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

APPROVED
by First Vice-Rector, Professor
_____ I.N.Moroz
_____ 29.06.2020
Reg. № UD-1.79-25/2021/edu.

STANDARDIZATION OF DRUGS

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 "STANDARDIZATION OF DRUGS", approved 28.08.2015, registration # УД-L.79-25/1516/edu.

COMPILERS:
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RECOMMENDED FOR APPROVAL:

Pharmaceutical Chemistry Department of the Educational Institution "Belarusian State Medical University"
(protocol # 12 of 29.04.2020);

by the Scientific Methodical Council of the Educational Institution "Belarusian State Medical University"
(protocol #10 of 26.06.2020)

EXPLANATORY NOTE

"Standardization of drugs" is an academic discipline, containing systematized scientific knowledge about management systems, quality assurance and quality control of a medicinal product at all stages of its circulation within the framework of good pharmaceutical practices and other regulatory legal acts.

The curriculum of the discipline "Standardization of drugs" includes the latest scientific data about medicine, chemistry and pharmacy.

The aim of teaching and learning the discipline "Standardization of drugs" is to provide the students with the scientific knowledge about on the systems of management and quality assurance of medicines, the procedure for their state registration and the acquisition of practical skills in quality control of medicines at all stages of their circulation in accordance with regulatory legal acts.

The tasks of studying the discipline "Standardization of drugs" 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:

– the most important concepts of standardization of medicines, its goals and objectives;

– structure and main directions of activity of the system for ensuring and controlling the quality of medicines;

– the main stages of development and procedures of state registration of original and generic medicines;

– principles of conducting studies of equivalence of medicinal products;

– the role and place in the system of metrology standardization of medicines.

The tasks of teaching the discipline "Standardization of drugs" include the formation of students' social, personal and professional competences, based on the knowledge and application of:

– have qualities of citizenship;

– be capable of social interaction;

– have the ability for interpersonal communication;

– be able to work in a team;

– form a registration dossier for a medicinal product, pharmaceutical substance in order to carry out the procedure for their state registration;

– perform quality control of medicinal products, pharmaceutical substances, medicinal plant raw materials using chemical, spectrometric, chromatographic and other methods provided for by regulatory documents;

– participate in the solution of certain research and applied problems for the creation of new technologies and methods in the field of pharmacy.

Teaching and successful learning of the discipline "Standardization of drugs" is carried out on the basis of the knowledge and skills previously acquired by the students in the following disciplines:

Pharmaceutical chemistry. Modern methodology for creating original medicines. Quality assurance of pharmaceutical substances and medicinal products, regulatory documents regulating their quality. Stability and shelf life of pharmaceutical substances and medicines. Pharmacopoeia analysis. Methods for the

identification and quantitative analysis of pharmaceutical substances and medicines. Impurities in pharmaceutical substances and medicinal products. Determination of medicinal products and their metabolites in biological fluids.

Pharmaceutical development with the basics of biopharmacy. Pharmaceutical development of medicines, its purpose and main components. Biopharmaceutical classification of medicines. Risk management systems for quality assurance of medicines. Procedures for the effective management of the medicines development. The main stages of the medicines development. Pharmaceutical Development Report.

Industrial technology of medicines. General principles of organizing the production of medicines at pharmaceutical enterprises. Rules of Good Manufacturing, Laboratory, Clinical Practice. Validation of production processes for sterile and non-sterile medicines. Certification of Clean Rooms and water treatment systems. Dossier of the production site.

Industrial technology of medicines. General principles of organizing the production of medicines at pharmaceutical enterprises. Rules of Good Manufacturing, Laboratory, Clinical Practice. Validation of production processes for sterile and non-sterile medicines. Certification of clean rooms and water treatment systems. Dossier of the production site.

Organization and economics of pharmacy. Standardization of pharmaceutical activities. Organization of work of pharmacies, pharmacy warehouses, control and analytical laboratories. Staffing the pharmaceutical health sector. Labor protection of employees of pharmacy organizations.

