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 practice: PRACTICE FOR DRUG QUALITY CONTROL

Type of practice: INDUSTRIAL

Specialty: 33.05.01 PHARMACY

Qualification: PHARMACIST

Department: Pharmaceutical Chemistry and Pharmacognosy

Mode of study: full-time

Labor intensity of practice- 4 CU (144 academic hours)

Practice duration -2 and 2/3weeks (school days 16)

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 order of the Ministry of Science and Higher Education of the Russian Federation on March 27, 2018 N 219.

Developers of the working program:
O.A.Vorobeva, Associate Professor of the Department, PhD;
D.S. Malygina, Associate Professor of the Department, Ph.D.

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

Head of the Department of Pharmaceutical Chemistry
and pharmacognosy, Ph.D. _____ / O.V. Zhukova /

01.06.2021

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

01.06.2021

1. Type of practice - industrial

2. Method of conducting practice - visiting.

3. The form of the practice - continuously.

4. Scope of practice - 4 AH.

5. Duration of practice - 2 and 2/3 (144 hours) weeks/academic hours (AH).
Practice is held in the 9th semester according to the schedule.

6. List of planned learning outcomes during internship, correlated with the planned results of mastering the educational program

6.1. The purpose and objectives of the internship

*Purposes of passing practice on quality control of medicines*are: participation in the formation of relevant competencies in order to consolidate and improve theoretical knowledge and norms of professional ethics, to consolidate the theoretical knowledge, practical skills and abilities obtained in the educational process to solve specific problems of practical activity of a pharmacist-analyst in pharmacies and testing laboratories (UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC-7*).*

As a result of completing practice, the student should

Know:

– general methods for assessing the quality of medicinal products, the possibility of using each method depending on the method of obtaining medicinal products, raw materials, the structure of medicinal substances, physical and chemical processes that may occur during storage and circulation of medicinal products;

– factors affecting the quality of medicines at all stages of circulation. Determination of the main factors depending on the properties of the drug (redox, ability to hydrolysis, polymerization, etc.). The possibility of preventing the influence of external factors on the good quality of medicines;

– chemical methods underlying the qualitative analysis of drugs. The main structural fragments of medicinal substances, according to which the identification of inorganic and organic medicinal substances is carried out. General and specific reactions to individual cations, anions and functional groups;

– chemical methods underlying the quantitative analysis of drugs. Equations of chemical reactions taking place during acid-base, redox, precipitation, complexometric titration;

– the principles underlying the physicochemical methods of drug analysis;

– equipment and reagents for chemical analysis of medicines. Requirements for reagents for testing for purity, identity and quantitation;

– equipment and reagents for physical and chemical analysis of medicinal substances. Schematic diagram of a refractometer, photocolorimeter, spectrophotometer, GLC, HPLC;

– the structure of normative documents regulating the quality of medicines. Features of the structure of FS and FSP;

– features of the analysis of individual dosage forms. The concepts of disintegration, dissolution, abrasion. Features of the analysis of soft dosage forms;

– methods for determining the physicochemical constants of medicinal substances: melting point, rotation angle, specific absorption rate, boiling point;

– concept of validation. Validation characteristics of qualitative and quantitative analysis methods;

Be able to:

– weigh on pharmacy and analytical scales;
– measure liquid volumes using measuring cylinders, burettes, pipettes;
– evaporate liquids in a water and sand bath;
– titrate with a pipette and burette;
– measure the refractive index with a refractometer;
– measure the amount of light absorption using a photocolorimeter and a spectrophotometer;
– measure the angle of rotation with a polarimeter;
– apply samples to a chromatographic plate or paper, prepare the mobile phase, carry out chromatography and development;
– fill the pycnometer;
– calculate the content of a substance based on the results of titrimetric or physico-chemical analysis;
– choose reactions for qualitative analysis of medicinal substances in accordance with the presence of certain structural fragments in them;
– interpret the results of drug analysis to assess their quality.

