MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
Department of Physiology and Pathological physiology

PHARMACOGENETICS

of educational component

WORK PROGRAM
of educational component

training for _____**Master**_____
(Higher Educational Level Name)
in specialty _____**226 Pharmacy, industrial pharmacy**_____
(Code and Specialty Name)
field of knowledge «___**22 Publik Health**_____
(Code and Knowledge Field Name)
of educational program ____**Pharmacy for foreign students**_____
(Educational Program Name)
in specialization(s)_____
(Code and Specialization Name)

2023 рік

The work program of educational component "Pharmacogenetics", in specialty "226 Pharmacy, industrial pharmacy", educational program "Pharmacy for foreign students" for applicants for higher education 4 year of study.

EDUCATIONAL COURSE TEAM:

KONONENKO Nadiia, head of the Department of Physiology and Pathological physiology, MD, Professor

CHIKITKINA Valentyna, associate professor of the Department of Physiology and Pathological physiology, MD, associate professor

Work program has been considered and approved at the Department meeting of the department of Physiology and Pathological physiology
Record from «31» August 2023 № 1

Head of the Department of Physiology and Pathological Physiology  Prof. Nadiia KONONENKO

Work program has been approved at the meeting Methodical Commission of biomedical sciences
Record from «01» September 2023 № 1

Head of Specialized Committee  Prof. Nadiia KONONENKO

1. Description of the educational component

Language of study: English
Status of the educational component: selective
Prerequisites for studying the educational component: "Pharmacogenetics studies the place and role of genetic factors in shaping the human body's response to medicines: effectiveness, ineffectiveness, and the development of adverse drug reactions. The regularities revealed by pharmacogenetics allow a clinical pharmacist to individually select both the medicines and their doses for each patient, ensuring the most effective and safe pharmacotherapy. Pharmacogenetics is a related discipline at the intersection of clinical pharmacology and genetics.
The subject of educational component study "Pharmacogenetics" is the peculiarities of the genetic apparatus associated with changes in the pharmacological response (genetically determined pharmacological response) in a patient, which allows predicting the effectiveness and safety of prescribing medicines.
Information content of the educational component. _3_ECTS credit _90__hours are assigned to the study of the educational component.

2. Objectives and tasks of the educational component

The purpose of teaching the educational component "Pharmacogenetics" is to develop knowledge about the relationship between human genetic characteristics and pharmacological response to drugs, toxicant.

The main tasks of the educational component "Pharmacogenetics" are:

- formation of the concept of pharmacogenetic patterns based on differences in the metabolism of xenobiotics;
- mastering theoretical and practical knowledge in the field of hereditary differences in the body's reactions to xenobiotics;
- explanation of differences in reactions to xenobiotics by peculiarities of human genetic polymorphism;
- identification of mechanisms of transmission from generation to generation of altered sensitivity and reactivity of the body to xenobiotics
- study of complex problems in the genetics of enzymes that ensure the metabolism of xenobiotics;
- studying the consequences of enzyme dysfunction in the metabolism of xenobiotics;
- consideration of the issue of prevention of unusual reactions to xenobiotics.

3. Competence and planned educational outcomes

Educational component "Pharmacogenetics" ensures the acquisition of applicants for higher education the following **competences**:

integrative:

- ability to solve typical and complex specialized tasks and critically comprehend and solve practical problems in professional pharmaceutical activity using the provisions, theories and methods of fundamental, chemical, technological, biomedical and socio-economic sciences; integrate knowledge and solve complex issues, formulate judgments with insufficient or limited information; clearly and unambiguously communicate own knowledge, conclusions and their validity to professional and non-specialist audiences.

general:

CG. 2. Ability to apply knowledge in practical situations, make reasonable decisions.
CG. 4. Ability to abstract thinking, analysis and synthesis, to learn and be modernly trained.

CG. 6. Knowledge and understanding of the subject area and understanding of professional activity.

professional (special):

PC 2. Ability to provide medical advice on prescription and over-the-counter medications and other products of the pharmacy range; pharmaceutical care during the selection and sale of over-the-counter medications by assessing the risk / benefit, compatibility, indications and contraindications based on data on the health of a particular patient, taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical characteristics of the medicine and other pharmaceutical products.

