Federal State Budgetary Educational Institution of Higher Education
"Privolzhsky Research Medical University"
Ministry of Health of the Russian Federation

APPROVED
Vice-Rector for Academic Affairs
_____ E.S. Bogomolova
31 August 2021

WORKING PROGRAM

Name of the academic discipline: Pharmaceutical Technology

Type of practice: industrial

Specialty: 33.05.01 PHARMACY

Qualification: "PHARMACIST"

Department: Pharmaceutical Chemistry and Pharmacognosy

Mode of study: full-time

Labor intensity of the academic discipline __216___ academic hours

Practice duration- 4_ weeks (school days _24_)

Nizhny Novgorod
2021

The working program has been developed in accordance with the Federal State Educational Standard for the specialty 33.05.01"Pharmacy", approved by the order of Ministry of Science and Higher Education of the Russian Federation of March 27, 2018 N 219 (Registered in the Ministry of Justice of Russia on April 16, 2018 N 50789).

Developers of the working program:
Associate Professor of the Department of Management and Economics of Pharmacy and Pharmaceutical Technology, Ph.D. Volkov A.A.

The program was reviewed and approved at the department meeting (protocol No. 1 of 08/29/2021)

Head of department,
Ph.D. _____ Zhukova O.V.

29 August 2021

AGREED
Deputy Head of EMA ph.d. of biology _____ Lovtsova L.V.
(signature)

29 August 2021

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1. Type of practice manufacturing.

2. The method of conducting the practice is stationary / visiting.

3. The form of the practice is discrete.

4. Scope of practice 6 CU.

5. Duration of practice 24 days

The purpose and objectives of mastering the academic discipline Pharmaceutical Technology (practice)

The purpose of mastering the discipline: *participation in forming the relevant competencies UC-1; GPC-1,6; PC-7,11.*

As a result of completing the discipline, the student should

Know:

- requirements for maintaining subject-quantitative accounting of medicines
- requirements for maintaining reporting documentation in pharmaceutical organizations, professional office work
- classification of narcotic drugs, psychotropic, toxic chemicals, biological agents, radioactive substances and their physical and chemical characteristics;
- technology of dosage forms obtained under the conditions of pharmaceutical production: powders, collections, granules, capsules, microgranules, microcapsules, dragees, tablets, aqueous solutions for internal and external use, solutions in viscous and volatile solvents, syrups, aromatic waters, tinctures, extracts, ophthalmic dosage forms, solutions for injections and infusions, suspensions for enteral and parenteral use, emulsions for enteral and parenteral use, ointments, suppositories, patches, pencils, films, aerosols;
- technology for the manufacture of medicines in a pharmacy: powders, aqueous solutions for internal and external use, solutions in viscous and volatile solvents, ophthalmic dosage forms, solutions for injections and infusions, suspensions for entheal and parenteral use, emulsions, aqueous extracts from medicinal plant materials , complex combined preparations with a liquid dispersion medium, ointments, suppositories;
- normative documentation regulating the production and quality of medicines in pharmacies and pharmaceutical enterprises;
- nomenclature of modern excipients, their properties, purpose;
- theoretical foundations of biopharmacy, pharmaceutical factors influencing the therapeutic effect in the extemporaneous and industrial production of dosage forms
- arrangement and principles of operation of modern laboratory and production equipment;
- analysis methods used in drug quality control and described in the State Pharmacopoeia
- normative documentation regulating the manufacture, production and quality of medicines at pharmaceutical enterprises;
- technology of dosage forms obtained in the conditions of pharmaceutical production

Be able to:

- maintain reporting documentation in accordance with established requirements

- register data on manufactured drugs
- draw up basic technological and instrumental schemes for the production of finished medicines
- draw up a material balance and carry out calculations taking into account the consumption rates of the entire technological process by stages
- draw up a technological section of the industrial regulation for the production of finished dosage forms
- carry out step-by-step control at the stages of manufacturing the finished product and during dispensing; as well as standardize the dosage form for technological and biopharmaceutical indicators in accordance with the current regulatory documents
- make fragments of ND on LF
- work independently with educational and reference literature;
- ensure compliance with the rules of industrial hygiene, environmental protection, labor, safety

