MINISTRY OF HEALTH PROTECTION OF UKRAINE

ODESSA NATIONAL MEDICAL UNIVERSITY

Department of Pharmaceutical Chemistry and Drug Technology

APPROVED

Vice-rector for scientific and pedagogical work

_____ Eduard BURYACHKIVSKY

September 1st 2024

WORKING PROGRAM IN THE DISCIPLINE «BIOPHARMACY»

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

Field of knowledge: 22 «Health care»

Specialty: 226 «Pharmacy, industrial pharmacy»

Educational and professional program: Pharmacy, industrial pharmacy

2024

The work program is based on the educational and professional program "Pharmacy, industrial pharmacy" of training specialists of the second (master's) level of higher education in specialty 226 "Pharmacy, industrial pharmacy" field of knowledge 22 "Health care", approved by the Scientific Council of ONMedU (protocol no. 10 of June 27, 2024).

Developers: docent Zamkovaya A.V., ass. Shyshkin I.O.

The work program was approved at the meeting of the Department of Pharmaceutical Chemistry and Drug Technology
Protocol No. 1 dated August 29, 2024.

Head of the department _____ Volodymyr HELMBOLDT

Agreed with the guarantor of OPP _____ Liana UNGURYAN

Approved by the subject cycle methodical commission for pharmaceutical disciplines of ONMedU
Protocol No. 1 from "30 " August 2024

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

_____ Natalia FIZOR

Reviewed and approved at a meeting of the department

_____

_____

___

Protocol No. ___ of "___" _____ 20__

Head of the department _____ _____
(signature) Volodymyr HELMBOLDT

Reviewed and approved at a meeting of the department

_____

_____

Protocol No. ___ of "___" _____ 20__

Head of the department _____ _____

(signature) Volodymyr HELMBOLDT

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: 9 Content modules: 1	Field of knowledge 22 "Health care" Specialty 226 "Pharmacy, industrial pharmacy" Level of higher education second (master's)	*Full-time education* *Compulsory discipline*
		Year of preparation: 5
		Semesters X
		Lectures (20 h.)
		Seminary (0 h.)
		Practical (40 h.)
		Laboratory (0 h.)
		Independent work (30 h.)
		including individual tasks (0 h.)
		The form of final control – credit

2. The purpose and tasks of the educational discipline, competencies, learning outcomes of the program.

Goal: mastering theoretical and practical basics of biopharmacy for the scientific substantiation of the composition and technology of new drugs and improvement of existing ones with the use of modern excipients, 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 medicinal products;
- know the importance of studying the bioavailability of a medicinal substance and developing methods for its determination;
- use knowledge about the therapeutic equivalence of medicinal products;
- to have methods for determining a medicinal substance or its metabolite in biological fluids.

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

General competencies (GC):

GC01. Ability to think abstractly, analyse and synthesise, learn and be modernly trained.
GC02. Knowledge and understanding of the subject area and understanding of professional activities.
GC03. Ability to communicate in the state language both orally and in writing.
GC04. Ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity.
GC05. Ability to evaluate and ensure the quality of work performed.
GC06. Ability to work in a team.
GC10. Ability to act socially responsibly and consciously.
GC11. Ability to apply knowledge in practical situations.
GC12. The desire to preserve the environment.
GC 13. Ability to show initiative and entrepreneurship.
GC14. Ability to adapt and act in a new situation.
GC15. Knowledge and understanding of the subject area and understanding of professional activities
GC16. Ability to conduct experimental research at the appropriate level.

GC17. Ability to make decisions and act in accordance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

Professional competencies (PC):

PC01. Ability to integrate knowledge and solve complex problems of pharmacy in broad or multidisciplinary contexts.

PC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.

PC08. Ability to provide advice on prescription and over-the-counter medicines and other pharmacy products; pharmaceutical care in 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 characteristics, indications / contraindications for use, guided by data on the health status of a particular patient.

PC09 Ability to provide first aid to patients and injured in extreme situations and in case of emergency.

PC12. Ability to ensure the proper storage of medicines of natural and synthetic origin and other pharmacy products in accordance with their physical and chemical properties and the rules of Good Storage Practice (GSP) in healthcare facilities.

PC16. The ability to organise and carry out the production activities of pharmacies for the manufacture of medicines in various dosage forms according to prescriptions and requirements (orders) of medical and preventive care institutions, including the justification of technology and the choice of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).

