MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS
Educational Institution
«BELARUSIAN STATE MEDICAL UNIVERSITY»

Контрольный экземпляр

APPROVED
by Rector of the Educational Institution «Belarusian State Medical University»
_____ S.P.Rubnikovich
25.06.2026
Reg. # UD-0912-01-29/2627/edu.

PHARMACEUTICAL DEVELOPMENT WITH THE FUNDAMENTALS OF BIOPHARMACEUTICS

Curriculum of the educational institution in the academic discipline for the specialty

1-79 01 08 «Pharmacy»

2026

Curriculum is based on the educational program «Pharmaceutical Development with Fundamentals of Biopharmaceutics», approved 26.06.2025, registration # УД-0912-01-29/2526/уч.; on the educational plan in the specialty 1-79 01 08 «Pharmacy», approved 15.05.2024, registration # 7-07-0912-01/2627/mf

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RECOMMENDED FOR APPROVAL:

by the Department of Pharmaceutical Technology with advanced training and retraining course of the Educational Institution «Belarusian State Medical University» (protocol # 14 of 16.05.2025);

by the Scientific and Methodological Council of the Educational Institution «Belarusian State Medical University»
(protocol # 10 of 25.06.2026).

EXPLANATORY NOTE

«Pharmaceutical Development with the Fundamentals of Biopharmaceutics» is an academic discipline containing systematized scientific knowledge on the stages of medicinal product development, including the evidence-based selection of their composition and dosage form; quality indicators and process characteristics (critical parameters); technology transfer from research departments to manufacturing; standardization of medicinal products ensuring their maximum bioavailability.

The aim of the academic discipline «Pharmaceutical Development with the Fundamentals of Biopharmaceutics» is to develop specialized competencies in students for participation in the pharmaceutical development of medicinal products, process validation to ensure their safety, efficacy and quality.

The objectives of the academic discipline «Pharmaceutical Development with the Fundamentals of Biopharmaceutics» are to develop in student's scientific knowledge regarding:

exploratory research conducted during pharmaceutical development of a medicinal product;

stages of developing the composition and manufacturing technology of medicinal products under industrial conditions;

structure of the registration dossier;

biopharmaceutical aspects of medicinal product development;

specifics of composition, technology and quality control of modified-release medicinal products;

technology transfer from research departments to manufacturing;

influence of critical parameters on the efficiency of the technological process and the quality of the final product.

Relations to other academic disciplines

The knowledge, skills and abilities acquired during the study of the academic discipline «Pharmaceutical Development with the Fundamentals of Biopharmaceutics» are necessary for the successful study of the academic discipline «Modern Methods of Analysis and Standardization of Medicinal Products».

A student who has mastered the content of the academic discipline should possess the following specialized competency: to participate in the development of medicinal products and dietary supplements.

As a result of studying the academic discipline «Pharmaceutical Development with the Fundamentals of Biopharmaceutics» the student should:

know:

basic terms and concepts of biopharmaceutics and pharmaceutical development;

quality indicators and process characteristics affecting the reproducibility of control points from batch to batch of medicinal products;

the concept of pharmaceutical, biological and therapeutic equivalence of medicinal products;

regulatory legal acts and information materials in the field of pharmaceutical development of medicinal products;

be able to:

scientifically substantiate the composition of a medicinal product in a specific dosage form;

take into account the influence of pharmaceutical factors in the development of medicinal products;

use regulatory legal acts and technical regulatory legal acts governing the production and quality assurance of medicinal products;

master:

methods for determining the bioavailability of medicinal products;

methods for biopharmaceutical quality assessment of medicinal products;

practical skills in working with regulatory legal acts and technical regulatory legal acts governing the production and quality assurance of medicinal products.

Total number of hours for the study of the discipline is 90 academic hours, of which 48 classroom hours and 42 hours of student independent work. Classroom hours according to the types of studies: lectures – 12 hours (including 3 hours of supervised student independent work (SSIW)), laboratory classes – 36 hours.

The intermediate assessment is carried out according to the syllabus of the specialty in the form of a credit (9 semester).

Form of higher education – full-time.