Analytical chemistry. Fundamentals of chemometrics.

Fundamentals of Medical Statistics. Processing of measurement results.

Pharmaceutical biotechnology. Equivalence problems, the concept of "biosimilar".

Management and economics of a pharmaceutical enterprise. Occupational safety management system. Good Engineering Practice.

As a result of studying the discipline the student should know:

– the most important concepts of the standardization of medicines, its purpose and tasks;

– structure and main directions of activity of the system for ensuring and controlling the quality of medicines;

– the main stages of development and procedures of state registration of original and generic medicines;

– principles of conducting studies of equivalence of medicinal products;

– the role and place of metrology in the standardization system of medicines.

be able to:

– carry out the development and validation of methods for the analysis of medicinal products;

– draw up documents for the registration dossier for a medicinal product

– draw up applications, record and store reagents in laboratories and pharmacies;

master:

– methodology for checking the quality of medicines and pharmaceutical substances in testing laboratories and pharmacies;

– organization of a quality assurance system for medicines at all stages of their circulation.

The structure of the curriculum in the educational discipline "Standardization of drugs": 1. Introduction to the discipline "Standardization of medicines". Medicines quality assurance system; 2. The system of quality control of medicines; 3. Stages of creation and state registration of medicines.

Total number of hours for the study of the discipline is 112 academic hours. Classroom hours according to the types of studies: lectures – 14 hours, laboratory studies 57 hours, student independent work (self-study) – 41 hours.

Current 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 (*part-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"	9	**112**	71	14	57	**41**	credit

THEMATIC PLAN

Section (topic) name	Number of class hours	
	lectures	practical *(laboratory or seminars)*
1. Introduction to the discipline "Standardization of drugs". Medicines quality assurance system	**4**	**18**
1.1. Standardization as the basis for the formation of quality assurance and quality control systems	1	3
1.2. Quality assurance and quality control of medicines in pharmaceutical production in accordance with the requirements of Good Manufacturing Practice	1	3
1.3. Quality assurance and quality control of medicines during wholesale and retail sales in accordance with the requirements of Good Distribution Practice and Good Pharmacy Practice	1	3
1.4. The system of state institutions providing quality control of medicines in the Republic of Belarus		3
1.5. Quality assurance and quality control of medicines in accredited testing laboratories	1	6
2. Medicines quality control system	**4**	**18**
2.1. Development and validation of analytical procedures	1	3
2.2. Statistical processing of the results of a chemical experiment	1	3
2.3. Quality control of industrial medicines		3
2.4. Intra-pharmacy quality control of medicines	1	3
2.5. Inspection of pharmacies by specialists from analytical laboratories	1	6
3. Stages of creation and state registration of medicines	**6**	**21**
3.1. Methodology for the development of original and generic medicines	1	3
3.2. Models for assessing the safety and efficacy of medicines at the stage of preclinical studies	1	3
3.3. Modern approaches to conducting clinical trials and assessing the equivalence of generic medicines	1	3
3.4. Preparation of pharmacopoeia articles of the State Pharmacopoeia of the Republic of Belarus and development of pharmacopoeia articles of manufacturers	1	3
3.5. The procedure for state registration of medicines	1	3
3.6. Formation of registration dossier for medicinal product in the "Common technical document"	1	6
Total hours	**14**	**57**

CONTENT OF THE EDUCATIONAL MATERIAL

1. Introduction to the discipline "Standardization of drugs". Quality assurance system

1.1. Standardization as the basis for the formation of quality assurance and quality control systems

Academic discipline "Standardization of drugs", its purpose and objectives, connection with other academic disciplines. Objects of standardization. Medicinal product and its circulation processes as objects of standardization. Principles of standardization of medicines. Bodies exercising state regulation and management in the field of technical regulation and standardization. Standard as a normative technical document. Types, main elements of standards and requirements for them. Leading global standards in the pharmaceutical industry. International Organization for Standardization (ISO) Standards and Good Manufacturing Practices (GMP). The main differences between ISO and GMP standards. Advantages and disadvantages of ISO standards. ISO standards in force in the Republic of Belarus. Application options for international standards. Group indicators of the quality of medicines. The concept of the safety and effectiveness of medicines. Medicines quality assurance system. Medicines quality control system. The relationship between management systems, quality assurance and quality control of medicines. The main directions of the functioning of the quality management system. Good Practice System. Types of good pharmaceutical practices in force in the Republic of Belarus and the Eurasian Economic Union.

