DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY

Department of Drug Technology and Biopharmaceutics

APPROVED
The first vice-rector on
scientific and pedagogical work,
assoc. prof. I.I. Solonynko
«__» _____ 2023

EDUCATIONAL PROGRAM
on discipline
«BIOPHARMACEUTICS»

for training specialists of the second (master's) degree of higher education
of the specialty 226 Pharmacy, industrial pharmacy
of the specialization 226.01 Pharmacy
of the branch of study 22 Health care
for the 5th year students of Faculty of Pharmacy
of the full-time and part-time forms of education
MC 30.2

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Department of Drug Technology and
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Head of the department
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INTRODUCTION

Educational program of the discipline
«Biopharmaceutics»
according to Standard of higher education of *second (master's) level*
branch of knowledge *22 "Healthcare"*
specialty *226 "Pharmacy"*
educational program of *master of pharmacy*

Description of the selective discipline (annotation)

The discipline "Biopharmaceutics" belongs to the cycle of the disciplines of professionally-oriented training of specialists in the specialty "Pharmacy, industrial pharmacy" and includes one content module.

The program of the discipline "Biopharmaceutics" is organized in accordance with Standard of Higher Education in Ukraine for specialty "Pharmacy, industrial pharmacy".

Program of the 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.

The general trends in the theory and practice of the biopharmaceutical aspects of the pharmaceutical technology are described in the program, as well as the necessity to conduct biopharmaceutical tests for medicines.

Structure of the academic discipline

Structure of educational discipline	Number of credits, hours, including				Year of study / semester	Types of control
	Total	Class hours		Independent study		
		Lectures	Laboratory classes			
Biopharmaceutics	3 credits ECTS / 90 hours	8	30	52	5 year course, semester IX	**credit**

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.

Interdisciplinary links:

- the discipline 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 and promotes the formation of pharmaceutical and technical thinking necessary for the professional activities;
- together with other pharmaceutical disciplines and social sciences, the discipline plays an important role in providing special training for professional activities.

1. The purpose and objectives of the discipline

1.1. 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.

1.2. 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 pharmaceutica, biological l and therapeutic non-equivalence of medicinal products.

1.3 Competencies and learning outcomes, which are contributed by learning the discipline (correlation with normative content of the training of higher education applicants formulated in terms of learning outcomes in Standard of Higher Education).

According to the Standard of Higher Education, the discipline provides gaining the following ***competencies*** – ***general and professional***.

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.

Matrix of competencies

No.	Competency	Knowledge	Skill	Communication	Autonomy and responsibility
	General competencies				
1	CG01		S2		
2	CG02	K1	S1		
3	CG03			C1	
4	CG04			C1	
5	CG05	K1	S1, S2, S3	C1	AR1, AR2, AR3
6	CG06		S3	C1	AR1, AR2
8	CG09		S1		AR1
Professional competencies					
1	PC01	K1	S1, S2		AR1, AR2
2	PC02	K1	S1		AR3
3	PC08	K1	S1, S2, S3	C1	AR1, AR2
4	PC16	K1	S1, S2		AR1, AR2
5	PC17	K1	S1, S2		AR1, AR2, AR3
6	PC19	K1	S1, S2, S3	C1	AR1, AR2
7	PC20	K1	S1, S2, S3		AR1, AR2, AR3

Program learning outcomes (PLO), the formation of which is facilitated

by the academic discipline:

PLO1. To possess specialized conceptual knowledge in the field of pharmacy and related fields, taking into account modern scientific achievements, and to be able to apply them in professional activities.

PLO2. To understand and to analyze critically scientific and applied problems in the field of pharmacy.

PLO3. To possess specialized knowledge and abilities/skills for solving professional problems and tasks, including for the purpose of improving knowledge and procedures in the field of pharmacy.

PLO4. To communicate freely in the national and English languages orally and in writing to discuss professional problems and results of activities, for presentation of scientific research and innovative projects.

PLO5. To assess and to ensure the quality and efficiency of activities in the field of pharmacy in standard and non-standard situations; to adhere to the principles of deontology and ethics in professional activity.

PLO6. To develop and to make effective decisions to solve complicated/complex problems of pharmacy personally and based on the results of joint discussion; to formulate the goals of one's own activity and the activity of the team, taking into account public and industrial interests, the general strategy and existing limitations, to determine the optimal ways to achieve goals.