Possess:

– skills in assessing the quality of medicines according to the criterion "description";
– methods for determining the general quality indicators of pharmaceutical substances: solubility, melting point, density, acidity and alkalinity, transparency, color, ash, weight loss upon drying;
– methods for carrying out reactions to establish the authenticity of drugs by their structural fragments;
– skills in interpreting the results of UV and IR spectrometry, HPLC and GLC analysis chromatograms to confirm the identity of drugs;
– methods of thin-layer and paper chromatography of medicinal products and interpretation of its results;
– skills in testing the purity of medicines and setting limits for the content of impurities by chemical and physical methods;
– skills in the preparation of reagents, reference, titrated and test solutions.
– skills in the quantitative determination of drugs in substances and drugs by titrimetric methods;
– skills in the quantitative determination of drugs in substances and drugs by physical and chemical methods;
– skills in performing analysis and quality control of medicines manufactured in pharmacies;
– skills in filling out documentation for quality control of medicines.

6.2. **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

p / no.	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	Evaluation tools
1.	UC-1.	Able to	UC-1.1. An-	• methodology of abstract thinking	• abstract, analyze and synthesize the	• methods of self-control, abstract	topic poll

		realize critical analysis of problem situations based on a systematic approach, develop strategy actions	alyzes the problem situation as a system identifying its components and connections between them UC-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 interdisciplinary approaches UC-1.5. Uses logical and methodological tools for critical	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.	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.	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	

			evaluation of modern concepts of philosophi-cal and so-cial nature in its subject areas				
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-1.1. Applies basic biological methods of analysis for the development, research and examination of pharmaceuticals and medicinal plant raw materials GPC-1.2. Applies basic physical-chemical and chemical analysis methods for the development, research and examination of medicinal products and medicinal plant raw materials GPC-1.3. Applies the basic methods of physical-chemical analysis in the manufacture of medicinal products	•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, physicochemical 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.	tests, practical work, written tests, tests

			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				
3.	GPC-3.	Able to carry out professional activities taking into account specific economic, environmental, social factors within the framework of the system of regulations of the medicine circulation sphere	GPC-3.1. Complies with norms and rules established by the authorized state authorities when solving the tasks of professional activity in the field of medicine circulation GPC-3.3. Performs labor actions taking into account their impact on the environment, preventing the occurrence of environmental hazards	• laws and legislative acts of the Russian Federation, normative and methodological materials of the Ministry of Health of Russia, regulating the procedure for conducting examinations provided for in the state registration of medicines; •general principles of development, testing and registration of medicines; • the basic principles, strategies, methods and procedures for quality control of medicines in the conditions of pharmaceutical organizations used in the course of examinations provided for in the state registration of medicines, in accordance with the requirements of the current regulatory and legislative framework.	• put into practice the basic principles of the system of quality control and safety of medicines in the conditions of pharmaceutical organizations; • to organize and carry out the procedure for quality control of medicines at the level of their production, transportation and storage using methods of pharmacopoeial analysis.	• skills in organizing and conducting quality control of medicines at the level of their production, transportation and storage; • the main methods of pharmaceutical analysis provided for in the state registration of medicines; • skills in carrying out preventive measures to ensure the quality of medicines at the level of their production, transportation and storage.	topic poll
4.	GPC-6.	Able to understand	GPC-6.2. Performs an	modern means of computing technology	use modern computer technology and basic office	methods of practical use modern computers to search	practical work

		the principles of modern information technologies and use them to solve the tasks of professional activity	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		applications And graphic packages; evaluate way of implementing information systems and devices for solving task	information processing and fundamentals numerical methods for solving applied tasks	
5.	PC-4.	Able to participate in monitoring the quality, effectiveness and safety of medicines and medicinal plant raw materials	PC-4.1. Conducts pharmaceutical analysis of pharmaceutical substances, excipients and medicines for medical use of factory production in accordance with quality standards PC-4.2. Performs intra-pharmacy quality control of medicines	•laws and legislative acts of the Russian Federation, regulatory and methodological materials of the Ministry of Health of Russia, regulating the procedure for quality control of medicines in the conditions of pharmaceutical organizations; • methods of analysis used in the quality control of drugs in the conditions of pharmaceutical organizations; • monitor drug quality assurance systems; • the process of providing equipment and consumables for quality control in the conditions of pharmaceutical organizations;	• apply chemical, physico-chemical methods of intra-pharmacy quality of drugs in the conditions of pharmaceutical organizations; • draw up documentation of the established form for the control of manufactured medicinal products in the conditions of pharmaceutical organizations; • monitor drug quality assurance systems; • provide the process of quality control in pharmaceutical organizations with equipment and consumables.	• basic chemical and physico-chemical methods of intra-pharmacy quality control of drugs in the conditions of pharmaceutical organizations; • registration of documentation of the established sample for the control of manufactured drugs in the conditions of pharmaceutical organizations.	tests, practical work, written tests, tests