PC17. Ability to carry out pharmaceutical development and participate in the production of medicines of natural and synthetic origin in pharmaceutical enterprises in accordance with the requirements of Good Manufacturing Practice (GMP).

PC24. Ability to use in professional activities the knowledge of regulatory and legal, legislative acts of Ukraine and recommendations of good pharmaceutical practices.

PC25. Ability to demonstrate and apply in practice communication skills, fundamental principles of pharmaceutical ethics and deontology based on moral obligations and values, ethical standards of

professional behaviour and responsibility in accordance with the Code of Ethics for Pharmacists of Ukraine and WHO guidelines.

PC26. Ability to organise and participate in the production of medicinal products in 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 execution of the necessary documentation. Determine the stability of medicines.

PC 31 Ability to carry out medical evacuation measures.

Programme learning outcomes (PLOs):

PLO01. To have and apply specialised conceptual knowledge in the field of pharmacy and related fields, taking into account modern scientific achievements.

PLO03. To have specialised knowledge and skills to solve professional problems and tasks, including for the purpose of further development of knowledge and procedures in the field of pharmacy.

PLO04. Communicate fluently in the state and English languages orally and in writing to discuss professional problems and performance, present research and innovative projects.

PLO07. Collect the necessary information on the development and production of medicines using professional literature, patents, databases and other sources; systematise, analyse and evaluate it, in particular, using statistical analysis.

PLO19. Develop technological documentation for the manufacture of medicines, choose a rational technology, manufacture medicines in various dosage forms according to prescriptions and requirements (orders) of healthcare facilities, and prepare them for release.

PLO20 - Carry out pharmaceutical development of medicines of natural and synthetic origin in industrial production.
PLO25. To comply with the norms of sanitary and hygienic regime and safety requirements in the performance of professional activities.
PLO25. To comply with the norms of sanitary and hygienic regime and safety requirements in the performance of professional activities.
PLO27. Perform professional activities using creative methods and approaches.
PLO30. To comply with the norms of communication in professional interaction with colleagues, management, consumers, to work effectively in a team.
PLO36. Plan and implement professional activities on the basis of regulatory legal acts of Ukraine and recommendations of good pharmaceutical practices
PLO38. Justify the technology and organise the production of medicines at pharmaceutical enterprises and draw up technological documentation for the production of medicines at pharmaceutical enterprises.
PLO43. To organise the necessary level of individual safety (own and persons under care) in the event of typical hazardous situations in the individual field of activity.

As a result of studying the academic discipline, the student of higher education should:

to know:

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

be able:

- 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 physical and chemical 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;
- to have methods of analysis of sulfonamide drugs in dialysate;
- prepare various dosage forms taking into account the aspects of biopharmacy;
- summarize the results of biopharmaceutical research, carry out statistical processing of the obtained results.

3. Content of the academic discipline

Topic 1. Biopharmacy as a scientific and educational discipline. The subject and tasks of biopharmacy. Main indicators of bioavailability of drugs. Factors affecting bioavailability.
Topic 2. The influence of the physical state of drugs on the speed of their release from dosage forms.
Topic 3. Influence of the nature of excipients on the process of release of drugs from dosage forms.
Topic 4. The influence of the route of administration and simple chemical modification of drugs on the process of their absorption.
Topic 5. The influence of the route of administration and simple chemical modification of medicinal substances on the process of their absorption.
Topic 6. The influence of technological factors on the rate of dissolution of tablets and the stability of injection solutions. Therapeutic non-equivalence of medicines.
Topic 7. Pharmaco-technological methods of evaluation of disintegration, solubility and release of medicinal substances from medicinal preparations.

Topic 8. Bioequivalence of medicines. Assessment of bioequivalence.
Topic 9. Bioavailability of drugs. Absolute, relative bioavailability. Classification of factors affecting the bioavailability of drugs.
Topic 10. Molecular weight, solubility, acidity, alkalinity, state of aggregation and polymorphism as physicochemical factors affecting the bioavailability of drugs.
Topic 11. Effect on bioavailability and therapeutic activity of spatial isomerism and optical properties of medicinal substances.
Topic 12. Lipophilicity and its influence on pharmacokinetic characteristics and dynamics of bioavailability of drugs.
Topic 13. Classification of pharmaceutical factors: aggregate state; excipients (their nature, physical state and quantity).
Topic 14. The choice of the dosage form and the route of introduction of the drug into the body.
Topic 15. Interaction of medicines with food products.
Topic 16. Interaction with other medicinal products.