Possess:

- the skills of conducting subject-quantitative accounting of certain groups of drugs and other substances subject to such accounting
- skills in maintaining reporting documentation in the prescribed manner
- skills in maintaining registration of data on the manufacture of medicinal products (filling out a written control passport; in the case of using in the manufacture of drugs that are subject to quantitative accounting, registration of the reverse side of the prescription)
- basic information transformation technologies: text, spreadsheet editors; technique of working on the Internet for professional activities;
- skills in compiling technological sections of industrial regulations for the production of finished dosage forms, including technological and instrumental schemes for the production of finished dosage forms;
- develop an accounting policy, keep records of inventory items: cash and settlements, prepare reports for internal and external users of accounting information

Position of the academic discipline in the structure of the General Educational Program of Higher Education (GEP HE) of the organization.

The discipline Pharmaceutical Technology (practice) refers to the core part *(*or *the part formed by the participants of educational relations)* of Block 2 Practices, incl. research work.

The discipline is taught in the 10th semester

The following knowledge, skills and abilities formed by previous academic disciplines are required for mastering the discipline:

- Latin language
- Informatics
- information technology in pharmacy
- botany
- physiology with the basics of anatomy
- microbiology
- physical and colloidal chemistry
- pathology

- pharmacology
- pharmaceutical chemistry
- bioethics
- psychology and pedagogy
- communication bases of pharmaceutical activity
- clinical pharmacology with the basics of pharmacotherapy
- pharmacognosy
- medical and pharmaceutical merchandising
- management and economics of pharmacy
- legal basis for the activity of a pharmacist
- pharmaceutical propaedeutic practice (educational practice)

Mastering the discipline is required for forming the following knowledge, skills and abilities for subsequent academic disciplines: -

Deliverables of mastering the academic discipline and metrics of competence acquisition

Mastering the discipline aims at acquiring the following universal (UC) or/and general professional (GPC) or/and professional (PC) competencies

№	Competence code	The content of the competence (or its part)	Code and name of the competence acquisition metric	As a result of mastering the discipline, the students should:		
				know	be able to	possess
1.	UC-1.	Able to realize critical analysis of problem situations based on a systematic approach, develop strategy actions	UC-1.1. Analyzes the problem situation as a system identifying its components and connections between themUC-1.2. Identifies gaps in the information needed to solve a problem situation, and designs processes for their elimination UC-1.3. Critically assesses reliability of information sources, works with conflicting information from different sources UC-1.4. Develops and meaningfully argues the strategy of solving the problem situations based on the system and	• methodology of abstract thinking for systematization of processes and construction of cause-and-effect relationships; • modern theoretical and experimental methods for the implementation of own and borrowed results of scientific research into practice.	• abstract, analyze and synthesize the information received; • highlight and to systematize the essential properties and connections of objects, to identify the main patterns of the objects under study; • search, select and analyze information obtained from various sources in order to make the best decision at the modern scientific level, in accordance with professional tasks and the requirements of legal documents.	• methods of self-control, abstract and analytical thinking; • skills in analyzing methodological problems that arise in solving research and practical problems, including those in interdisciplinary areas; • skills of presenting an independent point of view