PLO7. To analyze the necessary information on the development and production of medicinal products, using professional literature, patents, databases and other sources; to systematize, analyze and evaluate it, in particular, using statistical analysis.

PLO8. To develop and to implement innovative projects in the field of pharmacy, as well as related interdisciplinary projects taking into account technical, social, economic, ethical, legal and environmental aspects.

PLO9. To formulate, to argument, to convey clearly and concretely to specialists and non-specialists, including studetns, information based on own knowledge and professional experience, the main trends in the development of world pharmacy and related industries

PLO11. To determine the advantages and disadvantages of medicinal products of natural and synthetic origin of various pharmacological groups, taking into account their chemical, physical-chemical, biopharmaceutical, pharmacokinetic and pharmacodynamic features and the type of dosage form. To recommend medicinal products and other products of the pharmacy assortment with the provision of advisory assistance and pharmaceutical care.

PLO13. To record cases of side effects of medicinal products of natural and synthetic origin; to evaluate factors that can affect the processes of absorption, distribution, deposition, metabolism and excretion of medicines and are determined by the condition and characteristics of the human body and the pharmaceutical characteristics of medicines.

PLO15. To predict and to determine the influence of environmental factors on the quality and consumer characteristics of medicines and other products of the pharmacy assortment, organize their storage in accordance with their physical and chemical properties and the rules of Good Storage Practices.

PLO19. To develop technological documentation for the manufacture of medicinal products, to choose a rational technology, to produce medicinal products in various dosage forms according to the prescriptions of doctors and the requirements (orders) of treatment-prevention institutions, to prepare them for release.

PLO20. To carry out pharmaceutical development of medicinal products of natural and synthetic origin in the industrial conditions.

PLO22. To ensure and to implement quality control of medicinal products and to document its results; to document quality certificates and analysis certificates taking into account the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods, technological instructions, etc.; to take measures to prevent the distribution of low-quality, falsified and unregistered medicinal products.

PLO23. To determine the main chemical and pharmaceutical characteristics of medicinal products; to choose and/or develop quality control methods with the aim of their standardization using physical,

chemical, physical-chemical, biological, microbiological and pharmacotechnological methods in accordance with current requirements
PLO26. To plan and to implement professional activities on the basis of normative legal acts of Ukraine and recommendations of good pharmaceutical practices.
PLO27. To contribute to the preservation of health, in particular the prevention of diseases, the rational prescription and use of medicinal products

2. Information volume of the academic discipline

3 credits ECTS / 90 hours are given for learning the academic discipline.

Content module 1. Biopharmaceutics – theoretical basis of the technology of medicinal products

3. The structure of the discipline

Topic	Lections	Seminars	Inde-pendent study	Individual work
Content module 1. Biopharmaceutics – theoretical basis of the technology of medicinal products				
Topic 1. Biopharmaceutics as a scientific and academic discipline. Subject and objectives of biopharmaceutics. Biopharmaceutical factors and their role in the development of new drug products	2	3	6	-
Topic 2. Bioavailability and pharmaceutical availability. Investigation of bioavailability as a criterion of quality evaluation of drug products	2	6	6	
Topic 3. Biopharmaceutical factors and their influence on the pharmaceutical and biological availability of drug products	-	6	12	-
Topic 4. Methods of investigation of the pharmaceutical availability of drug products for oral administration	1	9	12	
Topic 5. Methods of investigation of the pharmaceutical availability of drug products for cutaneous application, suppositories and for parenteral administration	1	6	10	-
Topic 6. Bioequivalence of drug products. Methods of its determination	2	-	6	
Totally for discipline – 90 / 3 credits ECTS	**8**	**30**	**52**	
Final control				**Credit**

4. Thematic plan of lectures

No.	Topic	Hours
Content module 1. Biopharmaceutics – theoretical basis of the technology of medicinal products		
1	Biopharmaceutics as a scientific and academic discipline. Subject and objectives of biopharmaceutics. Biopharmaceutical factors and their role in the development of the composition and technology of drug products	2

