Syllabus of the discipline "**Biopharmaceutics**"

1. General information	
Faculty	Pharmacy
Educational program	22 Healthcare, 226 Pharmacy, industrial pharmacy the second (master's) degree of higher education, the full-time form of education
Educational discipline, code	Biopharmaceutics, MC 30.2 http://new.meduniv.lviv.ua/
Department	Department of Drug Technology and Biopharmaceutics; 79010, Lviv, Pekarska str.,75 (032) 276-85-84, (032) 276-85-98, kaf_biopharm@ meduniv.lviv.ua
Head of the depratment	Bilous Svitlana B, DSci, prof. svitlana.bilous@gmail.com
Academic year	5th
Semester	9
Type of discipline	obligatory
Educators	Vashchenko K.F., PhD, assoc.prof., vkf.07@ukr.net Vashchenko O.O., PhD, assoc.prof., o_vashchenko@ukr.net Shostak T.A., PhD, assist.prof., t_shostak8@ukr.net
Erasmus	No
Person responsible for syllabus	Vashchenko O.O., PhD, assoc.prof., o_vashchenko@ukr.net
Number of credits ECTS	3
Number of hours	Total – 90 h: lections – 8 h; laboratory classes – 30 h; independent study – 52 h
Language of instruction	English
Information on consultations	Consultations are provided in accordance with schedule of consultations by the responsible educators
Address, telephone and work schedule of the clinical base, office	

2. A brief review of the discipline
Discipline "Biopharmaceutics" is intended for applicants of higher education, provides theoretical knowledge and practical skills on the basic stages of the development of new medicinal products, general requirements for the production of medicines of different pharmaceutical types in the pharmaceutical enterprises, current development trends of the pharmaceutical branch in Ukraine and abroad. Object of the academic discipline is learning of pharmaceutical factors, the pharmaceutical and biological availability of medicinal products, the dependence of the therapeutic effect of medicinal products on various variable factors (exogenous and endogenous), the influence of physical and physical-chemical properties of active ingredients and excipients in medicinal products, which are produced in different dosage forms but in the same doses, on the therapeutic effect of medicines.

3. Purpose and objectives of the discipline

Purpose of the academic discipline "Biopharmaceuitcs" is learning by higher education applicants of the main statements of development of effective medicinal products and improving present ones to increase their therapeutic activity and reduce their adverse effects, mastering the knowledge of the determination of bioavailability of drug products by various methods, studying the effects of pharmaceutical factors on the therapeutic effictiveness of medicinal products, which makes it possible to more fully realize the scientific and creative potential of future professionals.

Primary objectives of the educational discipline "Biopharmaceuitcs" are:

- acquaintance with the stages of the development of new medicinal products and the principal statements of biopharmaceutics;
- study of constant and variable pharmaceutical factors affecting drug bioavailability;
- determination of the influence of variable pharmaceutical factors on the extent of drug release from various dosage forms, the absorption rate of active substances into the blood, distribution and excretion from the body;
- acquaintance with methods of determination of bioavailability and biological equivalence of medicines;
- study of pharmaceutical, biological l and therapeutic non-equivalence of medicinal products.

According to the Standard of Higher Education, the discipline provides gaining the following competencies – general and professional (pharmaceutical competencies in the field of health care, competencies in the providing pharmaceutical care to the population, professional and personal competencies, competencies in the quality assurance and management).

General:

CG01. The ability for abstract thinking, analysis and synthesis.
CG02. Knowledge and understanding of the subject area; understanding of professional activity.
CG03. The ability to communicate in the national language both orally and in writing.
CG04. The ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity.
CG05. The ability to evaluate and ensure the quality of the work performed.
CG06. The ability to work in a team.
CG09. The ability to use information and communication technologies.

