The syllabus for discipline « MECHANISMS OF PHARMACOLOGICAL ACTIVITY AND TOXICITY OF DRUGS»

1. General information	
Name ot the faculty	pharmaceutical faculty
Educational program	22 Health, 226 Pharmacy, Industrial Pharmacy, Second (master's) educational level, full-time course
Academic year	2021-2022
Course title, code	Mechanisms of pharmacological activity and toxicity of drugs; VB1.29,
Department (*address, phone, e-mail*)	Department of toxicological and analytical chemistry 79010, Lviv, Pekarska str., 69 +38 (032) 368437 kaf_toxchemistry@meduniv.lviv.ua
Head of department *(e-mail)*	Halkevych Irine, PhD, Associated professor, galkirin@meduniv.lviv.ua
Year of study	3rd year
Semester	V semester
Type of discipline	Optional
Lecturers	1. Halkevych I.Y., PhD, Associated professor, galkirin@meduniv.lviv.ua 2. Bidnychenko Yu.I., PhD, Associated professor, bidnyuri@i.ua 3. Kucher M.M., PhD, Associated professor, kuchermykh@gmail.com 4. Kostyshyn L.P., PhD, senior lecturer, kostyshynluba@gmail.com 5. Davydovych S.I., PhD, Assistant professor, ihlitska.sophia@gmail.com 6. Osypshuk L.I., PhD, Assistant professor,, osipshukl@gmail.com
Erasmus yes/no	no
Author	Assist. prof. Davydovych Sofiia e-mail: ihlitska.sophia@gmail.com
Total credits ECTS	3.0 credits
Total number of hours	90 h (Lectures –10/ Seminar classes – 20 / ISW – 60)
Language	English
Information about consultations	Consultations at the department take place in accordance with the approved schedule of consultations
2. Course description (abstract)	
The study of the *mechanisms of pharmacological activity and toxicity of drugs* is carried out during the third year of study of LNMU named after Danylo Halytsky. *Mechanisms of pharmacological activity and toxicity of drugs* as a discipline:	

It 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 to study special disciplines and in professional activities and integrates with pharmaceutical chemistry, toxicological chemistry and pharmacology.

3. Goals and objectives of the course

1. **The purpose of the course «** ***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 in students the necessary knowledge, skills and abilities in the field of toxicological chemistry.
2. **The main tasks of studying the discipline "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 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.
3. **Competencies and learning outcomes**, the formation of which contributes discipline (relationship with the normative content of training seekers of higher education, formulated in terms of learning outcomes in higher education).

According to the requirements of the Standard, the discipline "Mechanisms of pharmacological activity and toxicity of drugs " facilitates the acquisition of ***competencies for*** students ***:***

common :

- ability to apply knowledge in practical situations;
- knowledge and understanding of the subject area and understanding of the profession;
- ability to abstract thinking, analysis and synthesis, ability to learn and master modern knowledge;
- skills of using information and communication technologies;
- ability to evaluate and ensure the quality of work performed;
- ability to conduct research at the appropriate level;
- the desire to preserve the environment;

special (specialty, subject) :

- ability to analyze data from educational and special literature in solving professional problems related to toxicological research;
- ability to organize research to determine the biopharmaceutical safety parameters of chemicals;
- ability to analyze and interpret the results obtained during the study;
- ability to predict possible mechanisms of toxic action;
- ability to use specialized software in toxicological research;
- ability to document toxicological research (working journal).Detailing competencies according to the NRC descriptors in the form of the Competence Matrix.

4. Course prerequisites

To successfully learn and master the competencies in the discipline "Mechanisms of pharmacological activity and toxicity of drugs" requires the following basic knowledge in the following disciplines:

Organic chemistry, as classes involve the study and understanding of chemical transformations of organic molecules based on knowledge of the nature of functional groups; identification of the relationship between their molecular, electronic structure and physiological, in particular pharmacological, effects, identification of patterns of their transformations;

Biological chemistry - to understand the biochemical processes that take place in biological systems and the ability to interpret the peculiarities of metabolic transformations of bioorganic compounds in the body as the basis of their pharmacological action as drugs and their correction of pathological conditions.