ALLOCATION OF ACADEMIC TIME ACCORDING TO SEMESTERS OF STUDY

Code, name of the specialty	Semester	Total number of academic hours	Number of classroom hours				Out-of-class self-studies	Form of intermediate assessment
			Number of classroom hours	including				
				class lectures	SSIW	laboratory classes		
1-79 01 08 «Pharmacy»	9	90	48	9	3	36	42	credit

THEMATIC PLAN

Section (topic) name	Number of class hours	
	lectures (incl. SSIW)	laboratory
1. Biopharmacy as a science. Influence of biopharmaceutical factors on the therapeutic activity of dosage forms. Biopharmaceutical aspects of medicinal product development	1,5	4
2. Methods for determining in vitro bioavailability of tablets and capsules	1,5	4
3. Comparative dissolution kinetics test for solid dosage forms	1,5	4
4. Pharmaceutical development in tablet manufacturing. Process validation. Technology transfer	1,5	4
5. Bioequivalence studies of immediate-release tablets	1,5	4
6. Pharmaceutical development in the manufacturing of soft dosage forms. Process validation	1,5	4
7. Pharmaceutical development in the manufacturing of sterile dosage forms. Process validation	-	4
8. Pharmaceutical development in the manufacturing of modified-release dosage forms. Bioequivalence studies	1,5	4
9. Pharmaceutical development in the manufacturing of biosimilars. Bioequivalence studies	1,5	4
Total hours	**12**	**36**

CONTENT OF THE ACADEMIC DISCIPLINE

1. Biopharmacy as a science. Influence of biopharmaceutical factors on the therapeutic activity of dosage forms. Biopharmaceutical aspects of medicinal product development

Biopharmaceutics as the theoretical foundation for the development of high-quality, safe and effective dosage forms. History of the emergence and prospects for the development of biopharmaceutics. Characteristics of pharmaceutical factors. Physical state of medicinal products: degree of dispersity, polymorphism, stereoisomerism. Simple chemical modification of medicinal products, solubility of medicinal products in biological fluids. Quantity and nature of excipients used in the manufacturing of medicinal products. Type of dosage form and routes of administration. Manufacturing process of medicinal products. The LADMER system and its characteristics. Pharmaceutical, biological and therapeutic equivalence of medicinal products. Bioavailability. Biopharmaceutics Classification System (BCS). Determination of biopharmaceutical solubility of active pharmaceutical ingredients. Pharmaceutical, biological and physiological factors affecting the bioavailability of medicinal products.

2. Methods for determining in vitro bioavailability of tablets and capsules

Development of the dissolution test. Biopharmaceutical tests for solid dosage forms: Disintegration test, Dissolution test. Apparatus for conducting the dissolution

test: basket apparatus, paddle apparatus, reciprocating cylinder apparatus, flow-through cell apparatus. Testing conditions, interpretation of results. Analysis of the composition of immediate-release tablets. Analysis of the composition of soft gelatin capsules.

3. Comparative dissolution kinetics test for solid dosage forms

Regulatory requirements for conducting the Comparative Dissolution Kinetics Test (CDKT) for tablets and capsules: number of units, sampling time points. Reference product. Interpretation of results.

4. Pharmaceutical development in tablet manufacturing. Process validation. Technology transfer

Pharmaceutical development of tablet manufacturing technology. Risks and critical points of the tablet manufacturing process. Selection of the tablet manufacturing method depending on the physicochemical and technological properties of substances. Standardization of in-process and finished product. Development of specifications for in-process and finished product. Stability studies. Development of a stability study plan for the investigational medicinal product. Process validation. Technology transfer. Preparation of the registration dossier. Structure and scope of data to be presented in the pharmaceutical development report for medicinal products.

5. Bioequivalence studies of immediate-release tablets

Basic concepts of bioequivalence of medicinal products. Analysis of the composition of immediate-release tablets. Objects and subjects of bioequivalence studies of medicinal products. Blood sampling for bioequivalence studies of medicinal products. Methods for determining the concentration of medicinal products in blood samples for bioequivalence studies of medicinal products. Analysis of pharmacokinetic data. Registration requirements and rules for conducting bioequivalence studies of generic medicinal products in the form of immediate-release tablets.

6. Pharmaceutical development in the manufacturing of soft dosage forms. Process validation

Absorption of active substances from soft dosage forms through the skin. Factors affecting the bioavailability and release of active substances from ointments. Rules for incorporating medicinal substances into ointments and their influence on the bioavailability of medicinal products.