4. The structure of the academic discipline

Names of topics	Number of hours					
	In total	including				
		lectures	seminars	practical	laboratory	IWS
Topic 1. Biopharmacy as a scientific and educational discipline. The subject and tasks of biopharmacy. Main indicators of bioavailability of drugs. Factors affecting bioavailability.	10	6	0	2	0	2
Topic 2. The influence of the physical state of drugs on the speed of their release from dosage forms.	8	4	0	2	0	2
Topic 3. Influence of the nature of excipients on the process of release of medicinal products from dosage forms.	8	41	0	2	0	2
Topic 4. The influence of the route of administration and simple chemical modification of drugs on the process of their absorption.	8	2	0	4	0	2
Topic 5. The influence of technological factors on the rate of release of medicinal substances from dosage forms and the stability of medicinal preparations.	4	0	0	2	0	2

Topic 6. The influence of technological factors on the rate of dissolution of tablets and the stability of injection solutions. Therapeutic non-equivalence of medicines.	4	0	0	2	0	2
Topic 7. Pharmaco-technological methods of evaluation of disintegration, solubility and release of medicinal substances from medicinal preparations.	4	0	0	2	0	2
Topic 8. Bioequivalence of medicines. Assessment of bioequivalence.	4	0	0	2	0	2
Topic 9. Bioavailability of drugs. Absolute, relative bioavailability. Classification of factors affecting the bioavailability of drugs.	8	2	0	2	0	2
Topic 10. Molecular weight, solubility, acidity, alkalinity, aggregate state and polymorphism as physico-chemical factors affecting the bioavailability of drugs.	7	4	0	2	0	1
Topic 11. Effect on bioavailability and therapeutic activity of spatial isomerism and optical properties of medicinal substances.	4	0	0	2	0	2
Topic 12. Lipophilicity and its influence on pharmacokinetic characteristics and dynamics of bioavailability of drugs.	4	0	0	2	0	2
Topic 13. Classification of pharmaceutical factors: aggregate state; auxiliary substances (their nature, physical state and quantity).	6	0	0	4	0	2
Topic 14. Choice of dosage form and route of administration of the	6	0	0	4	0	2

medicinal product into the body.						
Topic 15. Interaction of medicinal products with food products.	6	0	0	4	0	2
Topic 16. Interaction with other medicines.	3	0	0	2	0	1
Total in hours	**90**	**20**	**0**	**40**	**0**	**30**

5. Topics of lectures / seminars / practical / laboratory lessons

5.1. Topics of lectures

№		
4		
5		

5.2. Topics of seminar lessons

Seminar lessons are not provided.

5.3. Topics of practical lessons

№		
	Topic 1. Practical lesson 1. Biopharmacy as a scientific and educational discipline. Subject and tasks of the discipline. Main indicators of bioavailability of drugs. Factors affecting the bioavailability of drugs.	
	Topic 2. Practical lesson 2. The influence of the physical state of drugs on the speed of their release from dosage forms.	
	Topic 3. Practical lesson 3. Influence of the nature of excipients on the process of release of drugs from dosage forms.	
	Topic 4. Practical lesson 4. The influence of the dosage form on the process of release of medicinal substances from medicinal preparations. Part 1.	
	Topic 4. Practical lesson 5. The influence of the dosage form on the process of release of medicinal substances from medicinal preparations. Part 2.	
	The influence of technological factors on the rate of dissolution of tablets and the stability of injection solutions. Therapeutic non-equivalence of medicines.	

		2
		2
	Molecular weight, solubility, acidity, alkalinity, state of aggregation and polymorphism as physicochemical factors affecting drug bioavailability.	
l		

6. Independent work of a student of higher education

№	Title of the topic / types of tasks	Number of hours
1.	Biopharmacy as a scientific and educational discipline. The 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 speed of their release from dosage forms.	2
3.	Influence of the nature of excipients on the process of release of drugs 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 rate of dissolution of tablets and the stability of injection solutions. Therapeutic non-equivalence of medicines.	2
7.	Pharmaco-technological methods of evaluation of disintegration, solubility and release of medicinal substances from medicinal preparations.	2
8.	Bioequivalence of medicines. Assessment of bioequivalence.	2
9.	Bioavailability of drugs. Absolute, relative bioavailability. Classification of factors affecting the bioavailability of drugs.	1
10.	Molecular weight, solubility, acidity, alkalinity, state of aggregation and polymorphism as physicochemical factors affecting drug bioavailability.	2
11.	Effect on bioavailability and therapeutic activity of spatial isomerism and optical properties of medicinal substances.	2
12.	Lipophilicity and its influence on pharmacokinetic characteristics and dynamics of bioavailability of drugs.	2
13.	Classification of pharmaceutical factors: aggregate state; auxiliary substances (their nature, physical state and quantity).	2
14.	The choice of the dosage form and the route of introduction of the drug into the body.	2
15.	Interaction of medicines with food products.	2
16.	Interaction with other medicinal products.	1
The number of hours of independent work on the discipline		**30**