			interdisciplinary approaches			
2.	GPC-1.	Able to use basic biological, physical-chemical, chemical, mathematical methods for the development, research and examination of medicines, the manufacture of medicinal products	GPC-1.3. Applies the basic methods of physical-chemical analysis in the manufacture of medicinal products GPC-1.4. Applies mathematical methods and performs mathematical processing of data obtained during the development of medicines, as well as research and examination of medicines and medicinal plant raw materials	•organization of a system of state control over the production and manufacture of drugs; • the main regulatory documents, production and manufacture, quality control, storage and use of medicines (domestic and international standards (GMP, GLP, GCP, GPP), pharmacopoeias, orders of the Ministry of Health of the Russian Federation, guidelines and instructions approved by the Ministry of Health of the Russian Federation) for examination using chemical, biological, physico-chemical and other methods; • pharmacopoeial methods of analysis used in the analysis of medicinal products using chemical, biological, physicochemical and other methods.	• apply chemical, biological, physico-chemical and other methods of analysis during the examination of medicines.	•ensuring the process of quality control of medicines with equipment and consumables; • basic chemical, biological, physico-chemical and other methods of analysis during the examination of medicines.
3.	GPC-6.	Able to understand the principles of modern information technologies and use them to solve the tasks of professional activity	GPC-6.2. Performs an effective search for information necessary to solve the tasks of professional activity using legal reference systems and professional pharmaceutical databases GPC-6.3. Uses specialized software for mathematical processing of observational and experimental data in solving problems of professional activity	modern means of computing technology	use modern computer technology and basic office applications And graphic packages; evaluate way of implementing information systems and devices for solving task	methods of practical use modern computers to search information processing and fundamentals numerical methods for solving applied tasks
4.	PC-7.	Able to carry out operations related to the technological	PC-7.1. Ensures the level of proper production in accord-	requirements of regulatory documentation for the raw materi-	carry out pharmacopoeial analysis of raw materials and	methods of quality control of raw materials and auxiliary materials used

		process in the production of medicines and their control	ance with the applicable rules and regulations PC-7.2. Participates in all technological operations carried out in the production of medicines at pharmaceutical enterprises PC-7.3. Monitors compliance with the requirements of the technological regulations of production in order to comply with the norms of the technological process PC-7.4. Monitors compliance of the equipment and control and measuring equipment used in production with the requirements of technological documentation PC-7.5. Monitors the compliance of the raw materials and excipients used with the requirements of regulatory documentation	als and auxiliary materials used	auxiliary materials used	
5.	PC-11.	Able to take part in measures to ensure the quality of medicines in industrial production	PC-11.1. Participates in events, including the preparation and verification of documents responsible for the quality of medicines PC-11.2. Provides a clear implementation and execution of the technological scheme in production, taking into account the verification of the quality indicators of the received drug, in-	• principles of search, processing, analysis and systematization of scientific information • conditions for the correct and productive formulation of problems and tasks • the most important stages of development and the most relevant areas of research in modern world and domestic science	• analyze and use the received information. Argumented and logically state the content of their own conclusions and conclusions • work with scientific literature, analyze the information received, highlight the main points, form primary hypotheses on the topic of scientific research	• skills to logically and consistently present the material of scientific research in oral and written form. • skills of collecting, processing, analyzing and systematizing information on the research topic • methods of statistical processing of experimental results of physical-chemical, chemical, biological and biopharmaceutical studies; • skills of inter-

			cluding the technological stages PC-11.3. Ensures the reliability and effectiveness of all types of quality control of the received medicinal product, primarily ensuring intrafactory control, as well as participation in state and arbitration control	• basic laws of physics and chemistry, physical and chemical phenomena and regularities used in physical and colloidal chemistry; • the basic laws underlying analytical chemistry; • the main provisions of the theory of ionic equilibria as applied to reactions of acid-base, redox, precipitation and complexometric character; • scientific bases of classification, nomenclature and isomerism of organic compounds; • classification of narcotic drugs, psychotropic, toxic substances, their physical and chemical characteristics; • normative documentation regulating the production and quality of medicines in pharmacies and pharmaceutical companies; • nomenclature of industrial preparations; • nomenclature of modern excipients, their properties, purpose; • modern biotechnological methods for obtaining drugs: genetic engineering, protein engineering, engineering enzymology, chromosome engineering, cell	• use at least 900 terminological units and terminological elements in the framework of oral and written communication; • independently work with educational, reference and scientific literature; • carry out elementary statistical processing of experimental data in physical and chemical experiments; process, analyze and generalize the results of physical and chemical observations and measurements; apply the acquired knowledge in the study of analytical, pharmaceutical chemistry, pharmacognosy, pharmacology, toxicology, drug technology; • calculate absolute and relative errors of measurement results; • carry out informational, educational and sanitary-educational work;	pretation of the calculated values of thermodynamic functions and on their basis to predict the possibility of implementation and direction of chemical processes; • the skills of conducting scientific research to establish the relationship between physical and chemical properties and pharmacological activity; • to predict physical and chemical transformations of medicinal substances in the course of their circulation and storage; • interpret the results of the analysis, the reasons for the poor quality of medicines, indicate ways to exclude their possible poor quality; • find and use the necessary information to solve synthetic problems; • basic information transformation technologies: text, spreadsheet editors; technique of working on the Internet for professional activities; • develop a business plan; • analyze the state of property and liabilities of a pharmaceutical organization and enterprise, assess the degree of risk of entrepreneurial activity; • carry out segmentation of the pharmaceutical market and select target segments; • methods for studying demand,