Pharmaceutical chemistry - ability to the complex analysis of communication structure-

activity of biologically active substances by a complex of physicochemical and pharmacological methods; ability to self-assess possible pharmacological activity of synthesized or isolated compounds;

Pharmacology for understanding the pharmacokinetic and pharmacodynamic features of drugs depending on their chemical structure, knowledge of the main ways of pharmacological influence on the functions of the executive organs;

Higher mathematics for mathematical processing of the results of pharmacological and toxicological research.

5. Program learning outcomes

List of learning outcomes

Code of learning outcomes	**Content of learning outcomes**	**Link to the code in the Competence Matrix**
Knowledge – Kn., Skill – Sk., Communication – C., Autonomy and responsibility – AR, Learning outcomes – *LO.*		
General competencies		
Kn-1	Have specialized conceptual knowledge acquired in the learning process.	*LO-2. Apply knowledge of general and professional disciplines in professional activities.*
Sk-1	Be able to solve complex problems and problems that arise in professional activities.	
C-1	Ability to apply knowledge in practical situations	
AR-1	Responsible for making decisions in difficult conditions	
Kn-2	Have deep knowledge of the structure of professional activity.	*LO-6. Argue the information to make decisions, take responsibility for them in standard and custom professional situations; adhere to the principles of deontology and ethics in professional activities.*
Sk-2	Be able to carry out professional activities that require updating and integration of knowledge.	
C-2	Knowledge and understanding of the subject area and understanding of the profession	
AR-2	To be responsible for professional development, ability to further professional training with a high level of autonomy.	
Kn-3	Know the methods of analysis, synthesis and further modern learning.	*LO-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.*
Sk-3	Be able to analyze information, make informed decisions, be able to acquire modern knowledge.	
C-3	Ability to abstract thinking, analysis and synthesis, the ability to learn and be modernly trained.	
AR-3	Be responsible for the timely acquisition of modern knowledge.	
Kn-4	Have in-depth knowledge in the field of information and communication technologies used in professional activities	*LO-9. Carry out professional activities using information technology, "Information Databases",*
Sk-4	Be able to use information and communication technologies in the professional field, which requires updating and integration of knowledge	
C-4	Skills in the use of information and communication technologies	
AR-4	Be responsible for the development of professional knowledge	

	and skills	*navigation systems, Internet resources, software and other information and communication technologies.*
Kn-5	Know the methods of evaluating performance indicators	*LO-11. Use methods for assessing performance indicators; identify reserves to increase labor efficiency.*
Sk-5	Be able to ensure quality work	
C-5	Ability to evaluate and ensure the quality of work performed	
AR-5	Be responsible for the quality of work	
Kn-6	Know the components of the health care system, planning and evaluating research	*LO-12. Analyze the information obtained as a result of scientific research, summarize, systematize and use it in professional activities.*
Sk-6	Search for scientific sources of information; to make a choice of methods of carrying out scientific research, to use methods of the mathematical analysis and modeling, theoretical and experimental research in pharmacy	
C-6	Ability to conduct research at the appropriate level	
AR-6	Be responsible for the development and implementation of planned projects	
Kn-7	Know the problems of environmental protection and ways to preserve it	*LO-3. Adhere to the norms of sanitary and hygienic regime and safety requirements when carrying out professional activities.*
Sk-7	Be able to form requirements for themselves and others to preserve the environment	
C-7	The desire to preserve the environment	
AR-7	Be responsible for the implementation of environmental protection measures within its competence	
Special (specialized, subject) competences		
Kn-8	Know the modern requirements for the organization and control of drug safety.	*LO-17. Use data from clinical, laboratory and instrumental studies to monitor the efficacy and safety of drugs.*
Sk-8	Be able to choose methods for studying the toxicity of drugs.	
C-8	Ability to organize research to determine different types of toxicity and safety of test substances.	
AR-8	Be responsible for organizing, ensuring and monitoring the safety of medicines.	
Kn-9	Know the pharmacological and toxicological properties of xenobiotics	*LO-18. Select biological objects of analysis, determine xenobiotics and their metabolites in biological environments and evaluate the results based on their distribution in the body.*
Sk-9	Be able to apply pharmacological and toxicological models to calculate pharmacokinetic parameters	
C-9	The ability to predict possible mechanisms of toxic action	
AR-9	Be responsible for deciding how to evaluate the results of drug safety studies	
Kn-10	Know the mathematical models for calculating pharmacological and toxicological parameters	*LO-14. To determine the advantages and disadvantages of drugs of different pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical,*
Sk-10	Be able to use special software to calculate the biopharmaceutical safety parameters of drugs	
C-10	Ability to use specialized software in toxicological research.	
AR-10	Responsible for making decisions about evaluating the safety of medicines	

