

MINISTRY OF HEALTH OF UKRAINE

ODESSA NATIONAL MEDICAL UNIVERSITY

Department of Pharmaceutical Chemistry and Drug Technology



Vice-rector for scientific and pedagogical work

Eduard BURYACHKIVSKY

September 1st, 2025

**WORKING PROGRAM IN THE DISCIPLINE
«BIOPHARMACY»**

Level of higher education: second (master's degree)

Area of Knowledge: 22 «Health care»

Specialty: 226 «Pharmacy, industrial pharmacy»

Specialization: 226.01 «Pharmacy»

Educational and professional program: Pharmacy, industrial pharmacy

The work program is based on the educational and professional program "Pharmacy, Industrial Pharmacy" for the training of specialists of the second (master's) level of higher education in the specialty 226 "Pharmacy, Industrial Pharmacy" of the field of knowledge 22 "Health Care", approved by the Academic Council of ONMedU (protocol No. 10 dated June 27, 2024).

Developers:

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The work program was approved at the meeting of the Department of Pharmaceutical Chemistry and Drug Technology
Protocol No. 1 dated 08/29/2025.

Head of Department



Volodymyr GELMBOLDT

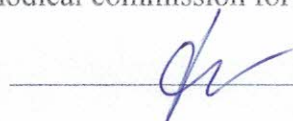
Agreed with the EPP guarantor



Liana UNHURIAN

Approved by the subject cycle methodical commission for pharmaceutical disciplines of ONMedU
Protocol No. 1 dated 08/29/2025

Head of the subject cycle methodical commission for pharmaceutical disciplines of ONMedU



Natalia FIZOR

Reviewed and approved at the department meeting _____

Protocol No. ___ from "___" _____ 20__.

Head of the department

_____ Volodymyr GELMBOLDT

Reviewed and approved at the department meeting _____

Protocol no. ___ from "___" _____ 20__.

Head of the department

_____ Volodymyr GELMBOLDT

1. DESCRIPTION OF THE ACADEMIC DISCIPLINE

Name of indicators	Field of knowledge, specialty, specialization, level of higher education	Characteristics of the academic discipline
Total number: Credits: 3 Hours: 90	Area of Knowledge 22 "Healthcare"	Full-time education
		Mandatory discipline
		Year of preparation: 5
		Semesters IX - X
		Lectures (20 h.)
		Practical (40 h.)
		Independent work (30 h.)
	Specialization 226.01 "Pharmacy"	Final control form – credit
	Level of higher education second (master's)	

2. GOALS AND OBJECTIVES OF THE ACADEMIC DISCIPLINE, COMPETENCES, PROGRAM LEARNING OUTCOMES

Goal: students master the theoretical and practical foundations of biopharmacy for scientific substantiation of the composition and technology of new drugs and improvement of existing ones using modern excipients and new technologies, by increasing their effectiveness and reducing side effects on the body.

Task: know the basics of the influence of pharmaceutical and biological factors on the pharmacodynamics and pharmacokinetics of drugs; know the importance of studying the bioavailability of a drug substance and developing methods for its determination; use knowledge about the therapeutic equivalence of drugs; possess methods for determining a drug substance or its metabolite in biological fluids.

The process of studying the discipline is aimed at forming elements of the following competencies:

General (GC):

GC 1 – The ability to think abstractly, analyze and synthesize, learn and be up-to-date.

GC 2 – Knowledge and understanding of the subject area and understanding of professional activity.

GC 6 – Ability to work in a team.

GC 9 – Ability to use information and communication technologies.

Specialists (SC)

SC 1 – Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.

SC 8 – Ability to provide advice on prescription and non-prescription medicines and other pharmacy products; pharmaceutical care during the selection and sale of medicines of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.

SC 16 – Ability to organize and carry out production activities of pharmacies for the manufacture of medicines in various dosage forms according to doctors' prescriptions and the requirements of medical and preventive institutions, including justification of technology and selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).

SC 19 – Ability to organize and carry out quality control of medicinal products of natural and synthetic origin in accordance with the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods (QCM), technological instructions, etc.; prevent the distribution of low-quality, falsified and unregistered medicinal products.

Program learning outcomes (PLO):

PLO 3 – Have specialized knowledge and skills to solve professional problems and tasks, including for the purpose of further developing knowledge and procedures in the field of pharmacy.

PLO 11 – To determine the advantages and disadvantages of medicines of natural and synthetic origin of various pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic, pharmacodynamic characteristics and the type of dosage form. To recommend medicines and other pharmacy products to consumers, providing advisory assistance and pharmaceutical care.

