



**MINISTRY OF HEALTH OF UKRAINE  
NATIONAL UNIVERSITY OF PHARMACY  
Faculty pharmaceutical  
Department pharmaceutical technology of drugs**

**BIOPHARMACY**

(the name of educational component)

**WORK PROGRAM  
of educational component**

training second master's level  
(name of higher education level)

in specialty 226 Pharmacy, industrial pharmacy  
(code and specialty name)

field of knowledge 22 Public Health  
(code and name of field of knowledge)

of educational program Pharmacy (for foreign students)  
(name of educational program)

in specialization(s) \_\_\_\_\_  
(name of specialization, if available)

**Kharkiv-2023**  
(Year of creation)

The work program of the educational component\_ «Biopharmacy» \_\_\_\_\_in specialty 226 Pharmacy, industrial pharmacy of the educational program Pharmacy (for foreign students)  
Phm (4,10d) engl. for applicants for higher education\_\_5rd \_\_ year.

**EDUCATIONAL COURSE TEAM:**

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(specify the LAST NAME, first name of the authors, their positions, scientific degrees and academic titles)

Work program has been considered and approved at the Department meeting  
Technology of Drugs

Record from of September 1, 2023 No. 1

Head of the department  prof. Liliia VYSHNEVSKA

Work program has been approved at the meeting of the Methodical Commission of technological disciplines

Record from of September 1, 2023 No. 1

/Head of the specialized commission  prof. Olena RUBAN

## 1. Description of the educational component

**Language of study:** English

**Status of the educational component:** obligatory

**Prerequisites for studying the educational component:** biophysics, pharmaceutical drug technology, drug factory technology, pharmacology, pharmacotherapy.

**The subject** of study of the educational component "Biopharmacy" is the study of the influence of variable factors on the bioavailability of active pharmaceutical ingredients during the creation of new and improvement of existing medicinal products in order to ensure their proper therapeutic activity.

**Information content of the educational component.** 90 hours, 3.0 ECTS credits are allocated to the study of the educational component.

## 2. Objectives and tasks of the educational component

**The purpose of teaching the educational component** "Biopharmacy" is to master the theoretical and practical foundations of biopharmacy for students of higher education for the scientific substantiation of the composition and technology of new drugs and the improvement of existing ones with the use of modern excipients, new technologies, by increasing their effectiveness and reducing side effects on the body.

**The main tasks** of the educational component "Biopharmacy" are:

- learn the theoretical foundations of biopharmacy; classify and distinguish between exogenous, endogenous, pharmaceutical, biological and other factors.
- learn biopharmaceutical research methods "in vitro" and "in vivo".
- to master techniques that allow controlling the influence of the nature, physical state of medicinal and auxiliary substances, simple chemical modification, type of dosage form, route of its administration and production processes on pharmacodynamics, pharmacokinetics and bioavailability of medicinal substances;
- to formulate the practical skills necessary for conducting bio-pharmaceutical research in students of higher education.

## 3. Competence and planned educational outcomes

The educational component "Biopharmacy" ensures that students acquire **competences**:

- *integral*:

the ability to solve typical and complex specialized tasks and practical problems in professional pharmaceutical activity using provisions, theories and methods of fundamental, chemical, technological, biomedical and socio-economic sciences; integrate knowledge and solve complex issues; clearly and unambiguously convey your conclusions and knowledge, rationally justifying them, to a professional and non-specialist audience.

- *general*:

GC 2. Ability to apply knowledge in practical situations, make informed decisions.

GC 4. Ability to think abstractly, analyze and synthesize, learn and be up-to-date.

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

GC 9. Skills in using information and communication technologies.

GC 11. Ability to evaluate and ensure the quality of the work performed.

- *special (professional, subject)*:

PC 2. 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 evaluating the risk/benefit ratio, compatibility, indications and contraindications guided by data on the health status of a specific patient, taking into account the biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical features of the medicinal product and other products of the pharmacy assortment .

