

Odessa national medical university
Faculty of Pharmacy
Department of Pharmaceutical chemistry and Drug technology

Syllabus of course
«Biopharmacy»

Amount:	Total -90, number of ECTS credits - 3.
Semester, year:	X, V year of study
Days, time, place:	According to the approved schedule
Teacher (s):	Candidate of Biological sciences, senior teacher Zamkovaya A. V.
Contact phones:	0507425467
E-mail:	zamkovaya@gmail.com
Workplace:	Odessa, Malinovsky Street, 37, Department of Drug Technology, office.122
Consultations:	<i>Online consultations:</i> remotely on the Microsoft Teams platform

COMMUNICATION

Communication in the audience on schedule. Other types of communication: face-to-face consultation on a schedule, remotely on the Microsoft Teams platform and with the help of an e-mail lecturer. The solution of "working issues" is possible by the specified phone number.

COURSE ANNOTATION

Subject of study of the discipline "Biopharmacy": mastering the methods of "in vitro" and "in vivo" to study the influence of major variables of pharmaceutical and biological factors on the degree of release of drugs from dosage forms, their rate of absorption into the blood, distribution and excretion, determination of therapeutic non-equivalence, as well as bioavailability of drugs to determine the quality of the drug and its impact on the patient's body.

Course prerequisites: the discipline belongs to the compulsory disciplines and is based on the knowledge gained in the study of general disciplines: Latin, botany, analytical chemistry, pharmacy drug technology, pharmacognosy, pharmacology, pharmaceutical chemistry, toxicological chemistry.

Postrequisites of the course: knowledge gained after the study of this discipline is necessary for the study of such disciplines as: homeopathy, pharmaceutical biotechnology.

The purpose of the course is to teach students the ability to act socially responsible and civic consciously, to apply knowledge in practical situations, to strive to preserve the environment, the ability to abstract thinking, analysis and synthesis; ability to learn and be modernly trained, to have skills in the use of information and communication technologies, the ability to evaluate and ensure the quality of work performed.

Tasks of the discipline:

- 1) know the basics of the influence of pharmaceutical and biological factors on the pharmacodynamics and pharmacokinetics of drugs;
- 2) know the importance of studying the bioavailability of the drug and the development of methods for its determination;
- 3) use knowledge about the therapeutic equivalence of drugs;
- 4) have methods for determining the drug substance or its metabolite in biological fluids.

Expected results:

As a result of studying the discipline, the applicant must:

Know:

- 1) the main tasks of biopharmaceutical research at the present stage and their role for practical health care;
- 2) the importance of biopharmacy in the development of the composition and technology of drugs;
- 3) biopharmaceutical factors and their influence on the therapeutic efficacy of drugs;
- 4) biopharmaceutical classification of drugs;
- 5) methods of research of pharmaceutical and bioavailability from various dosage forms;
- 6) basic equipment used to determine the pharmaceutical and bioavailability of drugs;
- 7) mechanisms for the release of drugs from solid dosage forms of rapid release and modified release;
- 8) criteria for assessing the quality of dosage forms (chemical, physicochemical, biological, as well as additional for each dosage form);
- 9) the importance of the study of pharmaceutical and bioavailability.

Be able:

- 1) own and use the necessary regulatory documentation and reference books;
- 2) determine and justify the method of preparation, route of administration and features of the use of drugs;
- 3) standardize the dosage form according to pharmaceutical (technological and analytical) parameters and know the requirements for safety and efficacy of drugs;
- 4) to predict the possible interaction of drugs with their simultaneous appointment;

Have:

- 1) skills and abilities to determine the pharmaceutical and bioavailability of drugs by different methods;

2) skills and abilities to build curves of dynamics of release of investigated drugs depending on various biopharmaceutical factors;

3) skills and abilities to calculate bioavailability, elimination constants and half-life of substances from different dosage forms.

COURSE DESCRIPTION

Module volume:

The course will be presented in the form of lectures - 10 hours, seminar classes - 30 hours, independent work of students - 50 hours. In addition to lecture and practical forms of work, individual and group consultations are provided.

The content of the discipline

Topic №1. Biopharmacy as a scientific and educational discipline. Subject and tasks of biopharmacy. The main indicators of bioavailability of drugs. Factors affecting bioavailability.

Topic №2. The influence of the physical state of drugs on the rate of their release from dosage forms.