1.2. Quality assurance and quality control of medicines in pharmaceutical production in accordance with the requirements of Good Manufacturing Practice

The principles of quality management in a pharmaceutical company in accordance with the technical code of good practice "Good Manufacturing Practice". Importance of GMP for quality assurance of medicines. Qualified person for quality in a pharmaceutical company. Pharmaceutical quality system (quality assurance system) and its guarantees. The main requirements for the quality control of medicines by the GMP. Product quality review and risk management. Quality control department in pharmaceutical production, its role and functions. Premises, personnel and equipment of the quality control department. Responsibilities of the head of the quality control department. Documentation of procedures and results of quality control of medicines. Features of testing of raw materials, intermediate, bulk and finished products.

1.3. Quality assurance and quality control of medicines during wholesale and retail sales in accordance with the requirements of Good Distribution Practice and Good Pharmacy Practice

Implementation of acceptance control of medicines at the pharmacy warehouse and in the pharmacy. Elements of quality assurance systems in a pharmacy warehouse and a pharmacy, their guarantees. Monitoring the storage conditions of medicines in pharmacy warehouses and pharmacies. Working with medicinal

products rejected by the testing laboratory and expired medicinal products. Monitoring the shelf life of medicines in the pharmacy warehouse and in the pharmacy. Return to the pharmacy warehouse and recall from the sale of medicines.

1.4. The system of state institutions providing quality control of medicines in the Republic of Belarus

The structure and functional division of the system of state institutions providing quality control of medicines (Ministry of Health of the Republic of Belarus, RUE Center for Expertise and Tests in Health Care, territorial accredited testing laboratories, pharmacist-analyst of a pharmacy). Organizational structure of RUE Center for Expertise and Tests in Health care. The main directions of activity and functions of the Department of Medicinal preparations, Department of Medical Equipment, Republican Control and Analytical Laboratory, Laboratory of Pharmacopoeial and Pharmaceutical Analysis, Republican Clinical and Pharmacological Laboratory, Department of Good Pharmaceutical Practices. Role and place in the global system of quality assurance and quality control of medicines of the World Health Organization (WHO), the European Medical Agency (EMA) and the Food and Drug Administration (FDA). International Conference on the Harmonization of Technical Requirements for the Registration of Pharmaceutical Products (ICH).

1.5. Quality assurance and quality control of medicines in accredited testing laboratories

The role and place of testing laboratories in the field of quality control of medicines. The main functions, personnel, premises and equipment of an accredited testing laboratory. The procedure and procedure for the accreditation of testing laboratories for testing the quality of medicines. Medicines tested for all and individual indicators. Medicines checked by the "Description" indicator and the "Packaging" and "Labeling" sections. Conducting and documenting the procedure for taking samples of medicines for quality control. Remains of samples of medicines, rules for their storage and disposal. Documentation of test results. Medicines test reports. Quality control of medicinal products prior to marketing and in circulation on the territory of the Republic of Belarus. Preparation of titrated solutions and reagents at the request of pharmacies. Storage of prepared titrated solutions and reagents in a testing laboratory. Accounting for the turnover of reagents of the general list, alcohol and silver-containing reagents in the testing laboratory. Control use and storage of reagents in pharmacies. Features of storage of narcotic and thermolabile medicines in a testing laboratory. The procedure for the destruction of medicines. Features of the quality control of purified water and water for injection in a testing laboratory.