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

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

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

PLO 2. Apply knowledge of general and professional disciplines in professional activities.

PLO 3. To comply with the norms of the sanitary and hygienic regime and the requirements of safety equipment when carrying out professional activities.

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

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 26. To choose a rational technology, to manufacture medicinal products in various dosage forms according to the prescriptions of doctors and orders of medical institutions, to process them before discharge. Perform technological operations: weigh, measure, dose various medicinal products by weight, volume, etc. Develop and draw up technological documentation for the manufacture of medicinal products in pharmacies.

PLO 27. To substantiate the technology and organize the production of medicinal products at pharmaceutical enterprises and draw up technological documentation for the production of medicinal products at pharmaceutical enterprises.

As a **result** of studying the educational component, the student of higher education should *know*:

- requirements of regulatory documentation regarding the conduct of biopharmaceutical research;
- characteristics of pharmaceutical factors – type of dosage form and route of its administration, physico-chemical properties of drugs and auxiliary substances, particle size, technological process and used equipment;
- characteristics of biological and exogenous factors affecting the effectiveness of drugs: human age, sex, biorhythms, temperature and body weight, individual sensitivity of the body, temperature of the external environment, magnetic field, meteorological conditions, etc.; influence of pharmaceutical, biological and other factors on the bioavailability and bioequivalence of medicinal products;
- the concept of chemical, biological and therapeutic equivalence of medicinal products; concept of generic drugs;
- rules for taking medicines as a factor in ensuring their effectiveness;

*be able*:

- work with normative documentation regulating the conduct of biopharmaceutical research, scientific and reference literature;
- conduct biopharmaceutical studies to determine the release of medicinal substances from dosage forms;
- calculate pharmacokinetic indicators, interpret the data of the kinetics curves of the release of substances from dosage forms;
- to summarize the received data and carry out their statistical processing;
- formulate conclusions about the influence of pharmaceutical factors on the process of release of medicinal substances from various dosage forms and about the therapeutic equivalence of drugs;
- take into account the influence of pharmaceutical, biological and other factors on the bioavailability and bioequivalence of medicines when recommending them to patients;
- recommend rules for taking medicines to ensure their effectiveness.

*possess*:

- skills in working with normative documentation regulating the conduct of biopharmaceutical research, scientific and reference literature;
- methods of conducting biopharmaceutical research "in vitro" and "in vivo" to determine the release of medicinal substances from dosage forms;

- skills of calculating pharmacokinetic indicators, their statistical processing;

#### 4. The structure of the educational component

Names of content modules and topics	The amount of hours				
	totally	including			
		l.	sem.	Pract. lesson	Self-study
1	2	3	4	5	6
<b>Module 1</b>					
<b>Content module 1.</b> Biopharmaceutics is the theoretical basis of drug technology					
<b>Topic 1.</b> Basic concepts and terms of biopharmaceutics. The current state and prospects of the development of biopharmaceutics. The influence of the nature of excipients on the therapeutic effectiveness of drugs	17	1	-	4	12
<b>Topic 2.</b> Influence of pharmaceutical factors on the therapeutic effectiveness of drugs. The influence of the degree of API grinding on the therapeutic efficacy of drugs	18	2	-	4	12
<b>Topic 3.</b> Pharmaco-technological methods of assessing the release of API from drugs. The influence of the type of dosage form and the route of administration on the therapeutic efficacy of drugs.	17	1	-	4	12
<b>Topic 4.</b> Influence of exo- and endogenous factors on the bioavailability of drugs. The effect of a simple chemical modification of API on the therapeutic efficacy of drugs.	17	1	-	4	12
<b>Topic 5.</b> Bioequivalence, its role in the evaluation of the quality of medicinal products. Bioavailability and methods of its determination. The influence of technological factors on the speed of API release and on the stability of drugs.	13	1	-	2	10
<b>Control of SM 1</b>					
Semester assessment	8		-	2	6
Together according to content module 1	90	6	-	24	60
<b>Total for Module 1</b>	<b>90</b>	<b>6</b>	<b>-</b>	<b>24</b>	<b>60</b>

