MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS
EDUCATIONAL INSTITUTION
BELARUSIAN STATE MEDICAL UNIVERSITY

APPROVED
by First Vice-Rector, Professor
_____ I.N. Moroz
16.01.2020
Reg. # UD-Л.597/1920/edu.

PHARMACEUTICAL DEVELOPMENT WITH THE FUNDAMENTALS OF BIOPHARMACEUTICS

Curriculum of higher educational institution in the educational discipline for the specialty:

1-79 01 08 «Pharmacy»

2020

Curriculum is based on the educational program «Pharmaceutical development with the fundamentals of biopharmaceutics», approved 01.03.2018, registration № УД-L.597/1718/уч.

COMPILERS:

N.S.Golyak, Head of the Department of Pharmaceutical Technology of the Educational Institution «Belarusian State Medical University», PhD, Associate Professor

O.G.Sechko, Assistant of the Department of Pharmaceutical Technology of the Educational Institution «Belarusian State Medical University», Master of Pharmaceutical Science;

RECOMMENDED FOR APPROVAL:

by the Department of Pharmaceutical Technology of the Educational Institution «Belarusian State Medical University»
(protocol № 5 of 05.12.2019);

by the Scientific Methodical Council of the Educational Institution «Belarusian State Medical University» (protocol № 5 of 15.01.2020)

EXPLANATORY NOTE

«Pharmaceutical development with the fundamentals of biopharmaceutics» is the educational discipline containing systematized scientific knowledge about the stages of pharmaceutical development, including the informed choice of their composition and dosage form, quality, quality indicators and characteristics of the technological process (critical parameters), transfer of technology from research units to production, development of system specifications at various stages of production, standardization of medicines ensuring their maximum bioavailability.

The aim of teaching and learning the discipline «Pharmaceutical development with the fundamentals of biopharmaceutics» is to provide the students with the scientific knowledge and skills about the stages of pharmaceutical development, validation of the production process to ensure their safety, efficacy and quality.

The tasks of studying the discipline are to develop the students' academic competences, based on the ability to self-search educational and information resources, as well as acquire and understand the knowledge of:

- search studies carring out at pharmaceutical development;
- procedures of development and validation of production technology of medicines in pharmaceutical industrial environments;
- methods of preparation for registration of medicines and compiling of registration document;
- biopharmaceutical aspects of production of medicines;
- methods of manufacturing of dosage forms and their standardization in industrial environments;
- principles of improving the technology of the production of medicines and developing new ways of manufacturing of medicines in dosage forms of periodic, prolonged and directed action.

Teaching and successful learning of the discipline «Pharmaceutical development with the fundamentals of biopharmaceutics» is carried out on the basis of the acquired knowledge and skills previously acquired by the students in the following disciplines:

Industrial Technology of Drugs: characteristics of the processes and industrial pharmaceutical equipment.

Microbiology: basic properties of microorganisms, sources and ways of microbial contamination at industrial production of medicines, methods of microbiological control of pharmaceutical substances and medicines.

Pathological Physiology: typical pathological processes, general legitimacies of violations of the functions of various human organs and body systems.

Fundamentals of Medical Statistics: mathematical analysis; elements of probability theory; statistics, design of experiments.

General and Inorganic Chemistry: solutions, theory of solutions, the solubility of a solid, liquid or gaseous substances; complexation, getting of inorganic substances; chemical reactions.

Organic Chemistry: the structure of organic compounds; chemical reactions of organic compounds; synthesis of organic compounds.

Physical and Colloid Chemistry: thermodynamics of phase equilibria (rule of Gibbs, extraction); thermodynamics of chemical equilibrium (the law of mass action, the chemical equilibrium constant); thermodynamics of dilute solutions (the Vant-Goff's laws and Raul's laws), isotonic solutions; macromolecular substances, surfactants, colloidal solutions, suspensions, emulsions.