		pharmacokinetic and pharmacodynamic features. To recommend to consumers over-the-counter medicines and other products of the pharmacy range with the provision of counseling and pharmaceutical care.
Kn-11	Know the standard procedures of statistical analysis	*LO-32 - To determine the main organoleptic, physical, chemical, physicochemical and pharmacotechnological indicators of medicines, to substantiate and choose methods of their standardization, to carry out statistical processing of results in accordance with the requirements of the current State Pharmacopoeia of Ukraine.*
Sk-11	Be able to justify the sample size, apply methods of statistical analysis, provide results of statistical data processing.	
C-11	Ability to analyze and interpret the results obtained in the study	
AR-11	Be responsible for conducting analysis and obtaining reliable and reproducible results.	

6. The course format

The format of the course	Full-time course
Type of classes	The total number of hours
Lectures	10
Seminars	20
Self-study	60

7. Topics and content of the course

Type of classes	Theme	Code of learning outcomes
L-1	The basic concepts of pharmacology - pharmacological activity, pharmacological action, pharmacological effect of chemicals.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
L-2	Physico-chemical and chemical mechanisms of action of pharmacological substances.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
L-3	Quantitative patterns of pharmacological effect.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
L-4	The concept of types of drug antagonism: pharmacological, physiological, chemical.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
L-5	The concept of additivity, synergism and potentiation during drug interaction.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.

Type of classes	Theme	Content	Code of learning outcomes
S-1	Basic concepts of pharmacology.	Pharmacological action and pharmacological effect of chemicals; factors that provide a therapeutic effect of drugs; pharmacodynamic action, placebo effects; acquaintance with the terms "drug substance", "drug", "drug", "dosage form"; dose, types of doses, dosage units of drugs, purpose of drug dosing; therapeutic and toxic ranges (intervals) of drug concentrations in the blood; the concept of an adequate mode of administration of discrete doses.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
S-2	Physico-chemical and chemical mechanisms of action of pharmacological substances.	The importance of non-covalent and covalent interactions in the effect of drugs; Ferguson's principle; the concept of receptors in pharmacology: the molecular nature of receptors, signaling mechanisms of action of drugs; the main types of transmembrane signaling and secondary mediators involved in the implementation of the drug; molecular "targets", classification of receptors and their structural features.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
S-3	Quantitative patterns of pharmacological effect.	General type of dependence concentration - effect in normal and lognormal coordinates; the Clark-Ariens model and its consequences; basic concepts of quantitative pharmacology: effect, efficacy, activity, agonist (complete, partial), antagonist (competitive, non-competitive).	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
S-4	The concept of types of drug antagonism: pharmacological, physiological, chemical.	Biological orientation of biotransformation and its phase; physical, chemical and pharmacological properties of metabolites; reactions of the first phase of biotransformation; regularities of hydroxylation of aliphatic, acyclic and aromatic hydrocarbons and radicals, substituted and condensed aromatic compounds, heterocyclic compounds of N-hydroxylation; N- and S-oxidation; oxidative desulfurization; N-, O-, and S-demethylation; dealkylation and deamination; oxidation of alcohols and aldehydes; non-microsomal oxidation; reduction reactions of azo compounds, disulfides, sulfoxides, aldehydes, multiple carbon-carbon bonds, N-oxides, nitro- and nitroso groups; hydrolysis reactions - esters, amides, carbonates, hydrazides, nitriles, halides, sulfate conjugates and glucuronides. enzymes that catalyze reduction and hydrolysis reactions; reactions of the second phase of biotransformation - conjugation	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.

