Summary of the working program of the academic discipline

« Pharmaceutical manufacturing technology »
(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 discipline: participation forming the relevant competencies (UC 1 (1.1.-1.4.)), general professional (GPC-1 (1.3., 1.4), GPC -6 (6.2., 6.3.)) and professional (PC-7 (7.1.-7.5.); PC-11 (11.1-11.3.)) competencies

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

2.1. The discipline refers to the core part of Block 1 of GEP HE. The discipline is taught in 8,9 semester of study.

3. 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	• 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

			strategy of solving the problem situations based on the system and 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, 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.
3.	GPC-6.	Able to understand the principles of modern information technologies and use them to solve the tasks of	GPC-6.2. Performs an effective search for information necessary to solve the tasks of professional activity using legal reference	modern means of computing technology	use modern computer technology and basic office applications And graphic packages; evaluate way of	methods of practical use modern computers to search information processing and fundamentals numerical methods for solving

		professional activity	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		implementing information systems and devices for solving task	applied tasks
4.	PC-7.	Able to carry out operations related to the technological process in the production of medicines and their control	PC-7.1. Ensures the level of proper production in accordance 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	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

			regulatory documentation			
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, including the technological stages PC-11.3. Ensures the reliability and effectiveness of all types of quality control of the received medicinal product, primarily ensuring intra-factory control, as well as participation in state and arbitration control	• 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 • 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	• 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 • 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	• 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 interpretation 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

				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 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	measurement results; • carry out informational, educational and sanitary-educational work;	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, forming an assortment and forecasting the need for drugs • health education skills

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

Total labor intensity of the discipline is 8 CU (288 AH)

Type of educational work	Labor intensity		Labor intensity in semesters	
	volume in credit units (CU)	volume in academic hours (AH)	8	9
classroom work, including	4.2	152	66	86

Lectures (L)	1.1	40	20	20
Practicals (P)	3.1	112	46	66
Student's individual work (SIW)	2.8	100	42	58
Mid-term assessment				
exam	1	36		36
TOTAL LABOR INTENSITY	8	288		

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

№	Competence code	Section name of the discipline
1.	UC-1 GPC-1 GPC -6 PC-7 PC-11	State regulation of the manufacture and production of medicinal products.
2.	UC-1 GPC-1 GPC -6 PC-7 PC-11	The main processes and devices of pharmaceutical technology in the production of soft dosage forms
3.	UC-1 GPC-1 GPC -6 PC-7 PC-11	The main processes and devices of pharmaceutical technology in the production of transdermal therapeutic systems (TTS)
4.	UC-1 GPC-1 GPC -6 PC-7 PC-11	The main processes and devices of pharmaceutical technology in the production of medicinal herbal preparations (HRP, phytopreparations).
5.	UC-1 GPC-1 GPC -6 PC-7 PC-11	The main processes and equipment of pharmaceutical technology in the production of dosage forms for parenteral use
6.	UC-1 GPC-1 GPC -6 PC-7 PC-11	Aerodisperse dosage forms
7.	UC-1 GPC-1 GPC -6 PC-7 PC-11	The main processes and equipment of pharmaceutical technology in the production of solid dosage forms.
8.	UC-1 GPC-1 GPC -6 PC-7	Prospects for the creation of new generation dosage forms and therapeutic systems.

	PC-11	