Biological Physics: solid mechanics and plastic bodies; molecular physics (molecular-kinetic theory); physical optics, electricity and magnetism, ultrasound; thermal radiation.

Pharmaceutical Latin: Latin spelling and terminology.

Pharmacognosy: nomenclature of medicinal plants and medicinal plants raw materials; plant biologically active substances; medicines from medicinal plants.

Pharmaceutical Care: Hygiene pharmaceutical organizations, health in pharmaceutical organizations.

Organization and Economics of Pharmacy: standardization of pharmaceutical activity.

Pharmaceutical Chemistry: Relation between chemical structure, action, medicines storage conditions; basic methods of standardization of medicines.

Pharmacology: methods of medicaments introduction into the body; absorption, metabolism and elimination of medicines; pharmacokinetics of medicines; classification of medicines by pharmacotherapeutic groups.

As a result of studying the discipline «Pharmaceutical development with the fundamentals of biopharmaceutics» the student should

know:

– quality parameters and characteristics of the process, affecting the repeatability of control points from series to series of medicines;

– terms of pharmaceutical, biological and therapeutic equivalence of medicines;

– regulations and information material in the industrial production and pharmaceutical drug development;

be able to:

– justify the composition of the drug in a particular dosage form;

– consider the influence factors in creating pharmaceutical medicines;

master:

– methods of determining the bioavailability of the medicines;

– quality assessment methods of biopharmaceutical medicines.

The structure of the curriculum in the educational discipline «Pharmaceutical development with the fundamentals of biopharmaceutics» consists of two sections.

Total number of hours for the study of the discipline is 144 academic hours. Classroom hours according to the types of studies: lectures - 16 hours, laboratory studies - 75 hours. Student independent work (self-study) - 53 hours.

Current assessment is carried out according to the syllabus of the specialty in the form of a credit (8, 9 semesters).

Form of higher education - full-time.

ALLOCATION OF ACADEMIC TIME ACCORDING TO SEMESTERS OF STUDY

Code, name of the specialty	Semester	Number of academic hours					Form of current assessment
		total	in-class	including		out-of-class self-studies	
				lectures	laboratory studies (practical classes and seminars)		
1-79 01 08 «Pharmacy»	8	54	35	8	27	19	credit
	9	90	56	8	48	34	credit
Total hours		**144**	**91**	**16**	**75**	**53**	

THEMATIC PLAN

Name of section, topic	Number of class hours	
	lectures	laboratory
1. Introduction to the discipline «Pharmaceutical development with the fundamentals of biopharmaceutics»	**8**	**27**
1.1. Pharmaceutical development. Production of medicines. The procedure of the development and formulation of medicines for production	2	6
1.2. Biopharmacy like a science. Effect of biopharmaceutical factors on the therapeutic activity of dosage forms. Biopharmaceutical aspects of drug creation	2	6
1.3 Good Pharmacovigilance Practice (GVP)	2	6
1.4 Validation of processes for the production of sterile medicines	2	6
1.5 Validation of processes for the production of non-sterile medicines. The requirements for production equipment	-	3
2. Biopharmaceutical aspects of pharmaceutical development of medicines	**8**	**48**
2.1. Realization of pharmaceutical factors in process of pharmaceutical development	2	3
2.2. The concept of bioavailability of medicines. Methods for determining bioavailability: in vitro, in vivo, in situ	2	3
2.3. The absorption of pharmaceutical substances in the gastrointestinal tract. The release of active substances from tablets	2	3
2.4. The release of the active substance from the suppository	-	3
2.5. The release of active ingredients from soft medicinal forms	-	3
2.6. Realization of pharmaceutical development in the manufacture of sterile medicinal forms	-	3
2.7. Realization of pharmaceutical development in the production of tablets	-	3
2.8. Realization of pharmaceutical development in the production of soft medicinal forms	-	3
2.9. Realization of pharmaceutical development in the production of suppositories	-	3
2.10. Realization of pharmaceutical development in the production of medicines for children	-	3