2. Medicines quality control system

2.1. Development and validation of analytical procedures

Principles for the development of analytical techniques. Study of the release of active substances from the dosage form and medicinal plant materials at the stage of development of the analysis method. Selection of extraction conditions (choice of solvent and its concentration; time, temperature and frequency of extraction; phase ratio; degree of fineness). Ultrasonic extraction. Selection of analytical wavelengths for spectrophotometric determinations. Conditions for carrying out photometric

reactions (choice of reagent, its concentration and volume; reaction time; auxiliary reagents, their concentration and volume; dilution). Selection of the composition, pH and speed of the mobile phase, elution mode and sorbent for liquid chromatography. Optimal conditions for chromatographic separation. Definition of the concept of "validation". Technical Code of Practice "Validation of Test Methods". Development of a validation plan. Pharmacopoeia requirements for validation of analytical methods. Validation characteristics for different types of tests (identification, quantitative and limit tests for impurities, quantitative determination). Validation parameters: specificity, linearity, accuracy, accuracy, range of application, detection limit, limit of quantification, suitability chromatographic system, robustness. Accuracy assessment at levels of convergence, intra- and interlaboratory accuracy. Principles of validation of spectrophotometric and chromatographic methods. Preparation of a validation report. Pharmacopoeia methods of analysis.

2.2. Statistical processing of the results of a chemical experiment

Pharmacopoeia requirements for statistical processing of the results of a chemical experiment. Sample, variation series. Checking the homogeneity of samples, excluding outliers. Precision techniques. One- and two-sided confidence intervals. Metrological characteristics of the method of chemical analysis. Uncertainty of single and average results obtained using a validated analysis method. Comparison of two assay methods for reproducibility. Definition of concepts: "metrology"; "Metrological service"; "Ensuring the uniformity of measurements"; "Verification"; "Calibration"; "Standard unit of magnitude". The main purpose and components of metrology. Tasks and structure of the state metrological service. State system for ensuring the uniformity of measurements, its tasks and components. Ways to ensure the uniformity of measurements. Metrological control. Standard samples, their classification, use for quality control of medicines.

2.3. Quality control of industrial medicines

Pharmacopoeia requirements for quality control of industrial dosage forms. Sampling rules for medicinal products. Features of sampling of raw materials, intermediate, bulk and finished products. Standardized testing for dosage forms. Private tests for pharmaceutical substances and dosage forms. Features of quality control of medicines from medicinal plants and biotechnological medicines. Methodical approaches to determining the microbiological purity of medicines. Methodology for standardizing the content and determination of residual amounts of organic solvents in medicines. Classification of organic solvents according to the degree of risk. Technical Code of Practice "Stability Testing". Determination of the stability of medicines in vivo, accelerated testing and stress tests. Shelf life of medicines.

2.4. Intra-pharmacy quality control of medicines

Pharmacopoeia requirements for express analysis of pharmaceutical products. Titrimetric, refractometric and polarimetric methods as the basis for quality control of pharmaceutical products. Norms of deviations permissible in the manufacture of medicines in pharmacies. Intra-pharmacy quality control of medicines, its types. Features of quality control in a pharmacy of sterile dosage forms before and after sterilization. Receiving and quality control of purified water and water for injection in

a pharmacy. Responsibilities of a chemist-analyst. Equipment, chemical glassware and reagents at the workplace of the chemist-analyst. Documentation of the results of chemical control of purified water, water for injections and medicines manufactured in the pharmacy. Drawing up applications for reagents to the testing laboratory. Accounting for the turnover of reagents in the pharmacy. Return of waste reagents containing precious metals to the laboratory. Features of the analysis of pharmaceutical products in the testing laboratories. Documenting the selection of samples and the results of the analysis of pharmaceutical preparations.