			for medical use manufactured in a pharmacy organization PC-4.3. Conducts pharmacognostic analysis of medicinal plant raw materials and medicinal herbal preparations PC-4.4. Informs in accordance with the procedure established by law about the non-compliance of the medicinal product for medical use with the established requirements or about the non-compliance of the data on the effectiveness and safety of the medicinal product with the data on the medicinal product contained in the instructions for its use				
6.	PC-7.	Able to carry out	PC-7.5. Monitors the compliance of the raw materials	requirements of regulatory documentation	carry out pharmacopoeial analysis of raw	methods of quality control of raw materials and	practical work

		operations related to the technological process in the production of medicines and their control	and excipients used with the requirements of regulatory documentation	for the raw materials and auxiliary materials used	materials and auxiliary materials used	auxiliary materials used	

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

7.1. The discipline belongs to the section of basic *B2.P.2*.

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

- *mathematics, computer science, physics, general and inorganic chemistry, physical and colloidal chemistry, analytical chemistry, organic chemistry, microbiology, biological chemistry, pharmaceutical chemistry, pharmacognosy*

8. The content of the practice.

No .p/ n	**Name of the section of the practice**	Types of academic work* (in AH)			**Current control form**
		Types of work	**aud**	**SIW – student's individual work**	
1.	**Theoretical training**	Acquaintance with government and ministry regulations on the organization of quality control of medicines. The role of declaration and certification in protecting the market from counterfeit products. Justification of the choice of methods of analysis and their validation. Requirements of general pharmacopoeial articles for the analysis of injectable dosage forms, tablets, granules,	6	3	interview

		syrups, eye drops, suspensions, emulsions, ointments and suppositories, medicinal plant materials and preparations based on it. The study of regulatory documents, instructions, regulations for the manufacture, quality control, sanitary regime and storage of medicines in pharmacies.			
2	**Preparatory stage**	Acquaintance with the structure, staff, premises of a pharmacy and a drug quality control laboratory. Passing an introductory briefing on labor protection and safety. Acquaintance with organizational and methodological work, the workplace of a pharmacist-analyst. The study of the rights and obligations of a pharmacist-analyst, the features of his work. The study of scientific and technical documentation for standardization and certification (declaration) of medicines, for the identification of defective and counterfeit medicines.	6	3	Abstract
3	**Production stage**				
3.1	Work at Laboratory (part 1)		**36**	**18**	
	Preparation of reference, titrated solutions and reagents.	Make calculations andsat preparation: • standard solutions at Cl-, S042-, Ca2+; • titrated solutions0.1 mol/l HCI, 0.1 mol/l, HC104, 0.1 mol/l NaOH,0.05 mol/l Trilon B; •reagents (4 items)	6	3	Work lab
	Carrying out pharmacopoeial analysis of medicines in accordance with the NTD (GF, FS, FSP) by sections: description; solubility; authenticity; transparency and color; acidity, alkalinity or pH of solutions; physical and chemical constants (density,	Conduct quality control of dosage forms (number of analyzes) • substances - 1; • tablets - 1; • solutions for injections - 1; • eye drops - 1; • suppositories - 1: • ointments - 1;	30	15	Analysis Protocol