Name of section, topic	Number of class hours	
	lectures	laboratory
2.11. Production of medicines containing medicinal plants raw materials. The test methods and measures of acceptability for medicinal plants raw materials and medicines containing medicinal plants raw materials	-	3
2.12. Realization of pharmaceutical development in the production of medicines with modified release	-	3
2.13. Preclinical trials of medicines	-	2
2.14. Clinical trials of medicines	-	2
2.15. The requirements for the structure and volume of pharmaceutical development	-	3
2.16. The choice of methods of quality control for medicines	2	3
2.17. Bioequivalence of medicines	-	2
Total hours	**16**	**75**

CONTENT OF THE EDUCATIONAL MATERIAL

1. Introduction to the discipline «Pharmaceutical development with the fundamentals of biopharmaceutics»

1.1. Pharmaceutical development. Production of medicines. The procedure of the development and formulation of medicines for production

Aims and objectives of pharmaceutical development. Basic terms and definitions of pharmaceutical development. Grounds for pharmaceutical development and putting medicines into production. The plan of the pharmaceutical development of medicines. The main process steps of the pharmaceutical development of the original medicines. The main process steps of pharmaceutical development of generic medicines. The development (selection) of the dosage form and the development of the composition. The study of physico-chemical and biological properties of the pharmaceutical substance, excipients and medicines. The study of the compatibility of active substances and excipients. The study of impurities, carrying out stress tests. The choice of packaging for produced medicines in pharmaceutical development. The development of specifications and methods of testing raw and packaging materials, design of specifications and methods of testing for made medicinal products. Monitoring of the test series, stability studies, manufacturing laboratory series. Development of the project of pharmacopeia article manufacturer for medicinal products.

1.2. Biopharmacy like a science. Effect of biopharmaceutical factors on the therapeutic activity of dosage forms. Biopharmaceutical aspects of drug creation

Biopharmacy is the theoretical basis of the development and standardization of safe and effective medicines. History and perspectives of development of Biopharmacy.

The main directions of biopharmaceutical research. A pharmaceutical, biological and therapeutic equivalence of medicines. Pharmaceutical, biological and physiological factors affecting the bioavailability of medicines. The biological significance of pharmaceutical processes occurring in manufacturing of medicines.

1.3. Good Pharmacovigilance Practice (GVP)

Good Pharmacovigilance Practice, the scope of application, terms and definitions. Requirements for the system of the quality of the pharmacovigilance system. Master file of pharmacovigilance system. Inspections and audits of Pharmacovigilance systems. Risk Management System. Work with information about adverse drug reactions. Periodic report about the safety of medicines. Post-registration studies of drug safety. Informing about drug safety and risk minimization measures.

1.4. Validation of processes for the production of sterile medicines

The principles of the production of sterile medicines. General requirements for the manufacture of sterile medicinal products. Requirements for cleanliness of production facilities. Environmental parameters of production facilities used for validation. Use of the insulating technologies in production of sterile medicines. Critical factors insulating technology validation process.

Device for blow / fill / seal sterile products. Advantages of the insulating technologies for the production of sterile medicines. Selecting the cleanliness class production facilities. Requirements for personnel involved in the manufacture of sterile products. Validation of aseptic process. Validation of sterilization processes. Parameters used to validate the capping process of sterile medicines. Validation tests of sterility.

1.5. Validation of processes for the production of non-sterile medicines. The requirements for production equipment

Scope of validation processes for production of non-sterile medicines. The interconnection between the design, validation and registration process of production of medicines. Types and organization of the validation process production of medicines. Basic principles of the validation process of production of non-sterile medicines. The requirements for process equipment for the production of medicines. Validation of processes for the production of solid dosage of medicinal forms.