2	Bioavailability and pharmaceutical availability. Investigation of pharmaceutical availability as a criterion of quality evaluation of drug products	2
3	Procedures of the pharmaceutical availability study of solid and semi-solid medicinal products	2
4	Bioequivalence of drug products. Methods of its determination	2
	Totally	**8**

5. Thematic plan of laboratory classes

No.	Topic	Hours
Content module 1. Biopharmaceutics – theoretical basis of the technology of medicinal products		
1	Drug product and dosage form. Biopharmaceutical classification system of drugs. Criteria for quality evaluation of drug products	3
2	Pharmaceutical availability, methods of its investigation. Equipment and materials for investigation of pharmaceutical availability. Evaluation criteria, interpretation of results, validation	3
3	Study of the influence of physical and chemical properties of active substances on the drug release rate from a dosage form	3
4-5	Investigation of the influence of excipients and production on the drug release rate from tablets produced by different manufacturers	6
6	Investigation of the influence of excipients on the drug release rate from coated tablets	3
7	Investigation of the influence of excipients on the drug release rate from capsules	3
8	Investigation of the influence of simple chemical modification of drug substances on the drug release rate from semi-solid preparations for cutaneous application	3
9	Investigation of the influence of excipients and type of dosage form on the drug release rate from semi-solid preparations for cutaneous application	3
10	Investigation of the pharmaceutical availability of suppositories. Study of the influence of the dosage form type on the drug release	3
	Totally:	**30**

6. Thematic plan of individual work

No.	Topic	Hours	Type of control
Content module 1. Biopharmaceutics – theoretical basis of the technology of medicinal products			
1	Biopharmaceutics and physical-chemical aspects of suspensions. Release and bioavailability of active substances from this dosage form	6	Current control during laboratory classes
2	Biopharmaceutics and physical-chemical aspects of emulsions. Release and bioavailability of active substances from this dosage form	6	
3	Inhalation route of drug administration. Factors affecting the pharmaceutical and bioavailability of active substances from aerosols	6	
4	Biopharmaceutical aspects of oromucosal preparations	6	
5	Influence of physiological and pharmaceutical factors on pharmaceutical availability and absorption kinetics of rectal and vaginal preparations	6	Current control during laboratory classes
6	Biopharmaceutical aspects of eye preparations, ocular therapeutic systems such as “Ocusert”. Factors affecting quality and bioavailability of eye preparations	6	

7	Methods of bioavailability determination for prolonged release preparations	6	
8	Methods for the determination of bioequivalence of medicinal products	6	
9	Role of biopharmaceutics in the development of innovative medicinal products and improvement of existing ones	4	
	Totally	**52**	

7. Inidividual tasks

Individual tasks are not determined by the educational plan.

8. Teaching methods:

explanatory-illustrated (multimedia lectures with elements of discussion communication with applicants of higher education), reproductive, research, part-search (independent work of search character, work with literature).

The following teaching methods are used:

- *verbal* – story, explanation, conversation, instruction, lecture, discussion;
- *visual* – demonstration of films, visual equipment (means of small mechanization), illustrations, materials, display of operations and processes of manufacture of medicines in the conditions of pharmacies and industrial enterprises;
- practical methods – laboratory-practical activities;
- objective methods – generalization of the results of observations and experiments.

Active and interactive methods of teaching are preferable (multimedia lections, educational films).

Types of educational activities of students are:

a) lectures;
b) laboratory classes;
c) independent work of students.

The lectures includes the teaching of the most important topics based on the achievements of domestic and foreign science in the field of biopharmaceutical studies.

Laboratory classes on biopharmaceutics are organized based on the theoretical statements of technology of medicinal products,current requirements for dosage forms, knowledge of the properties of active ingredients and excipients. During the laboratory classes students acquire the skills and abilities to conduct different laboratory studies. Classes include elements of educational and research work.

Laboratory classes are based on independent work of students. In order to deepen theoretical knowledge, an oral examination of individual issues is planned, which is recommended to be conducted in the form of a discussion.

In the process of conducting the laboratory tasks, students must follow the safety rules, which are instructed on the first laboratory class and monitored by teachers on each class.

Laboratory classes include:

- discussion of theoretical issues;
- watching of educational videos;
- performing of laboratory tests;
- analysis and interpretation of the obtained results.

Basic stages of the class:

Preparatory stage – motivation of the topic, control of the initial level of knowledge, giving the tasks for independent work.