	refractive index, specific rotation); quantitative determination by various methods (alkalimetry, acidimetry, argentometry, iodometry, nitritometry, complexometry, non-aqueous titration, etc.)	• medicinal plant materials - 1; • tinctures - 1.			
3.2	Work at Laboratory (part 2)		**48**	**24**	
	Analysis of purified water and water for injection, defect analysis	Perform analysis of purified water and water for injection. Carry out identificationat least 10 medicines coming from the stock department to the assistant's table. Fill in the journal of registration of the results of control of medicines for authenticity.	6	3	analysis protocol
	Analysis of drugs manufactured in a pharmacy according to prescriptions. Eye drops. Analysis of injectable dosage forms	Perform an eye drop test. To exercise control over the technology of solutions for injections containing stabilizers and fill in the register of the results of individual stages of the manufacture of injection solutions. Perform analysis of prepared solutions.	12	6	analysis protocol
	Liquid dosage forms of extemporaneous production and for stationary institutions (children's hospital, sanatoriums, dispensaries, polyclinics).	Perform analysis of solutions for internal and external use.	8	4	analysis protocol
	Solid dosage forms of extemporaneous production.	Perform analysis of multicomponent powders.	8	4	analysis protocol
	Analysis of concentrates, liquid drugs, semi-finished products and packaging, in-pharmaceutical preparations, perishable drugs.	Perform analysis of concentrates by refractometric and titrimetric methods, semi-finished products and packaging, intra-pharmaceutical preparations.	8	4	analysis protocol
4	**Final stage**	Preparation of reporting documentation on production practice and passing the test	6	3	offset
	The total labor intensity of the Federal State Educational Standard of Higher Education 4 credits / 144 hours.		**96**	**48**	

* - L – lectures; LP – laboratory practicum; P – practicals; S – seminars; SIW – student's individual work.

8.2. Thematic plan of lectures:not provided for by the Federal State Educational Standard* (practice is carried out in the form of independent work of students under the guidance of a teacher)
* in the context of the implementation of the practice program with the use of EIOS and DOT (see Appendix 1).

8.3. Thematic lesson plan:not provided for by the Federal State Educational Standard* (practice is carried out in the form of independent work of students under the guidance of a teacher)
* in the context of the implementation of the practice program with the use of EIOS and DOT (see Appendix 1).

8.4.Types and topics for student independent work (SIW): Practice is carried out in the form of independent work of students under the guidance of a teacher.

9. Forms of reporting on practice.

9.1. Practice diary.

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

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	«Yandex»	3722	

	Browser					
6	Subscription to MS Office Pro for 170 PCs for FGBOU VO "PIMU" of the Ministry of Health of Russia	170	Office Applica-tion	Microsoft		23618/HN10 030 LLC "Softline Trade" from 04.12.2020

10. Organization of current, intermediate and final control of knowledge

No. p / p	Types of control	Name of section of academic discipline	Evaluation tools		
			types	number of test questions	number of test task options
1	2	3	4	5	6
	offset	All sections of the discipline	Control questions	30	75
			Situational tasks	30	45

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

11.1. Key literature references

No.	Name according to bibliographic requirements	Number of copies	
		At the department	In the library
1.	Huynh-Ba K. Handbook of Stability Testing in Pharmaceutical Development (Regulations, Methodologies, and Best Practices) Electronic resource. - Springer, 2009. - 390 p.	Electrical version	-
2.	Jouyban A. Handbook Of Solubility Data For Pharmaceuticals Electronic resource. - CRC Press, 2010. - 554 p.	Electrical version	-
3.	Putz M. V. (Ed.) Quantum Frontiers of Atoms and Molecules[Electronic resource]. - Nova Science Publishers, 2011. - 673 p.	Electrical version	-
4.	The British Pharmacopoeia 2012. – London: The Stationery Office on Behalf of the Medicines and Healthcare Products Regulatory Agency (MHRA) [Electronic resource].	Electrical version	-
5.	The International Pharmacopoeia. 4th Edition[Electronic resource]. - WHO Pharmacopoeia Library. 2011.	Electrical version	-
6.	The United States Pharmacopeia (USP 32) and the 27th edition of the National Formulary (NF 27)	Electrical version	-

	[Electronic resource]. – Washington, DC: The United States Pharmacopeial Convention. 2009. - 815 p.		
7.	The Japanese Pharmacopoeia Sixteenth Edition[Electronic resource]. – Tokyo, The Committee on Japanese Pharmacopoeia, 2011. 2326 p.	Electrical version	-
8.	Pyatigorskaya N.V. and others. Rules for the organization of production and quality control of medicinal products from plant materials: textbook Electronic resource. - St. Petersburg: SpecLit, 2013. - 367 p.	Electrical version	-
9.	Pleteneva T.V. and others. Quality control of medicines: textbook Electronic resource. - M. : GEOTAR-Media, 2015. - 560 p. – Access mode: EBSStudent Advisor	Electrical version	-
10.	Order of the Ministry of Health of Russia dated October 26, 2015 N 751n "On approval of the rules for the manufacture and dispensing of drugs for medical use by pharmacy organizations, individual entrepreneurs licensed for pharmaceutical activities Electronic resource	Electrical version	-