2. Biopharmaceutical aspects of pharmaceutical development of medicines

2.1. Realization of pharmaceutical factors in process of pharmaceutical development

Pharmaceutical factors, their content and the effect on the bioavailability of medicines. Physical state of medicines: the degree of dispersion, polymorphism, stereoisomerism. Simple chemical modification of medicines, the solubility of medicines in biological fluids. The number and nature of the auxiliary substances used for the production of medicines. Type of dosage forms and ways of its administration to the organism. The technological process of production of medicines. The main purpose of the evaluation of pharmaceutical factors in the process of pharmaceutical development. Biopharmaceutical system of classification. Effect of the crystallographic parameters of the chiral properties of substances, the chemical stability of substances, surface area and particle size, amount and nature of the excipients, process parameters on the bioavailability of medicines. Groups of substances with a critical type dissolution parameters influence the bioavailability of medicines and therapeutic effect.

Pharmaceutical factors and pharmacokinetics.

2.2. The concept of bioavailability of medicines. Methods for determining bioavailability: in vitro, in vivo, in situ

Characteristics of bioavailability of medicines. Methods for determining bioavailability: pharmacokinetic and pharmacodynamic. Absolute and relative bioavailability. Reference medicines.

Determination of bioavailability of medicines in vitro for tablets on examples of single-phase, multi-phase and switching patterns of release of pharmaceutical substances.

Principles of calculations of bioavailability of medicines.

Key indicators of bioavailability of medicines. Effect of endogenous physiological, pathophysiological, clinical factors on the bioavailability of medicines: age and sex, body temperature, rhythms, pathological processes and the individual characteristics of the human body, alcohol and smoking. Effect of exogenous factors

on the bioavailability of medicines: the human environment temperature, magnetic field and meteorological factors.

Effect of medicines on the interaction bioavailability: pharmaceutical, pharmacokinetic, pharmacodynamic and physiological interaction.

Stages biopharmaceutical evaluation of the quality of medicines:device selection and conditions for determine the kinetics of drug release from the dosage form in vitro experiments. Study of bioavailability in experiments in vivo, the results of calculation of the correlation parameters in vitro and in vivo.

A study of bioavailability in situ experiments: experimental model systems, conditions for researching.

2.3. The absorption of pharmaceutical substances in the gastrointestinal tract. The release of active substances from tablets

Absorption mechanisms of active substances from tablets in the gastrointestinal tract. Effect of pharmaceutical factors on absorption and bioavailability of the active substances from tablets.

Biopharmaceutical tests for solid dosage forms: test «Disintegration», test «Dissolution». Instruments for test «Dissolution»: device with basket, device with a paddle stirrer, device with a piston cylinder, device with flow cell.

Automated Systems and Devices for determining the dissolution rate and drug release. Devices simulating processes release and absorption of medicines: «Sartorius», «Rezomat», «Rezotest Kocha».

2.4. The release of the active substance from the suppositories

Determining of the bioavailability of the active ingredients of the suppository in vitro experiments. Determining of the bioavailability of the active ingredients of the suppository in vivo experiments. Absorption of the active ingredients from the suppository. Factors influencing on the release of the active substances from the suppositories. Effect of auxiliary substances on the bioavailability of the active ingredients from the suppositories.

Advantages and disadvantages of rectal route of giving of medicines. Rules of introducing of medicines in suppository, their influence on bioavailability. Modern assessment of quality of suppositories. Devices for determining of the release of active substances from suppositories.

2.5. The release of active ingredients from soft medicinal forms

Absorption of the active ingredients from soft medicinal forms through the skin. Determining of the bioavailability of the active ingredients from soft medicinal forms by dialysis through a semipermeable membrane and diffusion in agar.

Factors influencing the bioavailability and the release of active ingredients from ointments. Determining the bioavailability of the active ingredients from ointments in in vitro and in vivo experiments. Rules of introducing of medicines in the ointments, their influence on the bioavailability of medicines.