		reactions; enzymes involved in conjugation reactions; conjugation reactions with acetate, sulfate, glucuronic acid, amino acids, N-, O-, and S-methylation. physical, chemical and pharmacological properties of conjugates and their effect on the elimination of other drugs that are simultaneously present in the body; enzyme inducers and inhibitors; the influence of the physical state of the organism and pathological processes on the biotransformation of drugs, in particular the influence of alcohol and tobacco smoke on the biotransformation of drugs; calculation of the rate of reaction of biotransformation of drugs of the 0th, 1st and 2nd order.	
S-5	The concept of additivity, synergism and potentiation during drug interaction.	Basic patterns of excretion of drugs from the body; mechanisms of renal excretion (glomerular filtration, reabsorption and active secretion); renal drug clearance and creatinine clearance; calculations of the rate of drug excretion by active secretion; features of drug excretion with bile, exhaled air, saliva and milk; the effect of pH of urine and blood plasma on the rate of excretion of weak electrolytes; features of excretion of drugs and their metabolites from the body, liver and cardiovascular system; calculation of the rate of elimination of drugs.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
S-6	Resorptive, systemic and local action of drugs.	Genetic features of pharmacokinetics; age features of pharmacokinetics; circadian features of pharmacokinetics (influence of human biorhythms); the effect of cholinesterase polymorphism on drug dosing; the effect of acetyltransferase polymorphism; the effect of blood plasma arylesterase polymorphism; study of individual variability of metabolic oxidation of drugs; general patterns of individual differences in drug metabolism rates.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
S-7	Variability and variability of drug action.	Features of physicochemical and chemical interaction of drugs; mechanisms of drug interaction at the absorption stage; mechanisms of drug interaction at the stage of distribution in the body; mechanisms of drug interaction in the process of biotranoformation; mechanisms of drug interaction at the stage of their excretion from the body; mechanisms of the main types of pharmacodynamic drug interactions; pharmacotherapeutic evaluation of pharmacokinetic and pharmacodynamic drug interactions.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
S-8	Basics of toxicometry. Drug safety assessment.	Biotransformation of drugs to adjust their doses in order to achieve a therapeutic effect;	Kn-1 – Kn-11; Sk-1 – Sk-11;

		determination of effective concentrations, in particular linear correlation "concentration - effect"; modern pharmacokinetic models: model with "saturation" effect; model with effector camera; "Maximum principle"; linear correlation “logarithm of concentration - effect”. Graphical expression of the effect as a function of the concentration of the drug in peripheral chambers; physiological and toxicokinetic models.	C-1 – C-11; AR-1 – AR-11.
S-9	Assessing the risks of adverse effects of drugs on human health. Final lesson	Consolidation of knowledge of the dependence of the distribution of the drug on the method of its administration; testing the ability to calculate basic pharmacokinetic parameters; modeling the behavior of xenobiotics with a single intravenous injection with parallel routes of excretion and complete resorption from the injection site; dose selection of the drug with a single injection to achieve a therapeutic effect; application of acquired knowledge for pharmacokinetic optimization of pharmacotherapy.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
S-10	Credit lesson. Assimilation of the connection between the mechanisms of action of pharmacological substances and toxic effects of drugs.	Enrollment of independent student work. Calculation of pharmacokinetic parameters; determination of the dose safety corridor; selection of the interval between doses using a single-particle model for drugs that do not cause induction or inhibition of metabolic enzymes and pharmacological activity shows only the original substance in its native form; testing the ability to calculate the dosage regimen of drugs with different half-lives. Therapeutic monitoring with long-term use of drugs.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
ISW-1	Basic concepts of pharmacology.	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.	Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.
ISW-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.	
ISW-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).
ISW-4	The concept of types of drug antagonism: 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.
ISW-5	The concept of additivity, synergism 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.
ISW-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.
ISW-7	Variability and variability of drug action.	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.
ISW-8	Basics of toxicometry. Drug safety assessment.	Toxicometry. Therapeutic index and standard safety margins. Teratogenic, embryotoxic, fetotoxic, mutagenic, carcinogenic effects of drugs.

Learning methods

Teaching methods: explanatory-illustrative, problem-based presentation, partial-search.

When studying an elective course, students use textbooks, lecture notes, chemical computer programs, support materials needed to solve situational problems.

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

a) lectures

b) seminars

c) independent work of students.

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

- synopsis or extended plan of lectures;
- thematic plans of lectures, classes, independent work of students;
- tasks for 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 elective discipline.

Classes according to the methodology of their organizations are seminars and involve discussion of issues in accordance with the calendar-thematic plan. Students also use exercises and solve situational problems.

The structure of the organization of classes includes:

- Discussion and explanation of the most difficult issues of the topic;
- Discussion of aspects of use and interpretation of results.
- The result of the lesson.

8. Verification of learning outcomes

Current control

Current control is carried out during each seminar in accordance with the specific objectives of each topic and aims to verify the assimilation of students' learning material.