11.2. Further reading:

p / no.	**Name according to bibliographic requirements**	**Number of copies**	
		in the library	at the department
1.	Belikov VG Synthetic and natural medicines : a brief guide / VG Belikov . - M.: Higher School, 1993. - 720 p.	2	-
2.	Laboratory work in pharmaceutical chemistry: Textbook / V. G. Belikov, I. Ya. Kul, G. I. Lukyanchikova, A. S. Saushkina and S. G. Tiraspolskaya; ed. E. N. Vergeichik and E. V. Kompantseva; Ed. organization Pyatigorsk State Pharmaceutical Academy. - 2nd ed., revised. and additional .. - Pyatigorsk: B.I., 2003. (2003) - 342 p.	203	-
3.	Guide to laboratory studies in pharmaceutical chemistry : textbook / EN Aksenova and OP Andrianova ; ed. A. P. Arzamastsev. - 3rd ed., revised. and additional .. - M .: Medicine, 2004. (2004) - 384 p.	20	-
4.	State Pharmacopoeia of the USSR: Issue 1: General methods of analysis. - 11th ed. - M.: Medicine, 1987. - 336 p.	32	-
5.	State Pharmacopoeia of the USSR: Issue. 2: General methods of analysis. Medicinal plant material. - 11th ed. - M.: Medicine, 2000. - 400 p.	5	-
6.	State Pharmacopoeia of the USSR: Issue. 2. General methods of analysis. Medicinal plant materials / redol. M. D. Mashkovsky, E. A. Babayan, A. N. Oboymakova, V. M. Bulaev, and V. A. Severtsev; Ed. organization Ministry of Health of the USSR. - 11th ed. - M.: Medicine, 1990. - 400 p.	25	-
7.	State Pharmacopoeia of the USSR. - 10th ed. - M.: Medicine,	1	-

	1968. - 1080 p.		
8.	Glushchenko N. N. Pharmaceutical chemistry: textbook / N. N. Glushchenko, T. V. Pleteneva and V. A. Popkov. - M. : Academy, 2004. (2004) - 384 s	118	-
9.	Soldatenkov A. T. Fundamentals of organic chemistry of medicinal substances / A. T. Soldatenkov, N. M. Kolyadina and I. V. Shendrik. - 3rd ed. - M.: Mir; M. : BINOM. Knowledge Laboratory, 2007. (2007) - 191 p.	1	-
10.	Granik V.G. Fundamentals of Medical Chemistry: Textbook / V.G. Granik. - M. : Vuzovskaya kniga, 2001. (2001) - 384 p.	1	-
11.	Slesarev V.I. Chemistry. Fundamentals of Living Chemistry: A Textbook for High Schools / V.I. Slesarev. - St. Petersburg. : Himizdat, 2000. - 768 p.	1	-

11.4. Electronic educational resources for teaching academic subjects:

11.4.1. 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 (VEBS)	Proceedings of the teaching staff of the Academy: 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

11.4.2. Electronic educational resources acquired by the University

No. p / p	*Name of the electronic resource*	*Brief description (content)*	*Access conditions*	*Number of users*
1.	DB “Medicine. Healthcare (HPE)" (EBS "Student Consultant")	Educational literature + additional materials (audio, video, interactive materials, test tasks) for higher medical and pharmaceutical education	from any computer on the Internet, using an individual login and password	General subscription of PIMU
2.	Electronic library system «BookUp»	Educational and scientific medical literature of Russian publishing houses, incl. translations of foreign publications	from university computers; from any computer on the Internet using an individual login and password Subscribed editions are available for reading.	General subscription of PIMU
3.	Electronic	National guidelines in	from any computer	General