Professional:

PC1. The ability to integrate knowledge and solve complex pharmacy/industrial pharmacy problems in broad or multidisciplinary contexts.
PC2. The ability to collect, interpret and apply data necessary for professional activity, research and implementation of innovative projects in the field of pharmacy.
PC3. Ability to solve pharmacy problems in new or unfamiliar environments in the presence of incomplete or limited information, taking into account aspects of social and ethical responsibility.
PC8. The ability to provide rational use and counseling regarding prescription and non-prescription medicines and other products of the pharmacy assortment, to provide pharmaceutical care during the selection and dispense of medicines by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physical-chemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.
PC16. The ability to organize and carry out the production activities of pharmacies for the formulaion of medicinal products in various dosage forms according to the prescriptions of doctors and the requirements (orders) of medical-preventive institutions, including the justification of technology and the selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice.
PC17. The ability to carry out pharmaceutical development, to determine the stability of medicinal products and to participate in the production of medicinal products in the conditions of pharmaceutical enterprises in accordance with the requirements of Good Manufacturing Practice with the appropriate development and preparation of the necessary documentation.
PC19. The ability to organize and carry out quality control of medicinal products in accordance with

the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods, technological instructions, etc.; to carry out standardization of medicinal products in accordance with current requirements; to prevent the distribution of low-quality, falsified and unregistered medicinal products.
PC20. The ability to develop and evaluate methods of quality control of medicinal products, including active pharmaceutical ingredients, medicinal plant raw materials and excipients using physical, chemical, physical-chemical, biological, microbiological and pharmaco-technological control methods.

4. Prerequisites of the discipline

The academic discipline “Biopharmaceuitcs”:

- is based on studying biophysics, physical and physical-chemical methods of analysis; higher mathematics; inorganic, analytical, biological, physical and colloidal chemistry; normal physiology; human anatomy; pathological physiology and pathological anatomy;
- the discipline summarizes the knowledge gained by students while studying the disciplines "Technology of medicinal products" (technology of medicinal products in pharmacy and industrial technology of medicinal products), pharmacology, pharmacotherapy, clinical pharmacy, etc.;
- the discipline is a foundation for professional training of future specialst and promotes the formation of pharmaceutical and technical thinking

5. Program learning outcomes

List of learning outcomes

Code of learning outcome	**Content of learning outcome**	**Reference to the code of the competency matrix**
K-1	To have specialized conceptual knowledge that includes modern scientific achievements in the field of professional activity and is the basis for original thinking and conducting research, critical understanding of problems in the field and on the border of the fields of knowledge	*PLO01- PLO09, PLO11, PLO13, PLO15, PLO19- PLO 23*
S-1	To be able to solve problems necessary for conducting research and/or carrying out innovative activities in order to develop new knowledge and procedures	*PLO01- PLO09, PLO11, PLO13, PLO15, PLO19- PLO23*
S-2	To be able to integrate knowledge and solve complex problems in broad multidisciplinary contexts	*PLO01- PLO08, PLO11, PLO 15, PLO19- PLO23*
S-3	To be able to solve problems in new or unfamiliar environments in the presence of incomplete or limited information, taking into account aspects of social or ethical responsibility	*PLO01- PLO09, PLO22- PLO23,*
C-1	To communicate own knowledge, conclusions and arguments clearly and unambiguously to specialists and non-specialists, in particular to people who are studying	*PLO01- PLO09, PLO11, PLO19, PLO22- PLO23*
AR-1	To manage work or learning processes that are complex, unpredictable and require new strategic approaches	*PLO01- PLO09, PLO11, PLO15, PLO19- PLO20, PLO22- PLO23*
AR -2	To be responsible for contributing to professional knowledge and practice and/or evaluating the performance of teams and teams	*PLO01- PLO09, PLO11, PLO19- PLO20, PLO19-*

AR -3	To have the ability to continue learning with a high degree of autonomy	*PLO20, PLO22- PLO23* *PLO01- PLO03, PLO06- PLO09, PLO11, PLO19- PLO20, PLO22- PLO23*

6. Mode and scope of the discipline

Form of the discipline	Full-time study	
Type of activity	Number of hours	Number of groups
lections	8	
practical	30	
seminars	-	
independent	52	