Control of the initial level of knowledge includes oral discussion of the main issues on the topic and writing the control work.

Main stage – students are given the tasks fot independent work, work in groups (4-5 stufents), write the protocols.

Final stage – control of the level of knowledge by solving the tasks, oral reports about the performed work. General evaluation of each student's work, comments during the class, homework assignments.

During laboratory classes, students write the protocols, in which the results of experimental studies are recorded.

9. Methods of control

Control measures include current and final semester control.

10. Current control is carried out during laboratory classes and is aimed to check an understanding of the educational material by students.

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 laboratory classes. Knowledge of the topics for independent study is controlled at final control.

Student who missed classes is allowed to work out an academic debt by the time determined by the schedule.

11. Final control is carried out to assess the learning results at a certain education qualification level and at the completed stages in accordance with the national scale and the ECTS scale. The form of final control on the discipline “Biopharmaceutics” is credit.

The ***credit*** is a form of final control, which consists of evaluating the student's knowledge of the discipline for the semester based on the results of the current control.

12. The scheme of calculation and distribution of points that students gain

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.

A maximum score *that student can achieve for current learning activities is 200.*

A minimum score – *not less than 72****.***

Scaled score is calculated by finding the arithmetic mean of the traditional marks (AM) for each topic that is rounded to second decimal. The AM is converted into the grade points using formula and a 200-point grading scale given in a table:

$$X = \frac{AMx200}{5}$$

Convertion of the average mark for the current activity into a multi-point scale for the discipline that ends with credit is given in the table.

Table

Convertion of the average mark for the current activity into a multi-point scale for the discipline that ends with credit

4-point scale	200-point scale		4-point scale	200-point scale		4-point scale	200-point scale		4-point scale	200-point scale
5	200		4.45	178		3.92	157		3.37	135
4.97	199		4.42	177		3.89	156		3.35	134
4.95	198		4.4	176		3.87	155		3.32	133
4.92	197		4.37	175		3.84	154		3.3	132
4.9	196		4.35	174		3.82	153		3.27	131
4.87	195		4.32	173		3.79	152		3.25	130
4.85	194		4.3	172		3.77	151		3.22	129
4.82	193		4.27	171		3.74	150		3.2	128
4.8	192		4.24	170		3.72	149		3.17	127
4.77	191		4.22	169		3.7	148		3.15	126
4.75	190		4.19	168		3.67	147		3.12	125
4.72	189		4.17	167		3.65	146		3.1	124
4.7	188		4.14	166		3.62	145		3.07	123
4.67	187		4.12	165		3.57	143		3.02	121
4.65	186		4.09	164		3.55	142		3	120
4.62	185		4.07	163		3.52	141		less than 3	not enough
4.6	184		4.04	162		3.5	140			
4.57	183		4.02	161		3.47	139			
4.52	181		3.99	160		3.45	138			
4.5	180		3.97	159		3.42	137			
4.47	179		3.94	158		3.4	136			

Grade points are converted to the corresponding ECTS grade and the mark of 4-point scale. ECTS grade points are not converted into grades of 4-point scale and conversely.

The scores of the students who study on the same specialty with consideration of the discipline scores are ranked into ECTS grades as follows:

ECTS grade	**Statistical indicator**
A	The best 10 % of students
B	The next 25 % of students
C	The next 30 % of students
D	The following 25 % of students
E	The weakest 10 % of students

Points for discipline for students who successfully completed the program are converted into traditional 4-pointed scale by absolute criteria listed in the table below:

Points for discipline	Mark according to the 4-point scale
from 170 till 200 points	5
from 140 till 169 points	4
From 139 points to minimal number of points that student must score	3
Below the minimum number of points that the student must score	2

The ECTS grade is not converted to the traditional scale, as the ECTS scale and the 4-point scale are independent.

The objectivity of the evaluation of students' educational activity is checked by statistical methods (correlation coefficient between the ECTS grade and the grade by the national scale).

13. Methodological support:

- Lecture material (multimedia presentations, lecture texts, schedules of lectures).
- Schedules of laboratory classes.
- Questions for independent work.
- Methodical guides for laboratory classes.
- Videofilms
- Resources from Internet.

14. RECOMMENDED LITERATURE

Main (basic)

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