PC 4. Ability to ensure the rational use of prescription and over-the-counter medications and other pharmaceutical products in accordance with physicochemical, pharmacological characteristics, biochemical, pathophysiological features of a particular disease and pharmacotherapeutic regimens for its treatment.

PC 5. Ability to monitor the effectiveness and safety of the population of medications 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 a patient.

Integrative final program learning outcomes (PLO), the formation of which is facilitated by the educational component:

PLO 2. To apply knowledge of general and professional disciplines in professional activities.

PLO 12. To analyze the information obtained as a result of scientific research, summarize, systematize and use it in professional activities.

PLO 14. To determine the advantages and disadvantages of medications of different pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic and pharmacodynamic features. To recommend to consumers over-the-counter medications and other products of the pharmaceutical range with the provision of counseling and pharmaceutical care.

PLO 16. To determine the influence of factors influencing the processes of absorption, distribution, deposition, metabolism and excretion of the drug and due to the condition, features of the human body and physico-chemical properties of medications/

PLO 17. To use clinical, laboratory and instrumental research data to monitor the efficacy and safety of medicines.

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

As a result of studying the educational component, the applicant for higher education will be

know:

- forecasts of possible toxic effects of drugs and the effectiveness of treatment tactics depending on the person's genotype;
- methods for diagnosing pharmacogenetic polymorphism;

be able to:

- solve situational tasks that reveal the level of students' knowledge;
- choose a test drug for the diagnosis of metabolic disorders associated with genetic polymorphism;
- analyze laboratory test results and recommend an individualized treatment program.

4. The educational component structure

Names of content modules and topics	The amount of hours	
	full time study	
	the	including

	whole amount	l.	sem	Practical lessons	lab	self-study
1	**2**	**3**	**4**	**5**	**6**	**7**
Content module 1. General pharmacogenetics. Systems of biotransformation of drugs.						
Topic 1. Basic principles of pharmacogenetics.	11	1		3		7
Topic 2. The system of biotransformation of drugs. Factors affecting drug metabolism.	11	1		3		7
Topic 3. Phase I reactions of drug biotransformation.	11	1		3		7
Topic 4. Phase II reactions of drug biotransformation.	11	1		3		7
The whole amount of hours for the content module 1	**44**	**4**		**12**		**28**
Content module 2. Problems of personalized medicine						
Topic 5. Clinical pharmacogenetics of drugs for the treatment of cardiovascular diseases.	10	1		3		6
Topic 6. Clinical pharmacogenetics of drugs used in rheumatology.	10	1		3		6
Topic 7. Pharmacogenetics of neuroreceptors.	10	1		3		6
Topic 8. Genetic basis of alcoholism and drug addiction.	9	1		2		6
The whole amount of hours for the content module 2	**39**	**4**		**11**		**24**
Semester credit from module 1	7			1		6
The whole amount of hours for the course	**90**	**8**		**24**		**58**

5. Contents of the educational component

Content module 1. General pharmacogenetics. Systems of biotransformation of drugs.

Topic 1. Basic principles of pharmacogenetics. The concept of pharmacogenetics, historical aspects of development, pharmacogenetic phenomena. Goals, objectives, methods of pharmacogenetics research. Indications for pharmacogenetic research, evaluation of results. Human genetic passport.

Topic 2. The system of biotransformation of drugs. Factors that affect the metabolism of drugs. Biotransformation and its influence on the pharmacological activity of drugs. Phases of biotransformation, their characteristics. Induction and inhibition of biotransformation enzymes. Factors affecting the biotransformation of drugs.

Topic 3. Phase I reactions of drug biotransformation. Microsomal monooxygenases. Cytochrome P-450 system. Characterization of the cytochrome system. Genetic polymorphism of cytochrome P-450 families. Characterization of DHPD and butyrylcholinesterase.