2.6. Realization of pharmaceutical development in the manufacture of sterile medicinal forms

Stages of development of sterile medicinal forms. A pharmaceutical development of composition, the technology and the dosage form of a sterile

medicinal form. Risks and critical points of the process of production of sterile medicines. Development and validation of the production technology of sterile medicines. Categories of manufacturing operations in the production of sterile medicines. Clean zones for the production of sterile medicines, examples of the necessary operations. Sterility assurance system in production. Results of pharmaceutical development of sterile medicines. Standardization of the finished product.

2.7. Realization of pharmaceutical development in the production of tablets

Pharmaceutical development of technology for tablet's manufacturing. Risks and critical points of the process of the manufacturing of tablets. Selection of tablet's production method according to the physico-chemical and technological properties of the substances. Modern equipment used for the manufacture of tablets. Validation of the tablets manufacturing process. Tablets for providing action in the stomach – gastroretentive tablets. Tablets containing individual drug carriers. Modern types of packaging of tablets. The results of the pharmaceutical development of the technology of tablets. Standardization and development of specifications for the raw materials for the manufacture of tablets. Standardization of intermediate and finished products. Development of specifications for the intermediate and finished product.

2.8. Realization of pharmaceutical development in the production of soft medicinal forms

Stages of pharmaceutical development of soft medicinal forms. Risks and critical points of the production process of soft medicinal forms. A pharmaceutical development of composition, technology and dosage form of soft medicinal form. The results of the pharmaceutical development of the composition, production technology and dosage form of soft medicines. The results of pharmaceutical development and formulation of soft medicines on production. Standardization and development of specifications for the raw materials for the manufacture of soft medicinal forms. Standardization of intermediate and finished products. Development of specifications for the intermediate and finished product.

2.9. Realization of pharmaceutical development in the production of suppositories

A pharmaceutical development of composition and production technology of suppositories. Risks and critical points of the manufacturing process suppositories. Stages of pharmaceutical development suppositories. The results of the pharmaceutical development of the composition and production technology of suppositories. Standardization and development of specifications for the raw materials for the manufacture of suppositories. Standardization of intermediate and finished products. Development of specifications for the intermediate and finished product.

2.10. Realization of pharmaceutical development in the production of medicines for children

General patterns of child body's response to medicines. Private technology of medicines for newborns and children up to the first year of life. Stages of

pharmaceutical development of medicines for children. The pharmaceutical development of composition, production technology and dosage forms of medicines for children. Features of the pharmaceutical development for production technology of medicines for children. Pharmaceutical development and validation of the production technology of sterile medicines for children. Standardization of the finished product.

2.11. Production of medicines containing medicinal plants raw materials. The test methods and measures of acceptability for medicinal plants raw materials and medicines containing medicinal plants raw materials

Stages of pharmaceutical developing of medicines based on medicinal plants raw materials. The pharmaceutical developing of composition, technology of production and dosage forms of medicines based on medicinal plants raw materials. Development and validation of technology of production of medicines based on medicinal plants raw materials. The test methods and measures of acceptability for medicinal plants raw materials and medicines based on medicinal plants raw materials. The results of pharmaceutical development of medicines based on medicinal plants raw materials.

2.12. Realization of pharmaceutical development in the production of medicines with modified release

Stages of pharmaceutical developing of medicines with modified release. Risks and critical points of manufacturing medicines with modified release. A pharmaceutical development of composition, technology and dosage forms of medicines with modified release. Test «Dissolution» for poorly soluble, long-acting medicines and transdermal therapeutic systems. Results of pharmaceutical development of composition, production technology and dosage forms of medicines with modified release. Production of medicines with modified release. Standardization and development of specifications of the raw materials for the manufacture of medicines with modified release. Standardization of intermediate and finished products. Development of specifications for the intermediate and finished product.

2.13. Preclinical trials of medicines

«Good Laboratory Practice», its structure and content.