7. Topics and content of the discipline

Code of activity type	Topic	Learning content	Code of learning outcome
L-1 2 h	Biopharmaceutics as a scientific and academic discipline. Subject and objectives of biopharmaceutics. Biopharmaceutical factors and their role in the development of new drug products	Biopharmaceutics as a theoretical basis of technology of medicinal products. Basic concepts and terms. The subject and objectives of biopharmaceutics. Main directions of biopharmaceutical investigations. Pharmaceutical factors and their content	*K1, S1-S3; C1, AR1-AR3*
L-2 2 h	Bioavailability and pharmaceutical availability. Investigation of pharmaceutical availability as a criterion of quality evaluation of drug products	Biological availability of medicines. Importance for evaluating the quality of medicinal products. Conditions and methods of determining bioavailability. Relationship between absorption processes of medicinal substances and the rate of their release from dosage forms. Pharmaceutical availability of medicines. Importance for evaluating the quality of medicinal products, methods for determining	*K1, S1-S3; C1, AR1-AR3*
L-3 2 h	Procedures of the pharmaceutical availability study of solid and semi-solid medicinal products	Classification of solid dosage forms. Pharmaceutical factors that are taken into account when determining the pharmaceutical availability of solid preparations for oral administration. Classification of dosage forms for cutaneous application. Methods of determining the pharmaceutical availability of medicinal substances from medicinal products for cutaneous application	*K1, S1-S3; C1, AR1-AR3*

L-4 2 h	Bioequivalence of drug products. Methods of its determination	Characteristics of generic preparations. Bioequivalence of medicinal products. Methods of determination, requirements and conditions of bioequivalence study. Characteristics of investigation objects	*K1, S1-S3; C1, AR1-AR3*
P-1 3 h	Drug product and dosage form. Biopharmaceutical classification system of drugs. Criteria for quality evaluation of drug products	Characteristics of medicinal products and dosage forms. Biopharmaceutical classification of medicines. Criteria for evaluating the quality of medicinal products. Characteristics of dosage forms with modified and unmodified drug release	*K1, S1-S3; C1, AR1-AR3*
P-2 3 h	Pharmaceutical availability, methods of its investigation. Equipment and materials for investigation of pharmaceutical availability. Evaluation criteria, interpretation of results, validation	"Pharmaceutical availability" and "biological availability" of medicines. Mechanisms of drug release depending on the type of dosage form. Equipment for determining the pharmaceutical availability of solid dosed preparations. Conditions for conducting the "Dissolution" test for solid dosed preparations. Interpretation of test results	*K1, S1-S3; C1, AR1-AR3*
P-3 3 h	Study of the influence of physical and chemical properties of active substances on the drug release rate from a dosage form	Pharmaceutical factors and their influence on the therapeutic effectiveness of medicinal substances. The influence of the physical state of active pharmaceutical ingredients and excipients on the rate of drug release and absorption. Polymorphism. The influence of the optical properties of active pharmaceutical ingredients, the nature of the solvent, the degree of viscosity and pH of the medium on the drug release and absorption	*K1, S1-S3; C1, AR1-AR3*
P-4-5 6 h	Investigation of the influence of excipients and production on the drug release rate from tablets produced by different manufacturers	Characteristics of tablets as a dosage form. Requirements of the State Pharmacopoiea of Ukraine for tablets. Dissolution of preparations. Methods of determining the dissolution of medicinal products. The effect of excipients and technological processes on the pharmaceutical availability of tablets	*K1, S1-S3; C1, AR1-AR3*
P-6 3 h	Investigation of the influence of excipients on the drug release rate from coated tablets	of coated tablets. Classification and characteristics of excipients used for coating tablets. Pharmaceutical factors affecting the pharmaceutical availability of coated tablets. Methods of determining the pharmaceutical availability of oated tablets	*K1, S1-S3; C1, AR1-AR3*
P-7 3 h	Investigation of the influence of excipients on the drug release rate from capsules	General characteristics of capsules as a dosage form. Classification of capsules. Methods of obtaining capsules and their influence on the therapeutic activity of active ingredietns. Methods for determining	*K1, S1-S3; C1, AR1-AR3*

