1132 p.
- 3. Randall C. Baselt. Disposition of Toxic Drugs and Chemicals in Man. California, Foster City; Chemical Toxicology Institute, 2000. 920 p.
- 4. Cronin M.T.D., Madden J.C., Enoch S.J., Roberts D.W. Chemical Toxicity Prediciton: The Royal Society of Chemistry, UK, 2013. 204 p.
- 5. Handbook of Toxicology. 2 ed. / Edited by Derelanko M.J., Hollinger_M.A. N.W.: CRC Press LLC, 2002 1380 p.
- 6. Poisoning and Drug Overdose. Fifth Edition / Edited by Kent R. Olson. San Francisco: The Mc-Graw-Hill Companies, 2007. – 1132 p.

7. Randall C. Baselt. Disposition of Toxic Drugs and Chemicals in Man. – California, Foster City; Chemical Toxicology Institute, 2000. – 920 p.

15. Information resources

- 1. https://pubmed.ncbi.nlm.nih.gov/20978361/
- 2. <u>https://www.researchgate.net/publication/47556196_Mechanisms_of_Drug_Toxicity_and_Relevance_to_Pharmaceutical_Development</u>
- 3. https://en.wikipedia.org/wiki/Mechanism_of_action