Preclinical trials as a stage of pharmaceutical drug development. Definition of preclinical trials of medicines. Planning and organization of preclinical trials of medicines. Requirements for premises, equipment and staff for preclinical trials. Requirements for the volume of preclinical trials. Protocol and report of preclinical trials, requirements to their writing and design.

2.14. Clinical trials of medicines

«Good Clinical Practice», its structure and content.

Clinical trials as a stage of pharmaceutical development of medicines. The objectives of the clinical trial. Types of clinical trials. Design of clinical trials. The protocol of clinical trials, its structure. Stages of clinical trials, their structure and characteristics. Report of clinical trials, its structure.

2.15. The requirements for the structure and volume of pharmaceutical development

The volume of pharmaceutical development for the original and generic drugs. The validity of the adequacy of the level of data during pharmaceutical development. Studying of the drug action in the human body: pharmacokinetics, bioequivalence, metabolism, drug distribution in organs. Study of physico-chemical properties of the medicines. Development of technology of production of pharmaceutical substances and medicines.

Organization of production of generic medicines, technology transfer.

Drawing up of the registration dossier. The structure, the amount of data that have to be represented in the report about the pharmaceutical development.

2.16. The choice of methods of quality control of medicines

Development and validation of methods of quality control of medicines. Types of validation procedures. Characteristic of efficiency of quality control method medicines, detection limit. The limit of quantification, linearity, precision, repeatability, reproducibility, accuracy. Issue of documents about methods of quality control of medicines.

2.17. Bioequivalence of medicines

Basic concepts of bioequivalence of medicines. Objects and subjects in the bioequivalence studies of medicines. Blood sampling at bioequivalence study medicines. Methods for determining of the concentration of medicines in the blood samples at bioequivalence study of medicines. Analysis of pharmacokinetic data. Assessment of bioequivalence of medicines. Registration of `requirements and the rules of the studies on bioavailability and bioequivalence of generic medicines.

EDUCATIONAL DISCIPLINE CURRICULAR CHART

number of section, topic	Section title, topic	Number of hours		Self-studies	Equipment	Form of control
		lectures	laboratory			
8th semester						
1.	**Introduction to the discipline «Pharmaceutical development with the fundamentals of biopharmaceutics»**	**8**	**27**	**19**	-	
1.1.	Pharmaceutical development. Production of medicines. The procedure of the development and formulation of medicines for production	2	6	4	-	survey; reports; decision of tasks; computer test
1.2.	Biopharmacy like a science. Effect of biopharmaceutical factors on the therapeutic activity of dosage forms. Biopharmaceutical aspects of drug creation	2	6	4	-	survey; reports; decision of tasks; computer test
1.3.	Good Pharmacovigilance Practice (GVP)	2	6	3	-	survey; reports; decision of tasks; computer test
1.4.	Validation of processes for the production of sterile medicines	2	6	4	-	survey; reports; decision of tasks; computer test
1.5.	Validation of processes for the production of non-sterile medicines. The requirements for	-	3	4	-	survey; reports; decision of tasks; computer test; credit

number of section, topic	Section title, topic	Number of hours		Self-studies	Equipment	Form of control
		lectures	laboratory			
	production equipment					
9th semester						
2.	**Biopharmaceutical aspects of pharmaceutical development of medicines**	**8**	**48**	**34**		
2.1	Realization of pharmaceutical factors in process of pharmaceutical development	2	3	2	-	survey; reports; decision of tasks; computer test
2.2	The concept of bioavailability of medicines. Methods for determining bioavailability: in vitro, in vivo, in situ	2	3	2	-	survey; reports; decision of tasks; protohol of practical work; computer test
2.3	The absorption of pharmaceutical substances in the gastrointestinal tract. The release of active substances from tablets	2	3	2	disintegration tester; spectrophotometer; gas chromatograph	survey; reports; decision of tasks; computer test
2.4	The release of the active substance from the suppository	-	3	2	-	survey; reports; decision of tasks; protohol of practical work; computer test
2.5	The release of active ingredients from soft medicinal forms	-	3	2	-	survey; reports; decision of tasks; protohol of practical work; computer test
2.6	Realization of pharmaceutical development	-	3	2	-	survey; reports; decision of