Topic 4. Phase II reactions of drug biotransformation. General characteristics of phase II biotransformation reactions. Genetic polymorphism of various reactions of the second phase of biotransformation. Characterization of drug transporters, their genetic polym

Content module 2. Problems of personalized medicine

Topic 5. Clinical pharmacogenetics of drugs for the treatment of cardiovascular diseases. Personalized selection of medicines. Characterization of groups of drugs for the treatment of cardiovascular diseases. Pharmacogenetics of indirect anticoagulants. Pharmacogenetics of β-adrenergic blockers. Angiotensin II receptor blockers. Clinical pharmacogenetics of statins.

Topic 6. Clinical pharmacogenetics of drugs used in rheumatology. Genetic polymorphism of drugs for the treatment of rheumatological diseases. Pharmacogenetics of non-steroidal anti-inflammatory drugs. Pharmacogenetics of azathioprine, sulfasalazine, methotrexate.
Topic 7. Pharmacogenetics of neuroreceptors. The role of neuroreceptors in the regulation of physiological functions of the body. Drugs for the treatment of neuropsychiatric diseases. Pharmacogenetics of antidepressants. Pharmacogenetics of benzodiazepine tranquilizers.
Topic 8. Genetic basis of alcoholism and drug addiction. The concept of epigenetics. Genes of alcoholism and drug addiction. Genome-wide association studies.
Semester credit from module «Pharmacogenetics»

6. Topics of lectures

№	Name of topic	The amount of hours
1	**Topic 1.** Basic principles of pharmacogenetics.	1
2	**Topic 2.** The system of biotransformation of drugs. Factors that affect the metabolism of drugs.	1
3	**Topic 3.** Reactions of the first phase of drug biotransformation.	1
4	**Topic 4.** Reactions of the second phase of biotransformation of drugs.	1
5	**Topic 5.** Clinical pharmacogenetics of drugs for the treatment of cardiovascular diseases.	1
6	**Topic 6.** Clinical pharmacogenetics of drugs used in rheumatology.	1
7	**Topic 7.** Pharmacogenetics of neuroreceptors.	1
8	**Topic 8.** Genetic basis of alcoholism and drug addiction.	1
	The whole amount of hours	**8**

7. Topics of seminars

It is not provided by the curriculum.

8. Topics of practical classes

№ з/п	Name of topic	The amount of hours
1	**Topic 1.** Basic principles of pharmacogenetics.	3
2	**Topic 2.** The system of biotransformation of drugs. Factors that affect the metabolism of drugs.	3
3	**Topic 3.** Reactions of the first phase of drug biotransformation.	3
4	**Topic 4.** Reactions of the second phase of biotransformation of drugs.	3
5	**Topic 5.** Clinical pharmacogenetics of drugs for the treatment of cardiovascular diseases.	3
6	**Topic 6.** Clinical pharmacogenetics of drugs used in rheumatology.	3
7	**Topic 7.** Pharmacogenetics of neuroreceptors.	3
8	**Topic 8.** Genetic basis of alcoholism and drug addiction.	2
	Semester credit from module	1
	The whole amount of hours	**24**

9. Topics of of laboratory classes

It is not provided by the curriculum.

10. Self-study work

№ з/п	Name of topic	The amount of hours
1	The emergence and development of pharmacogenetics. Fundamentals of individual sensitivity to drugs.	7
2	Genetic differences in drug receptors. Clinical significance of pharmacodynamic polymorphisms of gels.	7
3	Varieties of methods for determining genetic polymorphism.	7
4	Interpretation of pharmacogenetic tests and their significance for practical medicine.	7
5	Pharmacogenetics of drugs that affect hemostasis. Pharmacogenetics of anticoagulants.	6
6	Pharmacogenetics of drugs affecting the renin-angiotensin system.	6
7	Pharmacogenetic features of antidepressants.	6
8	Pharmacogenetic features that determine sensitivity to antitumor drugs.	6
9	Preparation for the semester test	6
	The whole amount of hours	**58**

Tasks for Self-study work

1. Higher education applicants independently work on topics of independent work in the discipline that are not included in the plan of classroom classes, using basic, additional educational literature and Internet resources.
2. Evaluation of topics that are submitted only for independent work and are not included in the topics of classroom training is controlled during the control of content modules.