PLO 20 – To carry out pharmaceutical development of medicinal products of natural and synthetic origin in industrial production conditions.

PLO 23 – Determine the main chemical and pharmaceutical characteristics of medicinal products of natural and synthetic origin; select and/or develop quality control methods for their standardization using physical, chemical, physicochemical, biological, microbiological and pharmaco-technological methods in accordance with current requirements.

As a result of studying the academic discipline, a higher education applicant must:

Know:

- exogenous and endogenous variable factors and their influence on the therapeutic activity of drugs;
- "in vitro", "in vivo" methods for determining the influence of the main variable factors (pharmaceutical factors) on the pharmacological action and degree of release of medicinal substances from dosage forms, the rate of their absorption into the blood, bioavailability;
- therapeutic equivalence of medicinal products;
- causes of polymorphic modifications of medicinal substances.

Be able to:

- use the influence of physical and technological factors on the rate of release of substances from the dosage form;
- prepare trituration ointments taking into account the quantity and physicochemical properties of medicinal substances;
- use the method of "agar plates" and diffusion through a semipermeable membrane to assess the degree of release of medicinal substances from the ointment;
- possess methods of analysis of sulfonamide drugs in dialysate;
- prepare various dosage forms taking into account aspects of biopharmacy;
- summarize the results of biopharmaceutical research, conduct statistical processing of the obtained results.

3. CONTENT OF THE COURSE

Topic 1. Biopharmacy as a scientific and educational discipline. Subject and tasks of biopharmacy. Main indicators of bioavailability of drugs. Factors affecting bioavailability.

- Purpose and objectives of the discipline;
- Research directions in biopharmaceutics;
- Leading directions of biopharmaceutical research;
- Specific biopharmaceutical terms.

Topic 2. The influence of the physical state of drugs on the rate of their release from dosage forms.

- Physical state of the substance (solid, liquid, amorphous, crystalline);
- Amorphous forms of medicinal substances;

- Particle size of solids;
- Polymorphism;
- Aggregate state of excipients.

Topic 3. The influence of the nature of excipients on the process of drug release from dosage forms.

- Physicochemical properties of the dosage form;
- Hydrophilic substances;
- Hydrophobic bases;
- Surfactants (surfactants);
- Polymer matrices and retarders.

Topic 4. The influence of the route of administration and simple chemical modification of drugs on their absorption process.

- Route of administration;
- Parenteral routes;
- Simple chemical modifications;
- Lipophilicity and degree of ionization of the substance;
- Modification of the molecule.

Topic 5. The influence of technological factors on the rate of release of medicinal substances from dosage forms and the stability of medicinal products.

- Technological parameters of production;
- Granulation or drying method;
- Type and method of tablet pressing;
- Coating technology;
- Compliance with optimal storage conditions and stabilizing technological methods.

Topic 6. The influence of technological factors on the dissolution rate of tablets and the stability of injection solutions. Therapeutic nonequivalence of drugs.

- Technological factors of tableting;
- The degree of grinding of the active substance and the uniformity of mixing of the components;
- Stability of injection solutions;
- Violation of technology during production or storage;
- Therapeutic non-equivalence.

Topic 7. Pharmaco-technological methods for assessing the disintegration, solubility and release of medicinal substances from medicinal products.

- Pharmaco-technological studies;
- Disintegration test;
- Dissolution test;
- Active ingredient release.

Topic 8. Bioequivalence of medicinal products. Bioequivalence assessment.

- Bioequivalence of medicinal products;
- Bioequivalent drugs;
- Pharmacokinetic parameters - area under the curve (AUC), maximum concentration (C_{max}) and time to reach it (T_{max}).
- Bioequivalence studies.

Topic 9. Bioavailability of drugs. Absolute, relative bioavailability. Classification of factors affecting the bioavailability of drugs.

- Bioavailability;
- Absolute bioavailability;
- Relative bioavailability;
- Factors affecting bioavailability;
- Optimization of dosage, choice of dosage form and ensuring a stable therapeutic effect.

Topic 10. Molecular weight, solubility, acidity, alkalinity, state of aggregation and polymorphism as physicochemical factors affecting the bioavailability of drugs.

- Molecular weight;
- Solubility;
- Acidity and alkalinity (pH) of the medium;
- State of aggregation (solid, liquid, gaseous)
- Polymorphism of crystalline forms of a substance.

Topic 11. The influence of spatial isomerism and optical properties of drug substances on bioavailability and therapeutic activity.