number of section, topic	Section title, topic	Number of hours		Self-studies	Equipment	Form of control
		lectures	laboratory			
	in the manufacture of sterile medicinal forms					tasks; protohol of practical work; computer test
2.7	Realization of pharmaceutical development in the production of tablets	-	3	2	disintegration tester; spectrophotometer; gas chromatograph	survey; reports; decision of tasks; protohol of practical work; computer test
2.8	Realization of pharmaceutical development in the production of soft medicinal forms	-	3	2	-	survey; reports; decision of tasks; protohol of practical work; computer test
2.9	Realization of pharmaceutical development in the production of suppositories	-	3	2	-	survey; reports; decision of tasks; protohol of practical work; computer test
2.10	Realization of pharmaceutical development in the production of medicines for children	-	3	2	-	survey; reports; decision of tasks; protohol of practical work; computer test
2.11	Production of medicines containing medicinal plants raw materials. The test methods and measures of acceptability for medicinal plants raw materials and medicines containing medicinal plants raw materials	-	3	2	-	survey; reports; decision of tasks; protohol of practical work; computer test

number of section, topic	Section title, topic	Number of hours		Self-studies	Equipment	Form of control
		lectures	laboratory			
2.12	Realization of pharmaceutical development in the production of medicines with modified release	-	3	2	-	survey; reports; decision of tasks; protohol of practical work; computer test
2.13	Preclinical trials of medicines	-	2	2	-	survey; reports; decision of tasks; computer test
2.14	Clinical trials of medicines	-	2	2		survey; reports; decision of tasks; computer test
2.15	The requirements for the structure and volume of pharmaceutical development	-	3	2	-	survey; reports; decision of tasks; computer test
2.16	The choice of methods of quality control for medicines	2	3	2	disintegration tester; spectrophotometer; gas chromatograph	survey; reports; decision of tasks; computer test
2.17	Bioequivalence of medicines	-	2	2	-	survey; reports; decision of tasks; computer test; credit.

INFORMATION AND INSTRUCTIONAL UNIT

LITERATURE

Basic:

1. Hillery A.M., Park K. (ed.). Drug delivery: fundamentals and applications. Second edition. – CRC Press, 2017.

Additional:

2. Kydonieus A.F. (ed.). Treatise on Controlled Drug Delivery: Fundamentals-Optimization-Applications. – Routledge, 2017.

LIST OF AVAILABLE DIAGNOSTIC TOOLS

The following forms are used for competences assessment:

1. Oral form:
- survey;
- reports.
2. Written form:
- decision of tasks;
- protohol of practical work.
3. Oral-written form:
- credit.
3. Technical form:
- computer test.

LIST OF PRACTICAL SKILLS

1. Drawing up a plan for the pharmaceutical development of medicines.
2. Determination the list of documents for the registration dossier for the pharmaceutical substance and for the medicine.
3. Determining the bioavailability of the drug.
4. Using methods of biopharmaceutical assessment quality of medicines at the biopharmaceutical analysis.
5. Assessment of influence factors on the quality of pharmaceutical and bioavailability of medicines.
6. Rationale composition of the drug in a particular dosage form.
7. Preparation of specifications to the medicinal plants raw materials, intermediate products and finished products (drug).
8. Preparation the Pharmacopoeia article of the manufacturer.
9. Preparation of a report about pharmaceutical development.

LIST OF LECTURES

8th semester

1. Pharmaceutical development. Production of medicines. The procedure for the development and formulation of medicines for production.
2. Biopharmacy like a science. Effect of biopharmaceutical factors on the therapeutic activity of dosage forms. Biopharmaceutical aspects of drug creation.
3. Good Pharmacovigilance Practice (GVP)
4. Validation of processes for the production of sterile medicines.
5. Validation of processes for the production of non-sterile medicines. The requirements for production equipment.

