

Summary of the working program of the academic discipline

« PRACTICE FOR DRUG QUALITY CONTROL »

(name of the academic discipline)

General Educational Program of higher education (specialist's degree programs)

33.05.01 “Pharmacy”

Department: Pharmaceutical Chemistry and Pharmacognosy

1. The purpose of mastering the practice: participation forming the relevant competencies (UC-1), general professional (GPC-1, GPC -3, GPC -6) and professional (PC-4, PC-7) competencies

2. Position of the practice in the structure of the General Educational Program (GEP).

2.1. The practice refers to the core part of section of basic *B2.P.2*. The discipline is taught in 8 semester of study.

3. Deliverables of mastering the practice 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

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
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 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	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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 UC-1.5. Uses logical and methodological tools for critical evaluation of modern concepts of philosophical and social 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 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	<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> apply chemical, biological, physico-chemical and other methods of analysis during the examination of medicines. 	<ul style="list-style-type: none"> 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-3.	Able to carry out professional activities taking	GPC-3.1. Complies with norms and rules	<ul style="list-style-type: none"> laws and legislative acts of the Russian 	<ul style="list-style-type: none"> put into practice the basic principles 	<ul style="list-style-type: none"> skills in organizing and conducting

		into account specific economic, environmental, social factors within the framework of the system of regulations of the medicine circulation sphere	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	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.	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.	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.
4.	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

5.	PC-4.	Able to participate in monitoring the quality, effectiveness and safety of medicines and medicinal plant raw materials	<p>PC-4.1. Conducts pharmaceutical analysis of pharmaceutical substances, excipients and medicines for medical use of factory production in accordance with quality standards</p> <p>PC-4.2. Performs intra-pharmacy quality control of medicines for medical use manufactured in a pharmacy organization</p> <p>PC-4.3. Conducts pharmacognostic analysis of medicinal plant raw materials and medicinal herbal preparations</p> <p>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</p>	<p>•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;</p> <p>• methods of analysis used in the quality control of drugs in the conditions of pharmaceutical organizations;</p> <p>• monitor drug quality assurance systems;</p> <p>• the process of providing equipment and consumables for quality control in the conditions of pharmaceutical organizations;</p>	<p>• apply chemical, physico-chemical methods of intra-pharmacy quality of drugs in the conditions of pharmaceutical organizations;</p> <p>• draw up documentation of the established form for the control of manufactured medicinal products in the conditions of pharmaceutical organizations;</p> <p>• monitor drug quality assurance systems;</p> <p>• provide the process of quality control in pharmaceutical organizations with equipment and consumables.</p>	<p>• basic chemical and physico-chemical methods of intra-pharmacy quality control of drugs in the conditions of pharmaceutical organizations;</p> <p>• registration of documentation of the established sample for the control of manufactured drugs in the conditions of pharmaceutical organizations.</p>
6.	PC-7.	Able to carry out operations related to the technological process in the production of medicines and their control	PC-7.5. Monitors the compliance of the raw materials and excipients used with the requirements of regulatory documentation	requirements of regulatory documentation for the raw materials and auxiliary materials used	carry out pharmacopoeial analysis of raw materials and auxiliary materials used	methods of quality control of raw materials and auxiliary materials used

4. Volume of the academic discipline and types of academic work

Duration of practice - 2 and 2/3 (144 hours) weeks/academic hours (AH).

Practice is held in the 9th semester according to the schedule.

5. Sections of the academic discipline and competencies that are formed

№	Competence code	Section name of the discipline
1.	UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC-7	Theoretical training
2.	UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC-7	Preparatory stage
3.	UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC-7	Production stage
4.	UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC-7	Final stage