2.5. Inspection of pharmacies by specialists from control and analytical laboratories

Persons responsible for the quality of medicines in pharmacies. Monitoring the storage conditions of medicines in pharmacies. Keeping records of temperature and humidity in the premises of the pharmacy. Verification and calibration of analytical equipment and chemical glassware in a pharmacy. The list of issues to be checked in the framework of supervision over the conditions of retail sale, transportation, storage and shelf life of medicinal products. Supervising the implementation of Good Pharmacy Practice. Supervision of compliance with the sanitary and hygienic regime in the pharmacy. Checking the rules for processing dishes, auxiliary materials and obtaining purified water and water for injection. Scheme of checking the control analytical room (table) of the pharmacy and the state of the intra-pharmacy quality control of medicines.

3. Stages of creation and state registration of medicines

3.1. Methodology for the development of original and generic medicines

Definition of concepts: original (innovative) and generic medicinal product. The main stages of creating an original medicinal product within the framework of the system of good pharmaceutical practices. The volume of scientific research carried out during the development original and generic medicines. Search for the chemical structure. Leader connection, improvement of its structure. Drag design. Life cycle of a medicinal product. Creation of medicines from medicinal plant materials. Features of the development of biological (including immunobiological) medicines.

3.2. Models for assessing the safety and efficacy of medicines at the stage of preclinical studies

Technical Code of Good Practice "Good Laboratory Practice". Personnel, premises and equipment at the preclinical stage. Responsibilities of the head of the preclinical study. The program (protocol) of the preclinical study of the medicinal product. Commission on Bioethics and Humane Treatment of Laboratory Animals. Quality assurance in preclinical studies. Characteristics of the main species and lines of laboratory animals used in preclinical studies. Maintenance and care of laboratory animals. Preclinical studies of medicines in cell culture in vitro. Toxicity at the preclinical stage, its types. Assessment of the general toxic effect of medicines. Classification of toxicological studies on the duration of observation and the volume of recorded indicators. Toxicity classes of substances. Types of specific toxicity. Basic preclinical models for the assessment of antioxidant, immunotropic and

hepatoprotective action of medicines. Documentary registration of the results of a preclinical study of a medicinal product.

3.3. Modern approaches to conducting clinical trials and assessing the equivalence of generic medicines

Technical Code of Good Practice Good Clinical Practice. Phases of clinical trials. Requirements for researchers and volunteers when conducting clinical trials. Informed consent of the volunteer. The program (protocol) of the clinical trial of the medicinal product. Ethics Committee. Documenting the results of a clinical trial. Formation of a report on a clinical trial of a medicinal product. Equivalence of medicines, types of equivalence. Methodological approaches to assessing pharmaceutical and biological equivalence. Pharmacokinetic curve and its parameters. Comparative pharmacokinetic, pharmacodynamic and clinical equivalence studies. Regulation and conduct of bioequivalence studies in humans. Comparative dissolution kinetics test. "Biowaiver" procedure. Groups of generic medicines, the state registration of which is carried out according to the "Biowaiver" procedure.

3.4. Preparation of pharmacopoeia articles of the State Pharmacopoeia of the Republic of Belarus and development of pharmacopoeia articles of manufacturers

Regulatory documentation for testing the quality of medicines in the Republic of Belarus. The structure of the State Pharmacopoeia of the Republic of Belarus (GF RB) of the second edition. Private pharmacopoeia monographs for pharmaceutical substances, excipients, medicinal plant raw materials and reagents. General Pharmacopoeia Monographs. The principles of harmonization of the GF RB with the European pharmacopoeia. International Pharmacopoeia. Pharmacopoeias of different countries (Great Britain, USA, Japan, China, Kazakhstan, Ukraine, Russian Federation). American Herbal Pharmacopoeia. Harmonization concept national pharmacopoeias within the framework of the Eurasian Economic Union. Pharmacopoeia monographs of manufacturers: definition, development procedure, presentation, construction, design and approval. Package of documents, submitted with the draft of the pharmacopoeia monograph for examination. Explanatory note to the draft monograph. The procedure for registration of pharmacopoeia monographs. Revision and updating of monographs. Sections included in monographs on pharmaceutical substances, various dosage forms, medicinal plant raw materials and medicines based on it. Requirements for methods of analysis included in the pharmacopoeia monographs of the State Pharmacopoeia of the Republic of Belarus and the monographs of manufacturers.