				engineering; • main trends in the development of pharmaceutical technology, new directions in the creation of modern dosage forms and therapeutic systems • theoretical foundations of biopharmacy, pharmaceutical factors influencing the therapeutic effect in the extemporaneous and industrial production of dosage forms		forming an assortment and forecasting the need for drugs • health education skills

8. The content of the practice.

9. Forms of reporting on practice.

9.1. Diary (report) on practice.

9.2. Feedback from the practice base (individual and/or generalized).

7. Types of assessment formats for ongoing monitoring and mid-term assessment

No. p / p	semester number	Types of control	Name of section of academic discipline	Competence codes	Assessment formats		
					types	number of test questions	number of test task options
1	2	3	4		5	6	7
1.	9	Control of the development of the topic, control of the student's independent work		*UC-1; GPC-1,6; PC-7,11*	Tests	20	10
					Control questions	2	10
					Situational tasks	1	15
2.	9	Exam	All sections of the discipline	*UC-1; GPC-1,6; PC-7,11*	Tests	20	10
					Control questions	2	10
					Situational tasks	1	20

8. Educational, methodological and informational support for mastering the academic discipline (printed, electronic publications, the Internet and other network resources)

Key literature references

No.	Name according to bibliographic requirements	Number of copies	
		At the department	In library
1.	Pharmaceutical technology: Technology of dosage forms: a textbook for students. Higher Proc. Institutions / I.I. Krasnyuk, S.A. Valevko, G.V. Mikhailova and others; ed. I.I. Krasnyuk, G.V. Mikhailova. - M.: Publishing Center "Academy", 2006. - 592 p.	4	153
2.	Workshop on the technology of dosage forms: study guide I.I. Krasnyuk, G.V. Mikhailova, O.N. Grigorieva and others; ed. I.I. Krasnyuk, G.V. Mikhailova. - M.: Publishing Center "Academy", 2006. - 432 p.		153
3.	Pharmaceutical technology. Guide to laboratory studies: a study guide. Bykov V.A. 2010		220
4.	Pharmaceutical technology. Manufacturing of drugs: a textbook. Gavrilov A.S. 2010	2	100
5	Pharmaceutical development. Concepts and practical recommendations Scientific and practical guide for the pharmaceutical industry Edited by Bykovsky S.N. – M, publishing center Pero2015	20	-

Further reading

No.	Name	Quantity copies	
		At the department	In library
1.	Pharmaceutical homeopathy: Proc. allowance for students. higher textbook institutions / I.I. Krasnyuk, G.V. Mikhailov; Ed. ON THE. Zamarenova. - M.: Publishing Center "Academy", 2005. - 272 p.	5	
2.	Tutorial. Medical cosmetics/I.I. Krasnyuk, G.V. Mikhailova, E.T. Chizhova. - M.: Publishing Center "Academy", 2006. - 240p.	5	thirty
3.	State Pharmacopoeia of the USSR X edition, 1968.	2	
4.	USSR State Pharmacopoeia XI edition, issue 1, 1987; issue 2, 1990	8	
5.	State Pharmacopoeia XIIth ed. - M: Scientific Center for Expertise of Medicinal Products, 2008.-704 p.	2	
6.	Uniform rules for registration of medicines prepared in pharmacies (enterprises) of various forms of ownership (Guidelines). - M. 1997.	3	
7.	Mashkovsky M.D. medicines. - 15th edition, revised, corrected. and additional - M.: RIA "New Wave", 2007. - 1206 p.	5	
8.	Guidelines for the production of sterile solutions in pharmacies. - M., 1994.	5	
9.	Order of the Ministry of Health of the Russian Federation 214 dated 16.07.97 "On quality control of medicines manufactured in pharmacies";	50	
10.	Order of the Ministry of Health of the Russian Federation No. 305	50	