11. Criteria and evaluation order of educational outcomes

The study of the educational component takes place during one semester, which ends with a semester test. Semester grades are based on the current academic performance of the student.

Evaluation system for the educational component

The results of the semester control in the form of a semester test are evaluated on a 100-point, undifferentiated scale ("passed", "failed") and on the EKTS scale.

Points from the educational component are calculated according to this ratio:

Types of evaluation	**Number of points**
Module 1	
Content module 1 1. Assessment of topics 1-4: in-class work (oral questioning, test tasks, practical assignments or case studies). 2. Control of content module 1: theoretical questions and test tasks.	30-50
Content module 2 1. Evaluation of topics 5-8: class work (oral questioning, test tasks, practical assignments or solving situational problems). 2. Control of content module 2: theoretical questions and test tasks.	30-50
Semester credit from module 1 (Σ3M1+3M2)	60-100

The independent work of higher education students is assessed during the current control and during the control of the content module.

Evaluation of the progress of a higher education student for each of the planned types of work in the classroom and during control is carried out according to the following criteria:

Types of work for which the applicant receives points	**Maximum number of points per type of work**	**Evaluation criteria**
work in classes (1-4) of content module 1 (min 12- max 20) work in classes (5-8) of content module 2 (min 12- max 20)		
oral survey	**3,0 points**	**3,0 points** - the student gives comprehensive answers to theoretical questions of the teacher; shows comprehensive and in-depth knowledge of theoretical material, demonstrates knowledge of additional literature on the topic of the class; thinks logically and constructs an answer.
		2,5 points - the student has mastered the theoretical material well, but makes certain inaccuracies and mistakes in the logic of the presentation of theoretical content, which he or she has eliminated with the help of the teacher.
		2,0 points - the student has basically mastered the theoretical knowledge of the educational component, but answers unconvincingly, additional questions cause uncertainty.
		1,0 points - the student has a low level of theoretical knowledge, confuses concepts, and additional questions indicate a lack of stable knowledge.
		0 points - the student has not mastered the educational material of the educational component, does not know scientific facts, definitions, and has little or no knowledge of primary sources and recommended literature.
preparation of test tasks	**2 points**	The applicant for higher education gave correct answers to 90-100% of the test tasks
Control of content modules 1, 2 (min-18- max30)		
oral interview or written work	**20**	**5 points за 1 питання**
		5,0 points - the student gives comprehensive answers to theoretical questions of the teacher; shows comprehensive and in-depth knowledge of theoretical material, demonstrates knowledge of additional literature on the topic of the class; thinks logically and constructs an answer.
		4 points - the student has mastered the theoretical material well, but makes certain inaccuracies in the logic of the presentation of theoretical content.
		3 points - the applicant has satisfactorily mastered the theoretical material, but makes mistakes in the logic of the presentation of theoretical content.
		2 points - the student has basically mastered the theoretical knowledge of the educational component, but answers unconvincingly, additional questions cause uncertainty.
		1 points - the student has a low level of theoretical knowledge, confuses concepts, and additional questions indicate a lack of stable knowledge.
		0 points - the student has not mastered the educational material of the educational component, does not know scientific facts, definitions, and has little or no knowledge of primary sources and recommended literature.
testing	**10**	One correct answer is worth 0.5 points. 20 tests x 0,5 = ***10 points***

Scoring scheme and distribution of points

Current testing and self-study					
Module 1					
Content module 1					
T1	T2	T3	T4	CCM 1	
3-5	3-5	3-5	3-5	18-30	***30-50***
Content module 2					
T5	T6	T7	T8	CCM 2	
3-5	3-5	3-5	3-5	18-30	***30-50***
Total for studying M1: (Σ3M1+3M2)					***60-100***

Based on the results of studying the topics of the discipline, an overall grade is formed by the sum of the current rating and the result of the final module control, respectively. The higher education applicant is assigned a grade in accordance with the following scale of knowledge assessment:

Total points	Marks ECTS	Score on the national scale	
		mark	credit
90 – 100	A	perfectly	satisfactorily
82-89	B	good	
74-81	C		
64-73	D	satisfactorily	
60-63	E		
35-59	FX	unsatisfactorily	satisfactorily

12.Forms of progress and semester supervision of academic achievements

Semester control is carried out in the form of a semester test and a semester exam.
Forms:
- current control: oral questioning, test control, content module control work.