3.5. The procedure for state registration of medicines

Preliminary technical work prior to state registration. Stages of the procedure for state registration of medicines. The procedure for issuing a marketing authorization. The structure, procedure for the formation and maintenance of the State Register of Medicines of the Republic of Belarus. Confirmation of state registration. Perpetual registration certificate. Reasons for refusing state registration. Medicines not subject to state registration. Cases of suspension and termination of the registration certificate. Exclusion of a medicinal product from the State Register.

3.6. Formation of a registration dossier for a medicinal product in the format of the "Common technical document"

The structure of the registration dossier for a medicinal product in the "Common technical document" format. Content of the module "Quality". List of documents for domestic and foreign medicinal products applied for state registration. Features of the registration dossier of original and generic medicines. Organization and timing of examination of documents of the registration dossier for a medicinal product. Cases of making changes to the registration dossier for a medicinal product. The procedure for making changes to the registration dossier.

EDUCATIONAL DISCIPLINE CURRICULAR CHART

Section, topic #	Section (topic) name	number of hours		Self-studies	Equipment	Form of control
		lectures	practical (*laboratory or seminars*)			
1	Introduction to the discipline "Standardization of drugs ". Medicines quality assurance system	4	18	10	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	1.1. Standardization as the basis for the formation of quality assurance and quality control systems	1	3	2	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	1.2. Quality assurance and quality control of medicines in pharmaceutical production in accordance with the requirements of Good Manufacturing Practice	1	3	2	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	1.3 Quality assurance and quality control of medicines during wholesale and retail sales in accordance with the requirements of Good Distribution Practice and Good Pharmacy Practice	1	3	2	computer	interviews; situational tasks and tests; control questioning;

	1.4. The system of state institutions providing quality control of medicines in the Republic of Belarus		3	2	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	1.5. Quality assurance and quality control of medicines in accredited testing laboratories	1	6	2	computer	interviews; situational tasks and tests; control questioning; electronic tests;
2	Medicines quality control system	4	18	10	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	2.1 Development and validation of analytical procedures	1	3	2	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	2.2.Statistical processing of the results of a chemical experiment	1	3	2	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	2.3. Quality control of industrial medicines	1	3	2	computer	interviews; situational tasks and tests; control questioning;

	2.4. Intra-pharmacy quality control of medicines		3	2	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	2.5. Inspection of pharmacies by specialists from analytical laboratories	1	6	2	computer	interviews; situational tasks and tests; control questioning; electronic tests;
3	Stages of creation and state registration of medicines	6	21	21	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	3.1 Methodology for the development of original and generic medicines	1	3	3	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	3.2. Models for assessing the safety and efficacy of medicines at the stage of preclinical studies	1	3	3	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	3.3. Modern approaches to conducting clinical trials and assessing the equivalence of generic medicines	1	3	3	computer	interviews; situational tasks and tests; control questioning;

	3.4. Preparation of pharmacopoeia articles of the State Pharmacopoeia of the Republic of Belarus and development of pharmacopoeia articles of manufacturers	1	3	3	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	3.5. The procedure for state registration of medicines	1	3	3	computer	interviews; situational tasks and tests; control questioning; electronic tests;
	3.6. Formation of registration dossier for medicinal product in the "Common technical document"	1	6	6	computer	final tests, credit

INFORMATION AND INSTRUCTIONAL UNIT LITERATURE

Basic (relevant):

1. David Roesti. Pharmaceutical Microbiological Quality Assurance and Control : Practical Guide for Non-Sterile Manufacturing / David Roesti, Marcel Goverde. John Wiley & Sons Inc., Florida. – 2019. – 592 p.

2. David M. Bliesner. Laboratory Control System Operations in a GMP Environment. – John Wiley & Sons Inc., Florida. – 2020. – 306 p.