	dated 10/16/97 "On the norms of deviations permissible in the manufacture of medicines and packaging of industrial products in pharmacies";		
11.	Order of the Ministry of Health of the Russian Federation No. 308 dated 10/21/97 on the approval of the "Instructions for the manufacture of liquid dosage forms in pharmacies";	50	
12.	Order of the Ministry of Health of the Russian Federation No. 309 dated 10/21/97 on the approval of the "Instructions on the sanitary regime of pharmacies";	50	
13.	Order of the Ministry of Health of the Russian Federation No. 318 dated 05.11.97 on approval of the "Instructions on the procedure for storage and handling in pharmaceutical (pharmacy) organizations with drugs and medical products with flammable and explosive properties";	50	
14.	Order of the Ministry of Health and Social Development of the Russian Federation No. 110 dated February 12, 2007 "On the procedure for prescribing and prescribing medicines, medical devices and specialized health food products";	50	
15.	Order of the Ministry of Health of the Russian Federation No. 330 of November 12, 1997 "On measures to improve the accounting, storage and use of narcotic drugs";	50	
16.	Order of the Ministry of Health of the Russian Federation No. 377 of November 13, 1996 on the approval of the "Instructions for organizing the storage of various groups of medicines and medical products in pharmacies";	50	
17.	Decree of the Government of the Russian Federation No. 681 of June 30, 1998 "On Approval of the List of Narcotic Drugs, Psychotropic Substances and Their Precursors Subject to Control in the Russian Federation".	50	
18.	Sinev D.Ya., Marchenko L.G., Sineva T.D. Reference manual for pharmaceutical technology of drugs. - St. Petersburg,1992.	5	

Electronic educational resources for teaching academic subjects
Internal Electronic Library System of the University (IELSU)

Name of the electronic resource	Brief description (content)	Access conditions	Number of users
Internal Electronic Library System of the University (IELSU)	Proceedings of the teaching staff of the department of UEF and FT: textbooks and teaching aids, monographs, collections of scientific papers, scientific articles, dissertations, abstracts of dissertations, patents.	From any computer on the Internet, using an individual login and password	Not limited

Electronic educational resources acquired by the University

No.	Name of the electronic resource	Brief description (content)	Access conditions	Number of users
1	Electronic database	Educational	From any computer on the	General

	"Student Advisor"	literature + additional materials (audio, video, interactive materials, test tasks) for higher medical and pharmaceutical education. Editions are structured by specialties and disciplines in accordance with the current Federal State Educational Standards of Higher Professional Education.	Internet, using an individual login and password [Electronic resource] - Access mode:http://www.studmedlib.ru/	subscription of PIMU
2	Electronic library system "Bukap"	Educational and scientific medical literature of Russian publishing houses, incl. translations of foreign publications.	From any computer located on the Internet by login and password, from the computers of the academy. Subscribed editions are available for reading. [Electronic resource] - Access mode: http://www.books-up.ru/	General subscription of PIMU
3	"Bibliopoisk"	Integrated search service "single window" for electronic catalogs, ELS and full-text databases. The results of a single search in the demo version include documents from domestic and foreign electronic libraries and databases available to the university as part of a subscription, as well as from open ac-	For PIMU, access to the demo version of the Bibliopoisk search engine is open: http://bibliosearch.ru/pimu.	General subscription of PIMU

		cess databases.		
4	Domestic electronic periodicals	Periodicals on medical topics and higher education	From the computers of the Academy on the platform of the electronic library eLIBRARY.RU Access mode: https://elibrary.ru/	Not limited
5	International scientometric database "WebofScienceCoreCollection"	WebofScience covers materials on natural, technical, social, humanities; takes into account the mutual citation of publications developed and provided by ThomsonReuters; has built-in search, analysis and management of bibliographic information.	Free access from PIMU computers Access mode:http://apps.webofknowledge.com	Free access from PIMU computers