		the drug release from capsules. Equipment used to determine the dissolution of capsules according to the State Pharmacopoiea of Ukraine	
P-8 3 h	Investigation of the influence of simple chemical modification of drug substances on the drug release rate from semi-solid preparations for cutaneous application	Simple chemical modification of active pharmaceutical ingredients and its effect on the rate of drug release and absorption. Methods of determining the pharmaceutical availability of semi-solid dosage forms	*K1, S1-S3;* *C1, AR1-AR3*
P-9 3 h	Investigation of the influence of excipients and type of dosage form on the drug release rate from semi-solid preparations for cutaneous application	Classification of excipients used in the production of semi-solid preparations and their characteristics. Methods of determining the drug release from semi-solid preparations. The influence of the nature of excipients and the type of dosage form on the rate of drug release from semi-solid preparations	*K1, S1-S3;* *C1, AR1-AR3*
P-10 3 h	Investigation of the pharmaceutical availability of suppositories. Study of the influence of the dosage form type on the drug release	Factors that affect the drug release from different dosage forms. The influence of the type of dosage form on the rate of drug release, their concentration in biological fluids	*K1, S1-S3;* *C1, AR1-AR3*
IW-1 6 h	Biopharmaceutics and physical-chemical aspects of suspensions. Release and bioavailability of active substances from this dosage form		*K1, S1-S3;* *C1, AR1-AR3*
IW-2 6 h	Biopharmaceutics and physical-chemical aspects of emulsions. Release and bioavailability of active substances from this dosage form		*K1, S1-S3;* *C1, AR1-AR3*
IW-3 6 h	Inhalation route of drug administration. Factors affecting the pharmaceutical and bioavailability of active substances from aerosols		*K1, S1-S3;* *C1, AR1-AR3*
IW -4 6 h	Biopharmaceutical aspects of oromucosal preparations		*K1, S1-S3;* *C1, AR1-AR3*
IW -5 6 h	Influence of physiological and pharmaceutical factors on pharmaceutical availability and absorption kinetics of rectal and vaginal preparations		*K1, S1-S3;* *C1, AR1-AR3*
IW -6 6 h	Biopharmaceutical aspects of eye preparations, ocular therapeutic systems such as “Ocusert”. Factors affecting quality and bioavailability of eye preparations		*K1, S1-S3;* *C1, AR1-AR3*
IW -7 6 h	Methods of bioavailability determination for prolonged release preparations		*K1, S1-S3;* *C1, AR1-AR3*
IW -8 6 h	Methods for the determination of bioequivalence of medicinal products		*K1, S1-S3;* *C1, AR1-AR3*
IW -9 4 h	Role of biopharmaceutics in the development of innovative medicinal products and improvement of existing ones		*K1, S1-S3;* *C1, AR1-AR3*
На лекціях використовується мультимедійна презентація; на практичних заняттях – роздаткові навчально-методичні матеріали, лабораторне обладнання, для перевірки засвоєних знань та			

умінь − тестові та розрахункові завдання, для самостійної роботи надано перелік необхідних літературних джерел.

8. Verification of learning outcomes			
Current control			
Code of learning outcome	Code of activity type	Method of the verification of learning outcomes	Evaluation criteria
K1, S1-S3; C1, AR1-AR3	*L-1 – L-4; P-1 – P-10; IW-1 – IW- 9*	Current control is carried out at each practical class in accordance with the specific objectives of the topic. In all practical classes, objective control of independent work, theoretical training and acquisition of practical skills is used. Current control includes: oral examination, test control, control of practical skills, reception of the protocols of practical work. Current control is performed on every laboratory class in accordance with specific objectives. The form of assessment of current educational activity is standardized and includes control of theoretical and practical preparing. Control of theoretical preparing is conducted by solving the tests, situational tasks, conducting the practical skills by assessing of quality and completeness of practical tasks and the ability to interpret the results. On each laboratory class student answers tests on the topic of laboratory class, and standardized questions, the knowing of which is required to understand the current theme; demonstrates knowledge, skills and practical abilities in accordance with topic of laboratory class. The mark for the laboratory class is determined by the sum of the results of the test control and the performance of practical tasks. Individual work is assessed by the current control of topic during the practical classes.	On each laboratory class student answers tests on the topic of laboratory class, and standardized questions, the knowing of which is required to understand the current theme; demonstrates knowledge, skills and practical abilities in accordance with topic of laboratory class. The mark for the laboratory class is determined by the sum of the results of the test control and the performance of practical tasks. *Evaluation criteria for current control.* Student's learning level is assessed during every class using a 4-point (national) scale. All types of activities provided by the discipline program are taken into consideration. A student receives a mark for each topic. Then this 4-point grade is converted into points using a multi-point (200-point) scale. *Excellent* ("5") – student answered correctly 100-90% tests of type A. Student gives correct, logical and full answers on the standardized questions on the topic, including the material from lectures and independent work. *Good* ("4") – student answered correctly 70-89% tests of type A. Student gives correct and logical answers on the standardized questions on the topic. Student can solve situational tasks with simple and moderate degree of complexity. *Satisfactory* ("3") – student answered correctly 50-69% tests of type A. Student gives incomplete answers on questions