Determination of bioavailability of active substances from ointments in in vitro and in vivo experiments. Determination of bioavailability of active substances from soft dosage forms by dialysis through a semipermeable membrane, diffusion into agar and using diffusion cells. Determination of the influence of the degree of dispersity of active pharmaceutical ingredients on the release process from ointments by the agar gel diffusion method.

Process validation: technology transfer, preparation of the registration dossier, structure and scope of data to be presented in the pharmaceutical development report for medicinal products.

7. Pharmaceutical development in the manufacturing of sterile dosage forms. Process validation

Stages of pharmaceutical development of the composition, technology and dosage form of a sterile medicinal product. Risks and critical points of the sterile

medicinal product manufacturing process. Development and validation of manufacturing technology for sterile medicinal products produced by terminal sterilization and those manufactured by aseptic filling. Clean areas for the production of sterile medicinal products, examples of operations performed. Sterility assurance system in manufacturing. Results of pharmaceutical development of sterile medicinal products. Standardization of finished products.

8. Pharmaceutical development in the manufacturing of modified-release dosage forms. Bioequivalence studies

Tablets and capsules for oral administration with modified release. Excipients that provide modified release. Manufacturing technologies that provide modified release. Examples of medicinal products. Bioequivalence studies of capsules and tablets for oral administration with modified release.

Liposomal medicinal products: excipients, manufacturing technologies, examples of medicinal products. Bioequivalence studies of liposomal products. Transdermal dosage forms. Excipients. Manufacturing technologies. Bioequivalence studies of transdermal medicinal products.

9. Pharmaceutical development in the manufacturing of biosimilars. Bioequivalence studies

Preclinical studies: assessment of efficacy and safety. Bioequivalence studies. Preparation of the registration dossier. Structure and scope of data to be presented in the pharmaceutical development report for medicinal products.

ACADEMIC DISCIPLINE «PHARMACEUTICAL DEVELOPMENT WITH THE FUNDAMENTALS OF BIOPHARMACEUTICS» CURRICULAR CHART

Section, topic #	Section (topic) name	Number of hours		Supervised student independent work	Literature	Practical skills	Form of control	
		lectures	laboratory				of practical skills	of current / intermediate assessment
	9 semester							
	Lectures	**9**	**-**	**3**				
1.	Biopharmacy as a science. Influence of biopharmaceutical factors on the therapeutic activity of dosage forms. Biopharmaceutical aspects of medicinal product development	1,5	-	-	1, 2, 10			
2.	Methods for determining in vitro bioavailability of tablets and capsules	1,5	-	-	1-5, 10			
3.	Comparative dissolution kinetics test for solid dosage forms	1,5	-	-	1, 2, 7-10			
4.	Pharmaceutical development in tablet manufacturing. Process validation. Technology transfer	1,5	-	-	1-5, 10			
5.	Bioequivalence studies of immediate-release tablets	-	-	1,5	1-5, 10			Tests
6.	Pharmaceutical development in the manufacturing of soft dosage forms. Process validation	-	-	1,5	1-5, 10			Tests
8.	Pharmaceutical development in the manufacturing of modified-release dosage forms. Bioequivalence studies	1,5	-	-	1-6, 10			

9.	Pharmaceutical development in the manufacturing of biosimilars. Bioequivalence studies	1,5	-	-	1-5, 10			
	Laboratory classes	**-**	**36**	**-**				
1.	Biopharmacy as a science. Influence of biopharmaceutical factors on the therapeutic activity of dosage forms. Biopharmaceutical aspects of medicinal product development	-	4	-	1, 2, 10	Determination of biopharmaceutical solubility of active pharmaceutical ingredients (ibuprofen, ketoprofen, etc.). Determination of the influence of the degree of dispersity of streptocide on the release process from ointments by the agar gel diffusion method	Report on laboratory work	Interview
2.	Methods for determining in vitro bioavailability of tablets and capsules	-	4	-	1-5, 10	Analysis of the composition of immediate-release tablets. Analysis of the composition of soft gelatin capsules	Report on laboratory work	Tests
3.	Comparative dissolution kinetics test for solid dosage forms	-	4	-	1, 2, 7-10	Comparative dissolution kinetics test using ibuprofen tablets as an example	Report on laboratory work	Account of practical exercise
4.	Pharmaceutical development in tablet manufacturing. Process validation. Technology transfer	-	4	-	1-5, 10	Development of a process validation plan for tablet manufacturing by direct compression. Development of a process validation plan for tablet manufacturing by wet granulation. Algorithm for selecting primary packaging materials for tablets. Technical part of the registration dossier: composition, manufacturing process flow diagram, brief description of the	Report on laboratory work	Tests, account of practical exercise