#### 5. 5. Content of the program of the educational component

##### *Content module 1. Biopharmaceutics - the theoretical basis of drug technology*

**Topic 1. Basic concepts and terms of biopharmaceutics. The current state and prospects of the development of biopharmaceutics. The influence of the nature of excipients on the therapeutic effectiveness of drugs**

Basic concepts and terms of biopharmaceutics. The current state of biopharmaceutical development abroad and in Ukraine. Biopharmaceutics as a scientific direction and its importance in the development of the composition and technology of dosage forms. The main tasks and directions of biopharmaceutical research at the current stage and their significance for practical health care. Modern requirements for the evaluation of the quality of medicinal products. The works of foreign and domestic scientists that contributed to the emergence

and further development of biopharmaceutics.

The nature of auxiliary substances and their quantity - ointment and suppository bases, the presence of absorption accelerators (various surfactants), melting point or ability to dissolve, adhesives, loosening agents, etc. The interaction of medicinal and auxiliary substances, the principle of selection of auxiliary substances. Types of chemical bonds that occur between active substances and excipients. The duality of the role of excipients. Factors affecting the rate of absorption of substances. Using the method of "agar plates" to determine the degree of release of medicinal substances from the ointment.

## **Topic 2. Influence of pharmaceutical factors on the therapeutic effectiveness of drugs.**

### **The influence of the degree of API grinding on the therapeutic efficacy of drugs**

Characteristics of pharmaceutical factors - the type of dosage form and the route of its administration, physicochemical properties of drugs and auxiliary substances, the technological process and the equipment used.

The physical state of medicinal substances in medicinal preparations (dispersion, aggregate state, crystallinity, solubility, viscosity, pH value, surface tension, degree of purity) and their influence on the release and absorption of medicinal substances. The use of different degrees of grinding in the development of drugs with different bioavailability. Dispersity, crystal structure and polymorphic forms of medicinal substances. Dependence of the therapeutic activity of drugs on the use of anhydrous forms or crystal hydrates of medicinal substances.

The influence of packaging and storage conditions on the stability of medicinal products. Methods of determining the stability of medicinal products.

Graphical method of calculating the area under the pharmacokinetic curve. Determination of the maximum concentration of medicinal substances, absorption constants and elimination constants.

Using the "in vitro" method of direct diffusion through a semipermeable membrane to establish the bioavailability of ointments.

## **Topic 3. Pharmaco-technological methods of assessing the release of API from drugs. The influence of the type of dosage form and the route of administration on the therapeutic efficacy of drugs.**

Tests to determine the solubility of tablets, plasters, suppositories, chewing gums by the "in vitro" method. Method of observed dissolution according to DFU.

Ways of introducing medicinal substances into the body. Characteristics of enteral and parenteral routes of drug administration, advantages and disadvantages. Rational selection of the type of dosage form (tablets, ointments, suppositories, injection solutions, etc.). The effect of the type of dosage form on the process of absorption of medicinal substances into the blood.

## **Topic 4. Influence of exo- and endogenous factors on the bioavailability of drugs. The effect of a simple chemical modification of API on the therapeutic efficacy of drugs.**

Microbiological, acanthous and radioisotope methods of biopharmaceutical research.

Simple chemical modification - salts, ethers, acids and bases ("in vivo" methods). The interaction of food and drugs, the time of taking drugs (before meals, during or after meals, etc.). Factors of the internal environment of the human body affecting the bioavailability of active pharmaceutical ingredients. The effect of body temperature on the bioavailability of drugs. Influence of magnetic field and meteorological conditions on the bioavailability of medicinal products.