7. Teaching methods

Practical lessons: conversation, solution of situational problems, control of knowledge, abilities and skills of higher education students, presentation of a general problem by the teacher and its discussion with the participation of higher education students, performance of control tasks, their verification, evaluation. Performance of laboratory work, in which students of higher education, under the guidance of a teacher, conduct educational experiments in specially equipped educational laboratories using equipment adapted to the conditions of the educational process.

Independent work: independent work with the textbook, independent work with test tasks, independent solution of situational tasks.

8. Forms of control and assessment methods (including criteria for evaluating learning outcomes)

Current control: oral survey, testing, assessment of performance of practical skills, problem solving.

Final control: credit.

Evaluation of the current educational activity in a practical session:

1. Assessment of theoretical knowledge on the topic of the lesson:
   - methods: survey, solving a situational problem
   - maximum score – 5, minimum score – 3, unsatisfactory score – 2.
2. Assessment of practical skills on the subject of the lesson:
   - methods: assessment of the correctness of the performance of practical skills
   - maximum score – 5, minimum score – 3, unsatisfactory score – 2.

The grade for one practical lesson is the arithmetic average of all components and can only have an integer value (5, 4, 3, 2), which is rounded according to the statistical method.

Criteria for current assessment in a practical lesson

Assessment	Assessment criteria
«5»	The applicant actively participates in the discussion of the most difficult 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.

«4»	The applicant participates in the discussion of the most difficult questions on the topic, gives at least 75% correct answers to standardized test tasks, makes some minor mistakes in the answers to written tasks, performs practical work and draws up a protocol.
«3»	The applicant participates in the discussion of the most difficult questions on the topic, gives at least 60% correct answers to standardized test tasks, makes significant mistakes in answers to written tasks, performs practical work and draws up a protocol.
«2»	The applicant does not participate in the discussion of complex questions on the topic, gives less than 60% correct answers to standardized test tasks, makes gross mistakes 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.

Credit is given to the applicant who completed all the tasks of the work program of the academic discipline, took an active part 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.

Assessment is carried out: at the last lesson before the beginning of the examination session - with the tape system of learning, at the last lesson - with the cyclical system of learning. The credit score is the arithmetic average of all components on a traditional four-point scale and has a value that is rounded according to the statistics method with two decimal places after the decimal point.

9. Distribution of points received by higher education applicants

The obtained average score for the academic discipline for applicants who successfully mastered the work program of the academic discipline is converted from a traditional four-point scale to points on a 200-point scale, as shown in the table:

Conversion table of a traditional assessment into a multi-point scale

Traditional four-point scale	Multipoint 200-point scale
Perfectly («5»)	185 – 200
Good («4»)	151 – 184
Satisfactorily («3»)	120 – 150
Unsatisfactorily («2»)	Less than 120

A multi-point scale (200-point scale) characterizes the actual success of each applicant in mastering the educational component. The conversion of a traditional assessment (average score for an academic discipline) into a 200-point one is performed by the information and technical department of the University.

According to the obtained points on a 200-point scale, the achievements of the applicants are evaluated according to the ECTS rating scale. Further ranking according to the ECTS rating scale makes it possible to evaluate the achievements of students in the educational component who are studying in the same course of the same specialty, in accordance with the points they received.

The ECTS scale is a relative-comparative rating, which establishes the applicant's belonging to the group of better or worse among the reference group of fellow students (faculty, specialty). An "A" grade on the ECTS scale cannot be equal to an " perfectly " grade, a "B" grade to a "good" grade, etc. When converting from a multi-point scale, the limits of grades "A", "B", "C", "D", "E" according to the ECTS scale do not coincide with the limits of grades "5", "4", "3" according to the traditional scale. Acquirers who have received grades of "FX" and "F" ("2") are not included in the list of ranked acquirers. The grade "FX" is awarded to students who have obtained the minimum number of points for the current learning activity, but who have not passed the final examination. A grade of "F" is given to students who attended all lessons in the discipline, but did not receive an average score (3.00) for the current academic activity and were not admitted to the final examination.