All classes use objective control over the performance of independent work and theoretical training.

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 the seminar, 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 lesson topic).

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.

The final grade for the current educational activity is set on a 4-point (national) scale, taking into account the approved criteria. This takes into account all types of work provided by the program of elective discipline. The student receives a grade from each topic for further conversion of grades into points on a multi-point (200-point) scale.

Criteria of assessment of current educational activity:

"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.

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.

Code of learning outcomes	**Type of classes**	**Verification of learning outcomes**	**Enrollment criteria**
Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.	S-1–S-10	Current control: • oral control over the topic of the lesson, standardized questions, knowledge of which is necessary to understand the current topic, questions of the lecture course that relate to the current lesson; • written test control, • solving situational problems, • conducting laboratory tests, • interpretation and evaluation of laboratory test results, • report on the performed laboratory work.	Assessment according to established criteria (see above) with 4-point (national) scale. To enroll in the discipline, it is necessary to confirm the achievement of each learning outcome.
Kn-1 – Kn-11; Sk-1 – Sk-11; C-1 – C-11; AR-1 – AR-11.	ISW-1–ISW-8	• Oral control in the form of a survey in accordance with the subject of independent work. • Test control on the subject of independent work.	Enrolled / not enrolled
The Final control			
General evaluation system	Final control is allowed for students who have completed all types of work required by the curriculum, have completed all training sessions, and have earned points above the minimum level when studying the module. Participation in the work during the semester - 100% on a 200-point scale		
Grades	4-point (national) scale, a multi-scale (200-point) scale, ECTS success scale		
Conditions of admission to the final control	Students who have completed all types of work required by the curriculum, have completed all training sessions, and have earned points above the 120 points when studying the course.		
Form of final control	The form of final control in the study of the selective discipline "Mechanisms of pharmacological activity and toxicity of drugs" is a test.		Evaluation criteria
A semester credit	All topics submitted for current control must be included. Grades from the 4-point scale are converted into points on a multi-point (200-point) scale in accordance with the Regulation "Criteria, rules and procedures for evaluating the results of students' learning activities"		*The maximum number of points - 200.* *The minimum number of points - 120*

Credit Regulations

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 in the test is 80. The minimum number of points is 50.

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 4-point 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:

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

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-point rate	**5**	**4.95**	**4.91**	**4.87**	**4.83**	**4.79**	**4.75**	**4.7**	**4.66**	**4.62**	**4.58**	**4.54**	**4.5**
200-point rate	120	119	118	117	116	115	114	113	112	111	110	109	108
4-point rate	**4.45**	**4.41**	**4.37**	**4.33**	**4.29**	**4.25**	**4.2**	**4.16**	**4.12**	**4.08**	**4.04**	**3.99**	**3.95**
200-point rate	107	106	105	104	103	102	101	100	99	98	97	96	95
4-point rate	**3.91**	**3.87**	**3.83**	**3.79**	**3.74**	**3.7**	**3.66**	**3.62**	**3.58**	**3.54**	**3.49**	**3.45**	**3.41**
200-point rate	94	93	92	91	90	**89**	88	87	86	85	84	83	82
4-point rate	**3.37**	**3.33**	**3.29**	**3.25**	**3.2**	**3.16**	**3.12**	**3.08**	**3.04**	**3**	**Less than 3**		
200-point rate	81	80	79	78	77	76	75	74	73	72	Not enough		

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 elective 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).

9. Course policies

Adherence to academic integrity by students provides:

1. Independent performance of educational tasks, tasks of current and final control of learning outcomes (for persons with special educational needs this requirement is applied taking into account their individual needs and opportunities);

2. References to sources of information in the case of the use of ideas, developments, statements, information; Compliance with copyright and related rights legislation;

3. Providing reliable information about the results of their own (scientific, creative) activities, used research methods and sources of information.

Violations of academic integrity are: academic plagiarism, self-plagiarism, fabrication, falsification, write-off, deception, bribery, biased evaluation.

For violation of academic integrity, students may be involved in re-assessment (test, test).