						manufacturing process, using ibuprofen tablets as an example		
5.	Bioequivalence studies of immediate-release tablets	-	4	-	1-5, 10	Evaluation of stability study results using ibuprofen tablets as an example	Report on laboratory work	Interview, account of practical exercise
6.	Pharmaceutical development in the manufacturing of soft dosage forms. Process validation	-	4	-	1-5, 10	Evaluation of drug substance release from ointments. Evaluation of stability study results using paracetamol syrup as an example	Report on laboratory work	Tests
7.	Pharmaceutical development in the manufacturing of sterile dosage forms. Process validation	-	4	-	1-6, 10	Evaluation of stability study results using ascorbic acid injection solution as an example	Report on laboratory work	Interview, tests
8.	Pharmaceutical development in the manufacturing of modified-release dosage forms. Bioequivalence studies	-	4	-	1-5, 10	Development of a process validation plan for the manufacturing of soft gelatin capsules	Report on laboratory work	Tests
9.	Pharmaceutical development in the manufacturing of biosimilars. Bioequivalence studies	-	4	-	1, 2, 10	Development of a stability study plan for the investigational medicinal product	Report on laboratory work	Interview, tests. Credit
	Total hours per academic discipline	**12**	**36**	**3**				

*This is a mandatory form of current certification.

INFORMATION AND INSTRUCTIONAL UNIT

LITERATURE

Basic:

1. Pharmaceutical Dosage Forms and Drug Delivery. Revised and Expanded. – 4th ed. / Ram I. Mahato, Ajit S. Narang, Virender Kumar. – CRC Press, 2024. – 566 p.

Additional:

2. Applied Biopharmaceutics and Pharmacokinetics / ed. by L. Shargel, A. B. C. Yu. – 8th ed. – McGraw-Hill Education, 2022. – 929 p.

3. Allen, L. V. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems / L. V. Allen, T. B. McPherson. – 12th ed. – Wolters Kluwer, 2022. – 704 p.

4. Taylor, K. M. G. Aulton's Pharmaceutics: The Design and Manufacture of Medicines / K. M. G. Taylor, M. E. Aulton. – 6th ed. – Elsevier, 2021. – 968 p.

5. Niazi, S. K. Handbook of Pharmaceutical Manufacturing Formulations / S. K. Niazi. – 4th ed. – CRC Press, 2009. – 646 p.

6. Singh, P. K. Novel Drug Delivery System (NDDS) / P. K. Singh, R. Bhasin [et al.]. – 1st ed. – IP Innovative Publication, 2024. – 372 p.

Normative regulatory acts:

7. European Pharmacopoeia. – 11th ed. – Strasbourg : European Directorate for the Quality of Medicines & HealthCare (EDQM), 2022. – 3016 p.

8. Pharmacopoeia of the Eurasian Economic Union. Vol. 1, part 1 / Eurasian Economic Commission. – Moscow : EEC, 2020. – 568 p.

9. Pharmacopoeia of the Eurasian Economic Union. Vol. 1, part 2 / Eurasian Economic Commission. – Moscow : EEC, 2022. – 518 p.

Electronic courseware for the academic discipline «Pharmaceutical Development with the Fundamentals of Biopharmaceutics»:

10. https://etest.bsmu.by/course/view.php?id=184.

METHODOLOGICAL RECOMMENDATIONS FOR THE ORGANIZATION AND PERFORMANCE OF STUDENT INDEPENDENT WORK IN THE ACADEMIC DISCIPLINE

The time allocated for independent work can be used by students for:

preparing for lectures and laboratory classes;

preparing for credit in the academic discipline;

studying the topics (issues) designed for independent work;

problem solving;

performing research and creative tasks;

preparing thematic reports, abstracts, presentations;

taking notes of educational literature;

preparing reports;

compiling a review of scientific literature on a given topic;

execution of information and demonstration materials (stands, posters, graphs, tables, newspapers, etc.);

making models, laboratory teaching aids;

compilation of a thematic selection of literature sources, Internet sources;

preparation of tests by students for the organization of mutual knowledge assessment.