## **Topic 5. Bioequivalence, its role in the evaluation of the quality of medicinal products. Bioavailability and methods of its determination. The influence of technological factors on the speed of API release and on the stability of drugs. Control of SM 1**

The concept of bioequivalence, pharmacodynamics and pharmacokinetics of drugs and their relationship with variable pharmaceutical factors. Calculations of pharmacokinetic parameters. Modern nomenclature of brands and generics on the domestic pharmaceutical market. Replacement of drugs with analogues.

Bioavailability, its types and definitions. Study of bioavailability during the development of new drugs, for control of existing and comparative evaluation of drugs manufactured by different enterprises. Modern modified types of dosage forms. Combined drugs and principles of their use. Control of content module 1. Control is carried out by means of a test survey and work on individual cards, which include a theoretical question and a situational task.

## Semester assessment

The semester assessment is conducted in order to check the level of assimilation of theoretical material and skills in conducting biopharmaceutical research.

### 6. Lecture topics

No	Name of the topic	Volume in hours
1	Basic concepts and terms of biopharmaceutics. The current state and prospects for the development of biopharmaceutics. The influence of the degree of API grinding on the effectiveness of drugs	1
2	The influence of pharmaceutical factors on the therapeutic effectiveness of drugs. The influence of the nature of excipients on the therapeutic effectiveness of drugs	2
3	Pharmaco-technological methods of assessing the release of API from drugs. The influence of the type of dosage form and the route of administration on the therapeutic efficacy of drugs.	1
4	Influence of exo and endogenous factors on the bioavailability of drugs.	1
5	The effect of a simple chemical modification of API on the therapeutic efficacy of drugs.	1
<b>Total amount of hours</b>		<b>6</b>

### 7. Topics of seminar classes *(not provided for in the curriculum).*

### 8. Topics of practical classes

No	Name of the topic	Volume in hours
1	Basic concepts and terms of biopharmaceutics. The current state and prospects for the development of biopharmaceutics. The influence of the degree of API grinding on the effectiveness of drugs.	4
2	The influence of pharmaceutical factors on the therapeutic effectiveness of drugs.. The influence of the nature of excipients on the therapeutic effectiveness of drugs.	4
3	Pharmaco-technological methods of assessing the release of API from drugs. The influence of the type of dosage form and the route of administration on the therapeutic efficacy of drugs.	4
4	Influence of exo and endogenous factors on the bioavailability of drugs.	4
5	Bioavailability of drugs and methods of its determination. Bioequivalence, its role in the evaluation of the quality of medicinal products. Content module control 1.	2
6	Semester assessment	2
<b>Total amount of hours</b>		<b>24</b>

### 9. Topics of laboratory classes *(not provided for in the curriculum).*

## 10. Self-study work

No	Name of the topic	Volume in hours
1	<b>Basic concepts and terms of biopharmaceutics. The current state and prospects for the development of biopharmaceutics. The influence of the degree of API grinding on the effectiveness of drugs</b> Contribution of domestic and foreign scientists to the development of biopharmaceutics. Using the "agar plate" method to establish the bioavailability of ointments.	12
2	<b>The influence of pharmaceutical factors on the therapeutic effectiveness of drugs. The influence of the nature of excipients on the therapeutic effectiveness of drugs</b> The use of direct diffusion through a semipermeable membrane to establish the bioavailability of ointments. Dependence of the therapeutic activity of medicinal products on the nature of the APIs used - anhydrous forms or crystal hydrates.	12
3	<b>Pharmaco-technological methods of assessing the release of API from drugs. The influence of the type of dosage form and the route of administration on the therapeutic efficacy of drugs.</b> Pharmacopoeia "dissolution" test for medicated chewing gums. Observed dissolution according to SPU.	12
4	<b>Influence of exo and endogenous factors on the bioavailability of drugs</b> Dependence of the bioavailability of API on the factors of the internal environment of the human body. The effect of body temperature on the bioavailability of drugs. The influence of magnetic field and meteorological conditions on the bioavailability of medicinal products.	12
5	<b>The effect of a simple chemical modification of API on the therapeutic efficacy of drugs.</b> Principles of use of combined medicines. Content module control 1.	16
<b>Total amount of hours</b>		<b>60</b>