9th semester

1. Realization of pharmaceutical factors in the performance of pharmaceutical development.
2. The concept of bioavailability of medicines. Methods of determining of bioavailability: in vitro, in vivo, in situ.
3. The absorption of pharmaceutical substances in the gastrointestinal tract. The release of active substances from tablets.

LIST OF LABORATORY STUDIES

8th semester

1. Pharmaceutical development. Production of medicines. The procedure of the development and formulation of medicines for production.
2. Biopharmacy like a science. Effect of biopharmaceutical factors on the therapeutic activity of dosage forms. Biopharmaceutical aspects of drug creation.
3. Good Pharmacovigilance Practice (GVP)
4. Validation of processes for the production of sterile medicines.
5. Validation of processes for the production of non-sterile medicines. The requirements for production equipment.

9th semester

1. Realization of pharmaceutical factors in the performance of pharmaceutical development.
2. The concept of bioavailability of medicines. Methods of determining of bioavailability: in vitro, in vivo, in situ.
3. The absorption of pharmaceutical substances in the gastrointestinal tract. The release of active substances from tablets.
4. The release of the active substances from suppositories.
5. The release of active ingredients from soft medicinal forms.
6. Realization of pharmaceutical development in the manufacture of sterile medicinal forms.
7. Realization of pharmaceutical development in the production of tablets.
8. Realization of pharmaceutical development in the production of soft medicinal forms.
9. Realization of pharmaceutical development in the production of suppositories.
10. Realization of pharmaceutical development in the production of medicines for children.
11. Production of medicines containing medicinal plants raw materials. The test methods and measures of acceptability for medicinal plants raw materials and medicines containing medicinal plants raw materials.
12. Realization of pharmaceutical development in the production of medicines with modified release.
13. Preclinical trials of medicines.
14. Clinical trials of medicines.
15. The requirements for the structure and volume of pharmaceutical development.
16. The choice of methods of quality control for medicines.
17. Bioequivalence of medicines.

PROTOCOL OF THE CURRICULUM APPROVAL BY OTHER DEPARTMENTS

Title of the discipline requiring approval	Department	Amendments to the curriculum of the academic discipline	Decision of the department, which designed the curriculum (date, protocol #)
1. Industrial technology of drugs	Pharmaceutical technology	Changes are made	05.12.2019 protocol №5

COMPILERS/AUTHORS:

Head of the Department of Pharmaceutical Technology of the Educational Institution «Belarusian State Medical University», PhD, Associate Professor _____ N.S.Golyak

Assistant of the Department of Pharmaceutical Technology of the Educational Institution «Belarusian State Medical University», Master of Pharmaceutical Science _____ O.G.Sechko

Curriculum content, composition and accompanying documents comply with established requirements

Dean of the Medical Faculty of International Students of the Educational Institution «Belarusian State Medical University» O.S.Ishutin
16. 01. 2020

Methodologist of the Educational Institution «Belarusian State Medical University»

16. 01. 2020 S.V.Zaturanova

Head of the Foreign Languages Department M.N.Petrova

Information about the authors (compilers) of the curriculum

Full Name	Golyak Natalya Stepanovna
Position, academic degree, academic title	Head of the Department of Pharmaceutical Technology Educational Institution «Belarusian State Medical University», PhD, Associate Professor
☎ office	(017) 365 72 40
mobile	+375 29 215 49 48
E-mail:	pharmteh@bsmu.by
Full Name	Sechko Volga
Position, academic degree, academic title	Assistant of the Department of Pharmaceutical Technology Educational Institution «Belarusian State Medical University», Master of Pharmaceutical Science
mobile	+375 29 343 71 45
E-mail:	SechkoOG@bsmu.by