METHODOLOGICAL RECOMMENDATIONS FOR THE ORGANIZATION AND PERFORMANCE OF SUPERVISED STUDENT INDEPENDENT WORK IN THE ACADEMIC DISCIPLINE

APPROXIMATE LIST OF TASKS FOR SUPERVISED STUDENT INDEPENDENT WORK:

preparation and presentation of abstracts;
presentation of reports;
studying topics and problems that have not been discussed at the lectures;
computer testing;
participation in active forms of education.

FORMS OF CONTROL OF SUPERVISED STUDENT INDEPENDENT WORK:

tests.

LIST OF AVAILABLE DIAGNOSTIC TOOLS

The following forms are used for competence assessment:
interview;
tests;
account of practical exercise;
report on laboratory work.

LIST OF AVAILABLE TEACHING METHODS

Traditional method;
active (interactive) methods:
Problem-Based Learning (PBL);
Team-Based Learning (TBL);
Research-Based Learning (RBL).

LIST OF PRACTICAL SKILLS

Name of practical skills	Form of practical skills control
1. Determination of biopharmaceutical solubility of active pharmaceutical ingredients (ibuprofen, ketoprofen, etc.)	Report on laboratory work
2. Determination of the influence of the degree of dispersity of streptocide on the release process from ointments by the agar gel diffusion method	Report on laboratory work
3. Analysis of the composition of immediate-release tablets	Report on laboratory work
4. Analysis of the composition of soft gelatin capsules	Report on laboratory work
5. Development of a stability study plan for the investigational medicinal product	Report on laboratory work

Name of practical skills	Form of practical skills control
6. Development of a process validation plan for tablet manufacturing by direct compression	Report on laboratory work
7. Development of a process validation plan for tablet manufacturing by wet granulation	Report on laboratory work
8. Development of a process validation plan for the manufacturing of soft gelatin capsules	Report on laboratory work
9. Evaluation of drug substance release from ointments	Report on laboratory work
10. Comparative dissolution kinetics test using ibuprofen tablets as an example	Report on laboratory work
11. Technical part of the registration dossier: composition, manufacturing process flow diagram, brief description of the manufacturing process, using ibuprofen tablets as an example	Report on laboratory work
12. Evaluation of stability study results using ibuprofen tablets as an example	Report on laboratory work
13. Evaluation of stability study results using ascorbic acid injection solution as an example	Report on laboratory work
14. Evaluation of stability study results using paracetamol syrup as an example	Report on laboratory work
15. Algorithm for selecting primary packaging materials for tablets	Report on laboratory work

LIST OF EQUIPMENT USED

1. Microscope.
2. Electronic balance / Digital balance.
3. Raytor RT806 Automatic Transdermal Diffusion Tester.
4. MI-2 Floor-standing Mixer for Solutions.
5. Erweka DT800 Dissolution Tester.
6. PTWS 820D Dissolution Testing Apparatus.
7. IKA T18 Laboratory Homogenizer.
8. MS7-H550-Pro Magnetic Stirrer.
9. HI 2211-02 Benchtop pH Meter.
10. Cary 50 Dual-Beam UV Spectrophotometer.

PROTOCOL OF THE CURRICULUM APPROVAL
BY OTHER DEPARTMENTS

Title of the discipline requiring approval	Department	Amendments to the curriculum in the academic discipline	Decision of the department, which designed the curriculum (date, protocol #)
Industrial Technology of Drugs	Pharmaceutical Technology with advanced training and retraining course	There are no offers	Recommended for use. Protocol # 14 of 16.05.2025
Modern Methods of Analysis and Standardization of Medicinal Products	Pharmaceutical Chemistry with advanced training and retraining course	There are no offers	Recommended for use. Protocol # 14 of 16.05.2025

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Curriculum content, composition and the accompanying documents comply with the established requirements.

Head of the Office of Educational Activities of the Educational Institution «Belarusian State Medical University»
24.06.2026 _____ I.L.Kotovich

Methodologist of the Educational and Methodological Department of the Office of Educational Activities of the Educational Institution «Belarusian State Medical University»
24.06.2026 _____ S.V.Zaturanova