Applicants who study on one course (one specialty), based on the number of points scored in the discipline, are ranked on the ECTS scale as follows:

Conversion of the traditional grade from the discipline and the sum of points on the ECTS scale

Assessment on the ECTS scale	Statistical indicator
A	Top 10% students
B	The next 25% students
C	The next 25% students
D	The next 25% students
E	The next 25% students

10. Methodical support:

- Working program of the academic discipline
- Syllabus of the academic discipline
- Textbooks:
- Multimedia presentations
- Situational tasks
- Methodical development of practical lessons
- Electronic bank of test tasks by subdivisions of the discipline.

11. The list of questions for the Credit

1. Biopharmacy 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 current stage and their role in practical health care.
4. Basic terms of biopharmacy.
5. Pharmaceutical factors and their classification.
6. Constant pharmaceutical factors, their influence on the effectiveness of medicines.
7. Variable pharmaceutical factors. Concept of polymorphism.
8. Advantages and disadvantages of oral, sublingual, injection, rectal, inhalation, transdermal dosage forms.
9. Basic biopharmaceutical methods of studying medicinal products. "in vitro" and "in vivo" methods.
10. Disintegration of solid dosage forms. Statistical methods of determination.
11. Dynamic methods of determining the disintegration of solid dosage forms.
12. Concept of solubility. Methods of assessing solubility. Instruments for determining solubility.
13. Methods of passage of 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 action of ointments.
19. Characteristics of degrees of grinding of active substances.
20. Concept of polymorphism.
21. Influence of the aggregate state of active substances on the therapeutic effect of the medicinal product.
22. Method of preparation of "agar plates".
23. Classification of groups of auxiliary substances for the manufacture of dosage forms, their purpose.

24. Rationing of the content of auxiliary substances.
25. Mechanisms and degree of influence of auxiliary substances effect of medicines.
26. The importance of a scientific approach in the process of selecting auxiliary substances.
27. Pharmacotherapeutic classification of ointments.
28. Requirements for ointment bases and the influence of their physical and chemical properties on the bioavailability of ointments.
29. The mechanism of penetration of medicinal substances from ointments through the skin.
30. Factors affecting the permeability of the skin to medicinal substances.
31. The main characteristics of the release process of medicinal substances (maximum concentration, time to reach the maximum concentration, area under the curve, release constant, half-release time).
32. Biopharmaceutical classification of dosage forms.
33. Advantages and disadvantages of different types of dosage forms.
34. Granules as LF, features of the technology.
35. Methods of obtaining tablets. The influence of pharmaceutical factors on the therapeutic activity of tablets.
36. Gelatin capsules, production and methods of filling. Influence of pharmaceutical factors on their therapeutic activity.
37. Medicines for vaginal and rectal use and methods of their assessment.
38. The effect of the type of dosage form on the rate of absorption of the medicinal substance, its concentration in biological fluids, and the stability of preparations.
39. Factors affecting the stability of the dosage form.
40. Enteral ways of introducing medicinal substances into the body.
41. Parenteral ways of introducing 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 stabilization of heterogeneous dispersed systems.
45. Excipients used in the production of suppositories, their classification.
46. Use of surface-active substances for the purpose of replacing the method of administration of active substances.
47. Pharmaceutical incompatibilities in various dosage forms and possible methods of their elimination.
48. Methods of determining the stability of medicinal products.
49. Concept of bioavailability of medicines. Types of bioavailability.
50. Bioequivalence as a defining characteristic of the action of the reproduced drug. Bioequivalence studies.
51. The concept of therapeutic non-equivalence.
52. Influence of physicochemical properties of medicinal substances on the pharmacokinetic activity of medicinal products.
53. Mechanisms of absorption of medicinal substances. Factors affecting absorption.
54. The influence of physiological factors on the kinetics of absorption of oral and rectal dosage forms.
55. Influence of the magnetic field and meteorological factors on the bioavailability of drugs.
56. The influence of age and sex of a person on the bioavailability of API. Dependence of bioavailability of medicines on human biorhythms.
57. Influence of alcohol and nicotine on the effectiveness of medicines.
58. Interaction of medicines with food. The influence of liquid for drinking drugs on their therapeutic activity.
59. Ways of improving traditional medicinal forms.
60. Therapeutic systems with regulated release of medicinal substances, their classification.