### Tasks for independent work

1. To characterize the contribution of domestic and foreign scientists to the development of biopharmaceutics.
2. Master the method of "agar plates" for establishing the bioavailability of ointments.
3. Master the method of direct diffusion through a semipermeable membrane to establish the bioavailability of ointments.
4. Explain the dependence of the therapeutic activity of drugs on the use of anhydrous forms or crystal hydrates of medicinal substances.
5. Learn the method of conducting the pharmacopoeial "dissolution" test for medicinal chewing gums.
6. Learn the technique of "observed dissolution" according to the SPU.
7. Characterize the dependence of API bioavailability on factors of the internal environment of the human body.
8. Characterize the influence of body temperature on the bioavailability of medicinal products.
9. Explain the influence of the magnetic field and meteorological conditions on the bioavailability of drugs.
10. Learn the principles of using combined medicines.

### 1. Criteria and procedure for evaluating learning outcomes

The criteria for evaluating the knowledge and skills of higher education seekers in education were developed in accordance with POL A2.2-25-031 Regulations on the evaluation of knowledge of higher education seekers at the National Pharmaceutical University.

The evaluation of the success of higher education institutions in the educational component is a rating, is presented on a one-point scale and is defined according to the ECTC system and according to the traditional scale adopted in



Ukraine.

Assessments (in points) are reflected in the calendar-thematic plans of laboratory classes.

Current Assessment: Module 1, Content Module 1							Sum
	T1	T2	T3	T4	T5	Semester assessment	61- 100
Phm (4,10d) engl	6-12	6-12	6-12	6-12	6-12	24 - 40	
36-60							

T1, T2 ... – content module topics.

Evaluation criteria for practical classes	Points	
	Daily Phm (4,10d) engl	
<ul style="list-style-type: none"> <li>➤ independently chose the methodology of the research according to ND;</li> <li>➤ selected objects and materials for research;</li> <li>➤ clearly followed the sequence of biopharmaceutical research;</li> <li>➤ carried out calculations and statistical processing of the obtained results;</li> <li>➤ summarized and recorded the results of practical work in a notebook;</li> <li>➤ formulated a full-fledged conclusion about the result of the practical task</li> </ul>	11-12	
<ul style="list-style-type: none"> <li>➤ based on the teacher's suggestions, he chose the research method according to the National Standard;</li> <li>➤ selected objects and materials for research;</li> <li>➤ followed the sequence of biopharmaceutical research with minor errors;</li> <li>➤ performed calculations, but did not perform statistical processing of the results;</li> <li>➤ summarized and recorded the results of the work in a notebook;</li> <li>➤ did not fully formulate conclusions about the results of the practical task</li> </ul>	9-10	
<ul style="list-style-type: none"> <li>➤ based on the teacher's suggestions, he chose the research method according to the National Standard;</li> <li>➤ selected research objects and materials based on the teacher's prompts;</li> <li>➤ did not follow the sequence of biopharmaceutical studies;</li> <li>➤ carried out partial calculations and statistical processing of the results;</li> <li>➤ did not fully summarize and record the results of the work;</li> <li>➤ formulated conclusions about the results of the practical task, which do not reflect the essence and content of the work carried out</li> </ul>	7-8	
<ul style="list-style-type: none"> <li>➤ could not choose the method of conducting research according to ND;</li> <li>➤ did not select objects and materials for research;</li> <li>➤ did not follow the sequence of biopharmaceutical studies;</li> </ul>	0-6	
<ul style="list-style-type: none"> <li>➤ did not (partially) perform calculations and statistics. processing of results;</li> <li>➤ did not summarize and record (partially) the results of the work;</li> <li>➤ did not formulate (incorrectly formulated) conclusions about the result of the practical task</li> </ul>		

**The student's self-study work** is monitored during each practical session, during the control of the content module.

In the event that the student came to the class unprepared, he must be present at the class. After working with educational literature and an individual conversation with the teacher on the topic of the lesson, the student is admitted to practical work.