- Spatial isomerism;
- Enantiomers;
- Optical activity;
- Control and study of stereochemical properties.

Topic 12. Lipophilicity and its effect on pharmacokinetic characteristics and bioavailability dynamics of drugs.

- Lipophilicity of the drug substance;
- Increased lipophilicity;
- Effect of lipophilicity on drug distribution in the body;
- Effect of lipophilicity on metabolism and excretion;
- Optimization of lipophilicity.

Topic 13. Classification of pharmaceutical factors: state of aggregation; excipients (their nature, physical state and quantity).

- Aggregate state of the dosage form (solid, liquid, gaseous);
- Excipients (hydrophilic, hydrophobic, surfactants and polymers) that affect the solubility and stability of the drug;
- Physical state of excipients (crystalline, amorphous, liquid, powdery);
- Number of excipients;
- Classification of pharmaceutical factors.

Topic 14. Choosing the dosage form and route of administration of the drug into the body.

- Physico-chemical properties of the active substance;
- Oral forms (tablets, capsules, syrups);
- Parenteral forms (injections, infusions);
- Local forms (ointments, creams, eye and nasal drops).

Topic 15. Interaction of medicines with food.

- The effect of food on pharmacokinetic processes;
- The effect of food on pharmacodynamic processes;
- The effect of food on metabolism and elimination processes;
- Time of drug administration in relation to food.

Topic 16. Interaction with other drugs.

- Drug interactions;
- Pharmacokinetic interactions;
- Pharmacodynamic interactions;
- Polypharmacy;
- Monitoring and dosage adjustment.

4. STRUCTURE OF THE ACADEMIC DISCIPLINE

Topic names	Number of hours of full-time study			
	Total	including		
		lectures	practical	IWS
<i>Topic 1.</i> Biopharmacy as a scientific and educational discipline. Subject and tasks of biopharmacy. Main indicators of bioavailability of drugs. Factors affecting bioavailability.	6	2	2	2
<i>Topic 2.</i> The influence of the physical state of drugs on the rate of their release from dosage forms.	6	2	2	2
<i>Topic 3.</i> The influence of the nature of excipients on the process of drug release from dosage forms.	6	2	2	2
<i>Topic 4.</i> The influence of the route of administration and simple chemical modification of drugs on their absorption process.	8	2	4	2
<i>Topic 5.</i> The influence of technological factors on the rate of release of medicinal substances from dosage forms and the stability of medicinal products.	6	2	2	2
<i>Topic 6.</i> The influence of technological factors on the dissolution rate of tablets and the stability of injection solutions. Therapeutic nonequivalence of drugs.	6	2	2	2
<i>Topic 7.</i> Pharmaco-technological methods for assessing the disintegration, solubility and release of medicinal substances from medicinal products.	6	2	2	2
<i>Topic 8.</i> Bioequivalence of medicinal products. Bioequivalence assessment.	6	2	2	2
<i>Topic 9.</i> Bioavailability of drugs. Absolute, relative bioavailability. Classification of factors affecting the bioavailability of drugs.	6	2	2	2
<i>Topic 10.</i> Molecular weight, solubility, acidity, alkalinity, state of aggregation and polymorphism as physicochemical factors affecting the bioavailability of drugs.	3	0	2	1
<i>Topic 11.</i> The influence of spatial isomerism and optical properties of drug substances on bioavailability and therapeutic activity.	4	0	2	2
<i>Topic 12.</i> Lipophilicity and its effect on pharmacokinetic characteristics and bioavailability dynamics of drugs.	4	0	2	2
<i>Topic 13.</i> Classification of pharmaceutical factors: state of aggregation; excipients (their nature, physical state and quantity)	6	0	4	2
<i>Topic 14.</i> Choosing the dosage form and route of administration of the drug into the body.	6	0	4	2
<i>Topic 15.</i> Interaction of medicines with food.	8	2	4	2
<i>Topic 16.</i> Interaction with other drugs.	3	0	2	1
Total hours	90	20	40	30