10. Recommended Literature

Compulsory course literature

1. Bidnychenko Y. Toxicological chemistry: Handbook for students. – Lviv, 2009. – 175 p.
2. Bondar V.S. Toxicological chemistry. Schemes and tables: Handbook for students of higher school / V.S. Bondar, S.A. Karpushina – Kharkiv: NUPh:Golden Pages, 2009. – 120 p.
3. Hodgson E. A Textbook of Modern Toxicology, 4th Edition – John Wiley & Sons, 2004. – 672 p.
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8. Наказ МОЗ № 426 "Про затвердження Порядку проведення експертизи реєстраційних матеріалів на лікарські засоби, що подаються на державну реєстрацію (перереєстрацію), а також експертизи матеріалів про внесення змін до реєстраційних

матеріалів протягом дії реєстраційного посвідчення".
9. Наказ МОЗ № 944 "Про затвердження Порядку проведення доклінічного вивчення лікарських засобів, Порядку визначення установ, які проводять доклінічне вивчення лікарських засобів".
10. Общая токсикология./Под ред. Б.А. Курляндского, В.А. Филова. – М.: Медицина, 2002. - 608 с.

Auxiliary literature

1. 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 McGraw-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.
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11. Equipment, logistics and software of the discipline / course

Textbooks, computers

12. Additional information

The time and place (specialized, classroom, laboratory, studio, etc.) of the discipline is determined in accordance with the approved schedule. All compulsory and auxiliary literature are available as an e-books.

Tasks for independent 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.

List of questions for control in the discipline
"Mechanisms of pharmacological activity and toxicity of drugs"

1. The main tasks of clinical pharmacokinetics at the stage of clinical research of a new drug and a new dosage form.
2. Mechanisms of drug penetration through cell membranes. The effect of pH, pKa and solubility of the substance on its passage through cell membranes by simple diffusion.
3. Penetration of drugs through the blood-brain and blood-ophthalmic barrier, through the serous and synovial membranes.
4. Penetration of drugs into inflammatory sites and tumor tissues.
5. Study of the penetration of drugs into the cells of the body, into individual organs and tissues.
6. Absorption in the gastrointestinal tract. The effect of the amount and composition of gastric contents, pH and peristalsis and other xenobiotics on the rate of absorption.
7. Features of absorption from the oral cavity and rectum.
8. Absorption of drugs by parenteral administration.
9. Absorption in muscles, lungs, bladder and uterus.
10. The effect of the rate of absorption on the bioavailability of drugs and the effectiveness of pharmacotherapy.
11. The effect of presystemic elimination on the bioavailability of drugs.
12. .Binding of drugs to serum proteins. Binding mechanisms, degree of binding.
13. Factors influencing the degree of binding: the influence of the state of the organism, age, pathological processes, the presence of other xenobiotics.
14. The effect of binding of drugs to biological substrates on the dynamics of drug levels in blood plasma, penetration into body tissues, biotransformation, renal excretion and pharmacological activity.
15. Methods of studying the degree of binding of drugs to serum proteins and erythrocytes. Study of the penetration of drugs into the cells of the body, into individual organs and tissues.
16. Volumes of drug distribution in the body. Study of drug distribution in animal experiments. Species differences in drug distribution.
17. Characteristics of the stages of pharmacokinetics - absorption, distribution, biotransformation and excretion of xenobiotics.
18. Mathematical models for calculating the distribution of drugs in the body - in the central and peripheral chambers and in the cellular fluid.
19. Biological orientation of biotransformation. Phases of biotransformation. Physical, chemical and pharmacological properties of metabolites.
20. Reactions of the first and second phases of biotransformation.
21. Pharmacological properties of metabolites. Lethal synthesis.
22. Physical, chemical and pharmacological properties of conjugates. The effect of conjugates on the elimination of other drugs present in the body.
23. Characteristics of methods of drug analysis in body tissues.
24. Requirements for methods of analysis used in the study of pharmacokinetics of the drug - sensitivity, specificity, speed, reproduction.
25. The influence of pathological processes on the kinetics of drugs in diseases of organs and systems of the body.
26. General patterns of individual differences in the rates of drug metabolism.

27. Mechanisms of drug interaction at the stage of absorption, distribution in the body, in the process of biotransformation and excretion from the body.
28. Physico-chemical interaction of drugs with biological receptors in the body and the mutual influence of different drugs on their biological activity when taken together.
29. Mechanisms of renal excretion. Determination of renal clearance of drugs. Calculations of drug elimination rate by active excretion.
30. Side effects of drugs. Classification. Adverse effects in organs and systems during drug therapy.

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