12. Recommended literature

Basic:

1. Biopharmaceutics. From Fundamentals to Industrial Practice Edited by Hannah Batchelor; Strathclyde Institute of Pharmacy and Biomedical Sciences. University of StrathclydeGlasgow, United Kingdom, 2022 – 320 p.
2. "Preface." Applied Biopharmaceutics & Pharmacokinetics, 7e Eds. Leon Shargel, and Andrew B.C. Yu. McGraw Hill, 2016
3. Shargel L, Yu A. Impact of Biopharmaceutics on Drug Product Quality and Clinical Efficacy. In: Shargel L, Yu AC. eds. Applied Biopharmaceutics & Pharmacokinetics, 7e. McGraw Hill; 2016. Accessed November 24, 2023.
4. Kakhi M, Delvadia P, Suarez-Sharp S. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance. In: Ducharme MP, Shargel L. eds. Shargel and Yu's Applied Biopharmaceutics and Pharmacokinetics, 8e. McGraw Hill; 2022.
5. Sun C, Shargel L, Yu A. Biopharmaceutical Aspects of the Active Pharmaceutical Ingredient and Pharmaceutical Equivalence. In: Shargel L, Yu AC. eds. Applied Biopharmaceutics & Pharmacokinetics, 7e. McGraw Hill; 2016.
6. Dixit T, Shargel L. Rational Drug Product Development, Quality, and Performance. In: Ducharme MP, Shargel L. eds. Shargel and Yu's Applied Biopharmaceutics and Pharmacokinetics, 8e. McGraw Hill; 2022.
7. Shargel L, Ducharme MP. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence. In: Ducharme MP, Shargel L. eds. Shargel and Yu's Applied Biopharmaceutics and Pharmacokinetics, 8e. McGraw Hill; 2022.

Additional:

1. Фармацевтична енциклопедія / Голова ред. ради та автор передмови В.П.Черних. – 3-тє вид. – К.: «МОРІОН», 2016. – 1952 с
2. Половко Н.П., Вишневська Л.І., Шпичак О.С. Оцінка біофармацевтичних факторів при розробці та виробництві нових лікарських засобів // Сучасні досягнення фармацевтичної технології і біотехнології : збірник наукових праць, випуск 2. – Х.: Вид-во НФаУ, 2017. – С. 155-160.
3. Допоміжні речовини у виробництві ліків : навч. посіб. для студ. вищ. фармац. навч. закл. /О.А. Рубан, І. М. Перцев, С. А. Куценко, Ю. С. Маслій ; за ред. І. М. Перцева. Х. : Золоті сторінки, 2016. 720 с.
4. Біофармація : підруч. для студ. вищ. фармац. навч. зал. І фар мац. ф-тів вищ. Медич. Навч. зал. IV рівня акредитації / О.І. Тихонов, Т.Г. Ярних, І.А. Зупанець та ін.; За ред. О.І. Тихонова. – Х.: НФаУ: Золоті сторінки, 2010. – 240 с. (українсько мовою). Затверджено Міністерством освіти і науки України (лис № 1/11-1172 від 23.02.2010 р.).
5. Фармакологія: підручник для студ.мед.ф-тів / Чекман І.С., Горчакова Н.О., Казак Л.І. та ін., ред.. проф.. І.С. Чекмана. - Вид.4-тє. - Вінниця: Нова Книга, 2017. - 784 с.
6. Перцев І.М., Пиминов О.Х., Слободянюк М.М. та ін. Фармацевтичні та медико-біологічні аспекти ліків. Навчальний посібник / За ред. І.М. Перцева. Вінниця: НОВА КНИГА, 2007. 728 с.
7. Допоміжні речовини у виробництві ліків: навч. посіб. для студентів вищ. фармац. навч. закл. / авт.: О.А.Рубан, І.М.Перцев, С.А.Куцеко, Ю.С.Маслій; за ред. І.М.Перцева. – Харків: Золоті сторінки, 2016. 720 с.

13. Information resources

1. Технологія ліків ОНМедУ (odmu.edu.ua) – website of the Department of Drug Technology of ONMedU
2. Бібліотека ОНМедУ (odmu.edu.ua) – Scientific library of ONMedU
3. www.moz.gov.ua – official website of the Ministry of Health of Ukraine