5. TOPICS OF LECTURES / SEMINARS / PRACTICAL / LABORATORY CLASSES

5.1. Lecture topics

№ i/o	Topic name	Number of hours
		2
		2
4		2
5	.	2
	.	2
		2
		2
		2
		2
		2

5.2. Seminar topics

<i>Number of hours of practical classes in the discipline</i>		

6. INDEPENDENT WORK OF A HIGHER EDUCATION STUDENT

№ i/o	Topic name	Number of hours
1.	Biopharmacy as a scientific and educational discipline. Subject and tasks of biopharmacy. Main indicators of bioavailability of drugs. Factors affecting bioavailability.	2
2.	The influence of the physical state of drugs on the rate of their release from dosage forms.	2
3.	The influence of the nature of excipients on the process of drug release from dosage forms.	2
4.	The influence of the route of administration and simple chemical modification of drugs on the process of their absorption.	2
5.	The influence of the route of administration and simple chemical modification of medicinal substances on the process of their absorption.	2
6.	The influence of technological factors on the dissolution rate of tablets and the stability of injection solutions. Therapeutic nonequivalence of drugs.	2
7.	Pharmaco-technological methods for assessing the disintegration, solubility and release of medicinal substances from medicinal products.	2
8.	Bioequivalence of medicinal products. Bioequivalence assessment.	2
9.	Bioavailability of drugs. Absolute, relative bioavailability. Classification of factors affecting the bioavailability of drugs.	2
10.	Molecular weight, solubility, acidity, alkalinity, state of aggregation, and polymorphism as physicochemical factors affecting drug bioavailability.	1
11.	The influence of spatial isomerism and optical properties of drug substances on bioavailability and therapeutic activity.	2
12.	Lipophilicity and its effect on the pharmacokinetic characteristics and bioavailability dynamics of drugs.	2
13.	Classification of pharmaceutical factors: state of aggregation; excipients (their nature, physical state and quantity).	2
14.	Choosing the dosage form and route of administration of the drug into the body.	2
15.	Interaction of medicines with food.	2
16.	Interaction with other drugs.	1
<i>Number of hours of independent work on the discipline</i>		30

7. FORMS AND METHODS OF TEACHING

Forms of education:

The discipline is taught in the form of practical classes; organization of independent work of the applicant.

Methods of learning:

Practical classes: conversation, role-playing games, solving situational problems, solving test problems.

Independent work: independent work with the textbook, independent work with recommended basic and additional literature, with electronic information resources, independent solution of clinical tasks.

8. FORMS OF CONTROL AND CRITERIA FOR ASSESSING LEARNING OUTCOMES

Forms of current control: oral interview, testing, assessment of practical skills, assessment of communication skills during role-playing, solving situational tasks, assessment of activity in the lesson.

Final control form: credit.

Criteria for assessing the learning outcomes of higher education applicants during current control

Assessment	Assessment criteria
Excellent «5»	The applicant actively participates in the discussion of the most complex questions on the topic of the lesson, gives at least 90% correct answers to standardized test tasks, answers written tasks without errors, performs practical work and draws up a protocol.
Good «4»	The applicant participates in the discussion of the most complex questions on the topic, gives at least 75% of correct answers to standardized test tasks, makes some minor errors in answers to written tasks, performs practical work and draws up a protocol.
Satisfactory «3»	The applicant participates in the discussion of the most complex questions on the topic, gives at least 60% of correct answers to standardized test tasks, makes significant errors in answers to written tasks, performs practical work and draws up a protocol.
Unsatisfactory «2»	The applicant does not participate in the discussion of complex questions on the topic, gives less than 60% of correct answers to standardized test tasks, makes gross errors in answers to written tasks or does not give answers to them at all, does not perform practical work and does not draw up a protocol.

A credit is awarded to an applicant who has completed all the tasks of the work program of the academic discipline, actively participated in practical classes, completed and defended an individual assignment and has an average current grade of at least 3.0 and has no academic debt.

The credit is given: in the last lesson before the start of the examination session - in the case of a tape system of study, in the last lesson - in the case of a cyclical system of study. The credit score is the arithmetic mean of all components on a traditional four-point scale and has a value that is rounded using the statistical method to two decimal places.

9. DISTRIBUTION OF POINTS RECEIVED BY HIGHER EDUCATION STUDENTS

Points in the academic discipline for applicants who have successfully completed the program are converted into a traditional four-point scale according to the absolute criteria given in the table:

National assessment for discipline	Total points for the discipline
Excellent («5»)	185 – 200
Good («4»)	151 – 184
Satisfactory («3»)	120 – 150
Unsatisfactory («2»)	Lower 120

A **multi-point scale (200-point scale)** characterizes the actual success of each applicant in mastering the academic discipline. The conversion of the traditional assessment into a 200-point one is performed by the University's information and technology department using the "Contingent" program according to the appropriate formula: Average score of success (current success in the discipline) x 40.