3. K. P. R. Chowdary. A Textbook of Pharmaceutical Quality Assurance. – PharmaMed Press, Hyderabad. – 2020. – 311 p.

4. Steven A. Ostrove. How to validate a pharmaceutical process. – Academic Press, 2016. – 197 p.

5. The European Pharmacopoeia : (Ph. Eur.) : 10th Edition. – Strasbourg, Council of Europe, 2020.

Additional:

6. The State Pharmacopeia of the Republic of Belarus : (SP RB I) : Developed on the basis of the European Pharmacopoeia. In 2 vol. Vol.1. General Quality Control Methods of Medicinal Products / Ministry of Heath of the Republic of Belarus, RUE "Center for Expertise and Tests in Health Care"; under total. ed. S.I. Marchenko. – Molodechno: Printing House "Pobeda", 2012. – 1220 p.

7. The State Pharmacopeia of the Republic of Belarus : (SP RB II) : Developed on the basis of the European Pharmacopoeia. In 2 vol. Vol. 2. Quality Control of Substances for Pharmaceutical Use and Herbal Substances / Ministry of Heath of the Republic of Belarus, RUE "Center for Expertise and Tests in Health Care" ; under total. ed. S.I. Marchenko. – Molodechno: Printing House Pobeda", 2016. – 1368 p.

8. Pharmacopoeial monographs. Development and approval procedure : TCP 123-2008 (02040). – Introduced 01.05.2008. – Minsk: Ministry of Health of the Republic of Belarus, 2008. – 56 p.

9. Good Manufacturing Practice : TCP 030-2017 (33050). – Introduced 01.09.2017 (instead of TCP 030-2013). – Minsk: Ministry of Health of the Republic of Belarus, 2017. – 216 p.

Normative regulatory acts:

10. On ensuring the uniformity of measurements: Law of the Republic of Belarus, September 5, 1995, No. 3848-XII : in the wording of the Law of the Republic of Belarus dated 21.10.2016 No. 433-Z.

11. On technical regulation and standardization : Law of the Republic of Belarus, January 5, 2004, No. 262-Z : in the wording of the Law of the Republic of Belarus dated 18.12.2019 No. 278-Z.

12. On medicinal products : Law of the Republic of Belarus, July 20, 2006, No. 161-Z : in the wording of the Law of the Republic of Belarus dated 13.05.2020 No. 13-Z.

13. On Medicine Circulation : Decree of the President of the Republic of Belarus, December 31, 2019, No. 499.

14. On approval of the Provisions on the storage, transportation, withdrawal from circulation, return to the manufacturer or supplier, destruction on medicinal products : Resolution of the Council of Ministers of the Republic of Belarus, December 22, 2009, No. 1677 : in the wording of the Resolution of the Council of Ministers of the Republic of Belarus dated 29.09.2020 No. 565.

15. On approval of the Good Pharmacy Practice : Resolution of the Ministry of Health of the Republic of Belarus, December 27, 2006, No. 120 : in the wording of the Resolution of the Ministry of Health dated 23.02.2021 No. 14

16. On approval of the Good Storage Practice : Resolution of the Ministry of Health of the Republic of Belarus, October 23, 2020, No. 88.

17. On approval of the Instruction on the procedure and conditions for quality control of medicinal products registered in the Republic of Belarus prior to being sold, as well as medicinal products in circulation in the Republic of Belarus: Resolution of the Ministry of Health of the Republic of Belarus, March 1, 2010, No. 20 : in the wording of the Resolution of the Ministry of Health dated 23.10.2020 No. 88.

18. On approval of the Instruction on the procedure and conditions for quality control of medicinal products manufactured in pharmacies : Resolution of the Ministry of Health of the Republic of Belarus, April 17, 2015, No. 49 : in the wording of the Resolution of the Ministry of Health dated 14.08.2020 No. 71.

19. On approval of the Rules of Good Manufacturing Practice of the Eurasian Economic Union : Decision of the Eurasian Economic Commission, November 3, 2016, No. 77.