			on the topic, required additional questions to complete the answer. Student cannot give a clear and logical answer, makes mistakes. Student has only the required minimum of theoretical knowledge. *Fail* ("2") – student answered less than 50% tests of type A. Student does not know material on the topic, cannot give logical answer, does not understand the topic.

Final control

General system of evaluation	Form of final control is a credit. The knowledge of a student is assessed by the marks using a 4-point (traditional) scale and considering the approved criteria. Student must receive a mark for each topic. The results of the current control are considered to be an indicator of the student's learning level of the discipline program and conducting tasks for independent work.	
Evaluation scales	Traditional 4-graded scale, multi-point (200-point) scale, rating ECTS scale	
Conditions to be allowed to write the final control	Students who have completed the all types of activities provided by the program and scored for current educational activity not less than minimum	
Type of final control	Procedure of final control	Evaluation criteria
Credit	Student is required to pass all topics of the current control. Grades from the 4-point scale are converted into points on a multi-point (200-point) scale in accordance with the Regulation "Criteria, rules and procedures for evaluating the results of students' learning activities."	Maximum score that student can get is 200 points, minimum score – 120. Points for discipline are then converted in traditional 4-graded scale using absolute criteria.

9. Policy of the discipline

To organize the educational process, students, educators and administration act in accordance with:

- Regulations on the organization of the educational process (https://cutt.ly/3ySk64r);
- Regulations on the criteria and rules for evaluation (https://cutt.ly/lySlyw0);
- Regulations on academic integrity (https://cutt.ly/EySkNHu)

10. Literature

Main

1. Біофармація: навчальний посібник / упоряд .: Борисюк І.Ю., Фізор Н.С., Акішева А.С. - Одеса, ОНМедУ, 2020. - 98 с.
2. Державна Фармакопея України. – Х.: РІРЕГ, 2001. – 556 с.; Доповнення 1, 2004. – 520 с.; Доповнення 2, 2008. – 617 с.; Доповнення 3, 2009. – 280 с.; Доповнення 4, 2011. – 540 с.
3. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т.1. – 1128 с.

4. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т.2. – 724 с.
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6. Про лікарські засоби: закон України від 4.04.96 № 123/96 // Відомості Верховної Ради України. – 1996. – № 123.
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8. Настанова СТ-Н МОЗУ 42-7.2:2018 Лікарські засоби дослідження біоеквівалентності. – Київ, 2018. – 77 с.
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12. Технологія лікарських препаратів промислового виробництва: навч. посіб./ за ред. проф. Д.І. Дмитрієвського. – Вінниця: Нова книга, 2008. – 280 с.
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Additional

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Information sources

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2. Журнал «Фармацевт практик»: fp.com.ua.
3. Журнал «Провізор»: www.provisor.com.ua.
4. Компендіум. − [Електронний ресурс]. – Режим доступу: http://compendium.com.ua/.
5. Державний реєстр лікарських засобів України. − [Електронний ресурс]. – Режим доступу: http://www.drlz.com.ua/.

11. Equipment, material, technical, and software support of the discipline

Educational and methodical materials, laboratory equipment and apparatus

12. Additional information

Responsible person for the educational process at the Department – Yakymiv O.V., PhD, assoc.prof., e-mail: olga_yakymiv@ukr.net

There is a student scientific club in the department, the goal of which is the development of composition, technology and investigation of medicinal and cosmetic products. Responsible person for the student scientific club– Vashchenko O.O., PhD, assoc.prof., o_vashchenko@ukr.net

During Students must wear medical gowns and caps during lectures and practical classes.

Practical classes are held in the premises of the department at the address:

Lviv, Pekarska str., 75, educational and production pharmacy

Compilers of the syllabus:

Bilous S.B., DSci, prof. _____

Vashchenko K.F., PhD, assoc.prof. _____

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Head of the Department:

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