	Medical Library "Doctor's Consultant"	all areas of medicine, clinical guidelines, textbooks, monographs, atlases, pharmaceutical reference books, audio and video materials, ICD-10 and ATC, recent publications in foreign journals with brief annotations in Russian	on the Internet, using an individual login and password	subscription of PIMU
4.	Domestic electronic periodicals	Medical periodicals	from the university computers on the platform of the SCIENTIFIC electronic library eLIBRARY.RU Subscribed editions are available for reading.	Not limited
5.	DB Medline Complete	Foreign full-text database of articles from scientific periodicals and collections of medical and natural science topics	from university computers; from any computer on the Internet, using an individual login and password	Not limited
6.	Springer Electronic Collection	Full-text scientific publications (journals, books, articles, scientific protocols, conference materials, etc.) in the natural sciences, medical sciences and the humanities	from university computers	PIMU subscription
7.	Electronic collection "Freedom" on the Science Direct platform	Books and periodicals of the publishing house "Elsevier" in the natural sciences, medicine and humanities	from university computers	PIMU subscription
8.	DB Scopus	International Science Citation Abstract Database	from university computers	PIMU subscription
9.	DB Web of Science Core Collection	International Science Citation Abstract Database	from university computers; from any computer on the Internet, using an individual login and password	PIMU subscription
10.	DB Questel Orbit	Questel Patent Database	from university computers	PIMU subscription

11.4.3 Open access resources

No. p/p	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.).	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.	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.	from any computer on the Internet
4.	Russian State Library (RSL)	Abstracts for which there are copyright agreements with permission for their open publication	from any computer on the Internet
5.	Reference and legal system "Consultant Plus"	Federal and regional legislation, judicial practice, financial advice, legislative comments, etc.	from any computer on the Internet

12. **Material and technical support for mastering an academic discipline**:

12.1. List of premises for classroom activities for the discipline:

1. Production pharmacies of the regions of the Russian Federation, pharmacies at healthcare facilities

3. Scientific base of the department

12.2. List of equipment for classroom activities for the discipline

For the organizational and final stages of practice - the necessary classroom fund of the department, furniture and equipment of classrooms, electronic computers, educational and methodological developments, library fund.

Pharmaceutical analysis laboratories are equipped with a sufficient number of chemical glassware and reagents for the individual work of each student, the necessary instruments and apparatus: refractometers, polarimeters, spectrophotometers in the UV and Visible regions, as well as in the IR region, photoelectrocolorimeters, pH meters, a chromatograph for highly efficient liquid chromatography, a device for determining the friability of tablets, a device for determining the disintegration of tablets and capsules, a device for determining the dissolution of tablets, a device for determining the melting point (MTP) with electric heating, a muffle furnace, a dry-air cabinet, analytical balances, pharmaceutical scales, a set of weights and others

13. **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

Lectures using DOT and EIOS

No. p/n	Subject
12.	Acquaintance with government and ministry regulations on the organization of quality control of medicines. The role of declaration and certification in protecting the market from counterfeit products.
13.	Justification of the choice of methods of analysis and their validation. Requirements of general pharmacopoeial articles for the analysis of injectable dosage forms, tablets, granules, syrups, eye drops, suspensions, emulsions, ointments and suppositories, medicinal plant materials and preparations based on it.
14.	The study of regulatory documents, instructions, regulations for the manufacture, quality control, sanitary regime and storage of medicines in pharmacies.

Theoretical classes (practical classes or seminars) using DOT and EIOS

No. p/n	Subject
	Acquaintance with the structure, staff, premises of a pharmacy and a drug quality control laboratory.
	Acquaintance with organizational and methodological work, the workplace of a pharmacist-analyst. The study of the rights and obligations of a pharmacist-analyst, the features of his work. The study of scientific and technical documentation for standardization and certification (declaration) of medicines, for the identification of defective and counterfeit medicines.

Independent work

No. p/n	Subject
–	Methods for the preparation of reference, titrated solutions and reagents.
–	Methods for conducting pharmacopoeial analysis of medicines in accordance with the NTD (GF, FS, FSP) by sections: description; solubility; authenticity; transparency and color; acidity, alkalinity or pH of solutions; physical and chemical constants (density, refractive index, specific rotation); quantitative determination by various methods (alkalimetry, acidimetry, argentometry, iodometry, nitritometry, complexometry, non-aqueous titration, etc.)