20. On approval of the Rules of Good Clinical Practice of the Eurasian Economic Union : Decision of the Eurasian Economic Commission, November 3, 2016, No. 79.

21. On approval of the Rules of Good Distribution Practice within the Eurasian Economic Union : Decision of the Eurasian Economic Commission, November 3, 2016, No. 80.

22. On approval of the Rules of Good Laboratory Practice of the Eurasian Economic Union in the sphere of circulation of medicinal products : Decision of the Eurasian Economic Commission, November 3, 2016, No. 81.

23. On approval of the Rules of Good Pharmacovigilance Practice of the Eurasian Economic Union : Decision of the Eurasian Economic Commission, November 3, 2016, No. 87.

LIST OF AVAILABLE DIAGNOSTIC TOOLS

The following forms are used for competences assessment:

1. Oral form:
– interviews;
– situational tasks and tests.
2. Written form:
– tests;
– control questioning;
– final tests.
3. Oral-written form:
– credits.
4. Technical form:
– electronic tests.

LIST OF PRACTICAL SKILLS

– methodology for checking the quality of medicines and pharmaceutical substances in testing laboratories and pharmacies;

– organization of a quality assurance system for medicines at all stages of their circulation.

LIST OF LECTURES

1. Standardization as the basis for the formation of quality assurance and quality control systems. Quality assurance and quality control of medicines in pharmaceutical production in accordance with the requirements of Good Manufacturing Practice.

2. Quality assurance and quality control of medicines during wholesale and retail sales in accordance with the requirements of Good Distribution Practice and Good Pharmacy Practice. The system of state institutions providing quality control of medicines in the Republic of Belarus. Quality assurance and quality control of medicines in accredited testing laboratories.

3. Development and validation of analytical procedures. Statistical processing of the results of a chemical experiment.

4. Quality control of industrial medicines. Intra-pharmacy quality control of medicines.

5. Inspection of pharmacies by specialists from analytical laboratories. Methodology for the development of original and generic medicines.

6. Models for assessing the safety and efficacy of medicines at the stage of preclinical studies. Modern approaches to conducting clinical trials and assessing the equivalence of generic medicines.

7. Preparation of pharmacopoeia articles of the State Pharmacopoeia of the Republic of Belarus and development of pharmacopoeia articles of manufacturers. The procedure for state registration of medicines. Formation of registration dossier for medicinal product in the "Common technical document".

LIST OF LABORATORY *(PRACTICAL)* STUDIES

1. Standardization as the basis for the formation of quality assurance and quality control systems.

2. Quality assurance and quality control of medicines in pharmaceutical production in accordance with the requirements of Good Manufacturing Practice.

3. Quality assurance and quality control of medicines during wholesale and retail sales in accordance with the requirements of Good Distribution Practice and Good Pharmacy Practice.

4. The system of state institutions providing quality control of medicines in the Republic of Belarus.

5. Quality assurance and quality control of medicines in accredited testing laboratories.

6. Development and validation of analytical procedures.

7. Statistical processing of the results of a chemical experiment.

8. Quality control of industrial medicines.

9. Intra-pharmacy quality control of medicines.

10. Inspection of pharmacies by specialists from analytical laboratories.

11. Methodology for the development of original and generic medicines.

12. Models for assessing the safety and efficacy of medicines at the stage of preclinical studies.

13. Modern approaches to conducting clinical trials and assessing the equivalence of generic medicines.

14. Preparation of pharmacopoeia articles of the State Pharmacopoeia of the Republic of Belarus and development of pharmacopoeia articles of manufacturers.

15. The procedure for state registration of medicines.

16. Formation of registration dossier for medicinal product in the "Common technical document".

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. Analytical Chemistry	Pharmaceutical Chemistry Department	no changes	protocol # 6 of 18.11.2019
2. Pharmaceutical Chemistry	Pharmaceutical Chemistry Department	no changes	protocol # 6 of 18.11.2019

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

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