11.4.3. Open access resources.

No.	Name of the electronic resource	Brief description (content)	Access conditions
1	Federal Electronic Medical Library (FEMB)	Includes electronic analogues of printed publications and original electronic publications that have no analogues recorded on other media (dissertations, abstracts, books, magazines, etc.). [Electronic resource] - Access mode: http://neb.rf/	from any computer on the Internet
2	Scientific electronic library eLIBRARY.RU	The largest Russian information portal in the field of science, technology, medicine and education, containing abstracts and full texts of scientific articles and publications.[Electronic resource] - Access mode: https://elibrary.ru/	from any computer on the Internet.
3	Scientific electronic library of open access CyberLeninka	Full texts of scientific articles with annotations published in scientific journals in Russia and neighboring countries.[Electronic resource] - Access mode: https://cyberleninka.ru/	from any computer on the Internet

4	Russian State Library (RSL)	Abstracts for which there are copyright agreements with permission for their open publication[Electronic resource] - Access mode: http://www.rsl.ru/	from any computer on the Internet
5	Reference and legal system "Consultant Plus"	Federal and regional legislation, judicial practice, financial advice, legislative comments, etc. [Electronic resource] - Access mode: http://www.consultant.ru/	from any computer on the Internet

9. Material and technical support for mastering an academic discipline

9.1. List of premises for classroom activities for the discipline

pharmaceutical companies engaged in the manufacture of medicines

**structural divisions of educational and scientific organizations engaged in medical activities or pharmaceutical activities (clinics); medical organizations, including medical organizations that house structural units of educational and scientific organizations (clinical bases); organizations operating in the field of health care, including organizations in which structural units of educational and scientific organizations are located.*

9.2. List of equipment for classroom activities for the discipline

Industrial equipment of a pharmaceutical enterprise

*industrial, laboratory, instrumental equipment, etc.

9.3. A set of licensed and freely distributed software, including domestic production

Item no.	Software	number of licenses	Type of software	Manufacturer	Number in the unified register of Russian software	Contract No. and date
1	Wtware	100	Thin Client Operating System	Kovalev Andrey Alexandrovich	1960	2471/05-18 from 28.05.2018
2	MyOffice is Standard. A corporate user license for educational organizations, with no expiration date, with the right to receive updates for 1 year.	220	Office Application	LLC "NEW CLOUD TECHNOLOGIES"	283	without limitation, with the right to receive updates for 1 year.
3	LibreOffice		Office Application	The Document Foundation	Freely distributed software	
4	Windows 10 Education	700	Operating systems	Microsoft	Azure Dev Tools for Teaching Subscription	
5	Yandex. Browser		Browser	«Yandex»	3722	
6	Subscription to MS Office Pro for 170 PCs for FGBOU VO "PIMU" of the Ministry of Health of Russia	170	Office Application	Microsoft		23618/HN10030 LLC "Softline Trade" from 04.12.2020

10. List of changes to the working program (to be filled out by the template)

Federal State Budgetary Educational Institution of Higher Education
"Privolzhsky Research Medical University"
Ministry of Health of the Russian Federation
(FSBEI HE "PRMU" of the Ministry of Health of Russia)

Department of
Name of the department

CHANGE REGISTRATION SHEET

working program for the academic discipline
NAME OF THE ACADEMIC DISCIPLINE

Field of study / specialty / scientific specialty: _____
(code, name)

Training profile: _____
(*name) - for master's degree programs*

Mode of study: _____
full-time/mixed attendance mode/extramural

Position	Number and name of the program section	Contents of the changes made	Effective date of the changes	Contributor's signature
1				

Approved at the department meeting
Protocol No. _____of _____20__

Head of the Department
_____ _____/_____
department name, academic title signature print name

Annex 1

Diary Form

Title page

Federal State Budgetary Educational Institution
higher education
"Nizhny Novgorod State Medical Academy"
Ministry of Health of the Russian Federation
Faculty of Pharmacy

Department of Management and Economics of Pharmacy and Pharmaceutical Technology

DIARY OF FIELD PRACTICE
ON PHARMACEUTICAL TECHNOLOGY

Student _____ group _____ course _____
faculty

_____
__
Full Name

Place of practice: _____
Name

_____
address, phone

Head of practice from a pharmaceutical enterprise_____

Head of practice from the department _____

M.P.