According to **the ECTS rating scale**, the achievements of the students in the academic discipline who are studying in the same course of the same specialty are evaluated, according to the points they received, by means of ranking, namely:

ECTS grade	Statistical indicator
A	The best 10% of achievers
B	Next 25% of achievers
C	Next 30% of achievers
D	Next 25% of achievers
E	Next 10% of achievers

The ECTS scale establishes the applicant's belonging to the group of the best or worst among the reference group of fellow students (faculty, specialty), that is, his rating. When converting from a multi-point scale, as a rule, the boundaries of the grades "A", "B", "C", "D", "E" do not coincide with the boundaries of the grades "5", "4", "3" according to the traditional scale. The grade "A" on the ECTS scale cannot be equal to the grade "excellent", and the grade "B" - to the grade "good", etc. Applicants who received grades "FX" and "F" ("2") are not included in the list of ranked applicants. Such applicants automatically receive an "E" grade after retaking. The "FX" grade is given to applicants who have scored the minimum number of points for current educational activities, but who have not passed the final test. A grade of "F" is given to students who attended all classroom classes in the academic discipline, but did not achieve a grade point average (3.00) for current academic activities and were not admitted to the final examination.

10. METHODOLOGICAL SUPPORT

- Syllabus of the academic discipline;
- Work program of the academic discipline;
- Methodological recommendations for practical classes;
- Methodological recommendations for independent work of higher education applicants;
- Multimedia presentations;
- Illustrative materials;
- Situational tasks.

11. QUESTIONS FOR PREPARATION FOR THE FINAL TEST

1. Biopharmaceutics as a scientific direction and its importance in the development of the content and technology of dosage forms.
2. The purpose and tasks of biopharmacy.
3. The main tasks of biopharmacy at the present stage and their role in practical healthcare.
4. The main terms of biopharmacy.
5. Pharmaceutical factors and their classification.
6. Constant pharmaceutical factors, their influence on the effectiveness of drugs.
7. Variable pharmaceutical factors. The concept of polymorphism.
8. Advantages and disadvantages of oral, sublingual, injectable, rectal, inhalation, transdermal dosage forms.
9. The main biopharmaceutical methods for studying drugs. "In vitro" and "in vivo" methods.

10. Disintegration of solid dosage forms. Statistical methods of determination.
11. Dynamic methods for determining the disintegration of solid dosage forms.
12. The concept of solubility. Methods of assessing solubility. Devices for determining solubility.
13. Methods of passing medicinal substances through membranes. Types of devices with membranes.
14. Methods of determining the release of active substances from ointment bases.
15. Release of active substances from suppository bases.
16. Pharmaceutical factors and their classification.
17. Heterogeneous and homogeneous dispersed systems.
18. Physical properties of medicinal substances that affect the effect of ointments.
19. Characteristics of the degrees of grinding of active substances.
20. The concept of polymorphism.
21. The influence of the aggregate state of active substances on the therapeutic effect of a medicinal product.
22. Method of preparing "agar plates".
23. Classification of groups of excipients for the manufacture of dosage forms, their purpose.
24. Standardization of the content of excipients.
25. Mechanisms and degree of influence of excipients on the action of drugs.
26. The importance of a scientific approach in the process of selecting excipients.
27. Pharmacotherapeutic classification of ointments.
28. Requirements for ointment bases and the influence of their physicochemical properties on the bioavailability of ointments.
29. Mechanism of penetration of medicinal substances from ointments through the skin.
30. Factors affecting the permeability of the skin for medicinal substances.
31. Main characteristics of the release process of medicinal substances (maximum concentration, time to reach maximum concentration, area under the curve, release constant, half-life).
32. Biopharmaceutical classification of dosage forms.
33. Advantages and disadvantages of different types of dosage forms.
34. Granules as LF, features of technology.
35. Methods of obtaining tablets. The influence of pharmaceutical factors on the therapeutic activity of tablets.
36. Gelatin capsules, preparation and filling methods. The influence of pharmaceutical factors on their therapeutic activity.
37. Medicines for vaginal and rectal use and methods of their evaluation.
38. The influence of the type of dosage form on the rate of absorption of the medicinal substance, its concentration in biological fluids and the stability of drugs.
39. Factors affecting the stability of the dosage form.
40. Enteral routes of administration of medicinal substances into the body.
41. Parenteral routes of administration of medicinal substances into the body.
42. Biopharmaceutical aspects of improving the production of dosage forms.
43. Types of technological operations and processes.
44. Methods of stabilizing heterogeneous disperse systems.
45. Excipients used in the production of suppositories, their classification.
46. Use of surfactants to replace the method of administration of active substances.
47. Pharmaceutical incompatibilities in various dosage forms and possible ways to eliminate them.
48. Methods for determining the stability of drugs.
49. The concept of bioavailability of drugs. Types of bioavailability.
50. Bioequivalence as a defining characteristic of the action of a reconstituted drug. Bioequivalence studies.