**Control of mastering content** modules is conducted in the last classes of studying topics of content modules. The means of diagnosing students' knowledge are the test control of individual cards, the answer to a theoretical question and the

solution of a situational problem. Only those students who have completed all types of work provided by the curriculum (worked out, missed practical classes, etc.)

Evaluation criteria for control of mastery of the content module.	Amount of points
— showed comprehensive and deep knowledge of the theoretical material presented in the textbook, lecture texts and additional literature — fully understood the essence of the situational task and correctly formulated ways to solve it	37-40
— showed sufficiently complete knowledge of the theoretical material presented in the textbook and lecture texts — correctly understood the essence of the situational task, but did not give a complete answer about ways to solve this situation, or gave answers with some shortcomings	33-36
— showed knowledge of theoretical material, which is considered necessary and sufficient — did not fully understand the essence of the situational task or gave an answer with errors	29-32
— showed insufficient knowledge of theoretical material — did not fully understand the essence of the situational task or gave an answer with significant errors	24-28
— lack of an answer to a theoretical question or inconsistency of the answer to the formulation of the theoretical question — did not understand the essence of the situational task and could not offer any solution to the situation or gave a wrong answer	0-23

The sum of points for the study of ZM is the sum of the points received by the student during the study of all topics of the content module.

**The semester assessment** is conducted by summarizing the module study results, increasing the rating if desired and filling out the reporting documentation.

The overall rating consists of the current rating and the semester credit and is from 60 to 100 points.

## 2. Forms of current and final control of study success

*The current educational activity* is evaluated during each lesson: in the practical lesson - control of practical abilities and skills.

Control of mastering the content module consists of a test control of knowledge and a written answer to tickets containing a theoretical question (theoretical part) and solving a situational problem (practical part).

**The semester control** is carried out in the form of a semester credit in the last classes. The form of the final module control is a *credit*.

## 3. Methodological support

1. Working curriculum
2. Calendar plan of lectures and practical classes
3. Textbook
4. Guidelines.
5. Distance course
6. Multimedia texts of lectures
7. Video films
8. Educational equipment, technical teaching aids.

## 4. Recommended literature

### 1. Basic

1. Біофармація : підруч. для студ. вищ. фармац. навч. закл. і фармац. ф-тів вищ. медич. навч. закл. IV рівня акредитації / О. І. Тихонов, Т. Г. Ярних, І. А. Зупанець, Л. І. Вишневіська, О. С. Шпичак, Н. П. Половко, О. С. Данькевич, О. Є. Богуцька, Н. В. Бездітко, Ю. М. Азаренко, Ю. В. Левачкова, Т. М. Зубченко; За ред. О. І. Тихонова, 2-ге вид., перероб. і допов. – Х. : НФаУ : Золоті сторінки, 2019. – 256 с.

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15. The International Pharmacopoeia. — 7th Edition, 2017 [Electronic resource]. — Access mode: <http://apps.who.int/phint/2017/index.html#p/home> (Date of access: 28.02.2020). — The name from the screen.
16. USP 41 – NF 36. — The United States Pharmacopoeia and National Formulary 2018 / United States Pharmacopoeial Convention, 2017. — 8200 p.

## 2. Information resources, including on the Internet

- 1.Офіційний сайт Державного експертного центру Міністерства охорони здоров'я України [Електронний ресурс]. - Режим доступу: <https://dec.gov.ua>
- 2.Сайт кафедри технології ліків НФаУ – <http://tl.nuph.edu.ua>
- 3.Бібліотека НФаУ: e-mail [library@nuph.edu.ua](mailto:library@nuph.edu.ua)
- 4.Сайт дистанційного навчання НФаУ – <http://pharmel.kharkiv.edu>
- 5.Електронний архів НФаУ – <http://dspace.nuph.edu.ua>