Topic №3. The influence of the nature of excipients on the process of releasing drugs from dosage forms.

Topic №4. Influence of the route of administration and simple chemical modification of drugs on the process of their absorption.

Topic №5. Influence of the route of administration and simple chemical modification of drugs on the process of their absorption.

Topic №6. Influence of technological factors on speed of dissolution of tablets and stability of injectable solutions. Therapeutic non-equivalence of drugs.

Topic №7. Pharmaco-technological methods for assessing the decomposition, solubility and release of drugs from drugs.

Topic №8. Bioequivalence of drugs. Bioequivalence assessment.

Sources of information:

Main:

1. 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. – 224 с
2. Настанова СТ-Н МОЗУ 4242-7.1:2005 «Лікарські засоби. Настанова з клінічних досліджень. Дослідження біодоступності та біоеквівалентності» - Київ, 2018.
3. Настанова СТ-Н МОЗУ 4242-7.1:2005 «Лікарські засоби. Настанова з клінічних досліджень. Дослідження біодоступності та біоеквівалентності» - Київ, 2018.
4. Настанова СТ-Н МОЗУ 42-7.2:2018 Лікарські засоби дослідження біоеквівалентності. – Київ, 2018. – 77 с.
5. 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.
6. Біофармація: навчальний посібник / упоряд.: Борисюк І.Ю., Фізор Н.С., Акішева А.С Одеса, ОНМедУ, 2020. - 98 с.
7. 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.

8. Лікарські засоби. Належна виробнича практика : настанова СТ-Н МОЗУ 42-4.0:2016 / МОЗ України ; Державна служба України з ЛЗ. – Київ :Моріон, 2016. – 335 с.
9. Стандартні зразки N (5.12) // Державна Фармакопея України : в 3 т.Доповнення 1 / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-ге вид. – Харків : ДП «Український науковий фармакопейний центр якості лікарських засобів», 2016. – С. 95–96.
10. 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.

Additional literature

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. 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.

Electronic information resources

1. [Технологія ліків ОНМедУ \(odmu.edu.ua\)](http://odmu.edu.ua) – сайт кафедри технології ліків ОНМедУ

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
4. [Одеський національний медичний університет \(onmedu.edu.ua\)](http://onmedu.edu.ua) – офіційний сайт ОНМедУ56. Державний реєстр лікарських засобів України. – [Електронний ресурс]. – Режим доступу: <http://www.drlz.com.ua/> – станом на 10.01.2017 р.

EVALUATION

The final control in the form of tests is evaluated on a two-point scale:

- the grade "**passed**" is given to a student who has completed the curriculum of the discipline, has no academic debt; level of competence - high (creative);
- the grade "**not passed**" is given to a student who has not fulfilled the curriculum of the discipline, has academic debt (average score below 3.0 and / or absences); the level of competence is low (receptive-productive).

Final credit. Students who have fully completed the curriculum in the discipline have no academic debt, their average score of current performance is 3.00 or more, in the last class receive a credit, which is set as "passed" / "not credited".

Conversion of a traditional national score to a multi-point score (maximum 200 points) is required. If a student receives a minimum grade point average of 3.00 for current performance, even if there are unsatisfactory grades, he receives a credit for the discipline.

Independent work of students: on the topics of independent work - writing essays and preparing presentations. Assessment of independent work is performed on the traditional 4-point scale, the deadline - during the course of the discipline.

COURSE POLICY

Deadline and retake policy.

The final control is carried out in the audience in the penultimate week. In case of absence or low result, the final written control is rescheduled once in the last week on the day of the scheduled consultation (Thursday from 15.00 to 16.00). In case of non-compliance with the policy on deadlines and rescheduling, control measures are considered not passed.

Academic Integrity Policy: The course involves the writing of abstracts (Independent work) that will be tested for academic integrity (according to the Regulations on the Commission on Academic Integrity of Odessa National Medical University).

Attendance and lateness policy: Attendance at lectures and practical classes is mandatory, lateness is not desirable. Points for attending classes are not accrued. An important reason for absence from classes is an illness, which is confirmed by a certificate from a doctor.

Mobile devices: with the permission of the teacher it is allowed to use a smartphone, tablet or other device for storing and processing information.

Behavior in the audience or remotely on the Microsoft Teams platform: active, business and creative atmosphere.