51. The concept of therapeutic inequivalence.
52. The influence of physicochemical properties of drugs on the pharmacokinetic activity of drugs.
53. Mechanisms of absorption of drugs. Factors that affect absorption.
54. The influence of physiological factors on the kinetics of absorption of oral and rectal dosage forms.
55. The influence of magnetic fields and meteorological factors on the bioavailability of drugs.
56. The influence of age and gender on the bioavailability of APIs. The dependence of bioavailability of drugs on human biorhythms.
57. The influence of alcohol and nicotine on the effectiveness of drugs.
58. The interaction of drugs with food. The influence of the liquid for washing down drugs on their therapeutic activity.
59. Ways to improve traditional dosage forms.
60. Therapeutic systems with controlled release of drugs, their classification.

12. RECOMMENDED LITERATURE

Basic:

1. Patrick J. Sinko (ред.) Martin's Physical Pharmacy and Pharmaceutical Sciences, 8th edition, 2023. Lippincott Williams & Wilkins. ISBN-13: 978-1975174811
2. Sahu, Manoranjan. Text Book of Biopharmaceutics and Pharmacokinetics, 2024. Bright Sky Publications. ISBN: 978-81-968309-4-6
3. Contemporary Physical Pharmacy and Pharmaceutics for Professional Pharmacy Curriculum, Arindam Basu Sarkar – (, 2024). ISBN-13: 978-1-60797-973-9
4. Martin's Physical Pharmacy and Pharmaceutical Sciences, 8th edition (2023), Patrick J. Sinko – Lippincott Williams & Wilkins. ISBN-13: 978-1975174811
5. Shargel and Yu's Applied Biopharmaceutics & Pharmacokinetics, 8th edition (2022), Leon Shargel, Andrew B. C. Yu – McGraw-Hill. ISBN-13: 978-1260142990
6. Biopharmaceutics: From Fundamentals to Industrial Practice (1st edition, 2021/2022), edited by Hannah Batchelor – Wiley. ISBN-13: 978-1119678281

Additional:

1. Біофармація. Підручник для фармацевтичних ЗВО і факультетів. 2-ге видання. За редакцією В.В. Гладишева / Гладишев В.В., Давтян Л.Л., Бірюк І.А. та ін. – Львів: Видавець Марченко Т.В., 2023. – 176 с.
2. Біофармація: підручник для студентів закладів вищої освіти / В.В. Гладишев, Л.Л. Давтян, І.А. Бірюк та ін. За редакцією В.В. Гладишева. Дніпро: ЧМП «Економіка». 2022. 176 с.
3. Біофармація : підруч. для студентів закл. вищ. освіти / О. І. Тихонов [та ін.] ; за ред. О. І. Тихонова. – 2-ге вид., перероб. і допов. – Харків : НФаУ: Золоті сторінки, 2019. –
4. Настанова СТ-Н МОЗУ 4242-7.1:2005 «Лікарські засоби. Настанова з клінічних досліджень. Дослідження біодоступності та біоеквівалентності» – Київ, 2018.
5. Лікарські засоби. Дослідження біоеквівалентності, що затверджена Наказом МОЗ України від 02 листопада 2018 року № 2014 : настанова СТ-Н МОЗУ 42-7.2:2018 / МОЗ України. – Київ, 2018. – 80 с. 12.
6. Статистичний аналіз результатів хімічного експерименту N (5.3.N.1.) // Державна Фармакопея України : в 3 т. Доповнення 2 / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-ге вид. – Харків : ДП «Український науковий фармакопейний центр якості лікарських засобів», 2018. – С. 77–112.

7. Сучасні фармацевтичні технології: навч. посіб. до лабораторних занять магістрантів денної, вечірньої та заочної форми навчання спеціальності 8.110201 «Фармація» / під ред. О.А. Рубан. – Х. : Вид-во НФаУ, 2016. – 256 с.
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13. Інформаційні ресурси:

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2. [Бібліотека ОНМедУ \(odmu.edu.ua\)](http://odmu.edu.ua) - Наукова бібліотека ОНМедУ
3. www.moz.gov.ua – офіційний сайт Міністерства охорони здоров'я України