13. Methodological support

1. Presentation of lectures.
2. Information posters and tables.
3. Guide for practical classes.
4. Tests for current control.
5. Tests for the final module control.

13.Reading suggestion

The main reading suggestions

1. Pharmacogenetics. Towards improving treatment with medicines. Geneva, 2005.224 p.
2. Pathological physiology. Module 1: teaching aid for teachers for practical training with applicants for higher education specialty «226 Pharmacy, industrial pharmacy» of the educational and professional program «Pharmacy» / N. M. Kononenko, V. V. Gnatyuk, V. A. Rybak [et al.]. Kharkiv: NUPh, 2021. 260 p.
3. Pathological physiology. Module 1: teaching aid for practical training for applicants for higher education in the specialty «226 Pharmacy, industrial pharmacy» of the educational and professional program «Pharmacy» / N. M. Kononenko, V. V. Gnatyuk , V. A. Rybak [et al.].

Kh.: NUPh, 2021. 245 p.
4. Pathological Physiology: Manual for students of higher schools / S. I. Kryzhna, N. M. Kononenko, T. I. Tyupka [et al.]. Kharkiv: NUPh: Golden Pages, 2012. 200 p.

Supplementary reading suggestions

1. Pathophysiology: textbook / N.V. Krishtal, V.A. Mikhnev, N.N. Zayko et al.; edited by N.V. Krishtal, V.A. Mikhnev. 2nd edition, corrected. Kyiv: AUS Medicine Publishing, 2018. 656 p.
2. General and clinical pathophysiology: textbook for students of higher educational institutions, of IV th level of accreditation /A. V. Kubyshkin [et al.]; ed. by.: A. V. Kubyshkin, A. I. Gozhenko; рец.: N. V. Krishtal, N. K. Kazimirko. 2nd ed. Vinnytsya: Nova Knyha Publishers, 2016. 656 p.
3. Simeonova N. K. Pathophysiology=Патофізіологія: textbook for students of higher medical educational institutions of the III-IV accreditation levels / N. K. Simeonova; ed. by V. A. Mikhnev. 3rd ed. Kyiv: AUS Medicine Publishing, 2017. 544 p.
4. Means of Protecting the Body from the Effects of Ionizing Radiation: study guide / T.O. Zhukova, V.F. Pocherniayeva, V.P. Bashtan. K.: ВСВ «Медицина», 2019.112 с.
5. Kathryn L. McCance, Sue E. Huether Study Guide for Pathophysiology - E- Book: The Biological Basis for Disease in Adults and Children. Elsevier Health Sciences, 2018. 325 p.
6. Lee-Ellen C. Copstead-Kirkhorn, Jacquelyn L. Banasik Study Guide for Pathophysiology - E-Book. Elsevier Health Sciences, 2013. 304 p.
7. Tommie L. Norris. Porth's Essentials of Pathophysiology. 5th edition, 2019. 1248 p.
8. Gary D. Hammer, Stephen J. McPhee. Pathophysiology of Disease: An Introduction to Clinical Medicine. 8th edition, 2018. 832 p.

15. Electronic resources, including the Internet

1. Website of the Department of Physiology and Pathological Physiology: https://pat.nuph.edu.ua/
2. Library of NUPh: e-mail https://lib.nuph.edu.ua/
3. Distance learning website: https://pharmel.kharkiv.edu/
4. Pharmacogenomics and Personalized Medicine https://www.mdpi.com/books/book/2700-pharmacogenomics-and-personalized- medicine
5. Principles of Pharmacogenetics and Pharmacogenomics https://assets.cambridge.org/97805218/85379/frontmatter/9780521885379_frontmatter.pdf
6. Pharmacogenetics and Pharmacogenomics https://biol.lf1.cuni.cz/ucebnice/pdf/Pharmacogenetics_and_Pharmacogenomics.pdf
7. Introduction to Pharmacogenomics https://www.encepp.eu/publications/documents/6.1_Pharmacogenomics.pdf