Summary of the working program of the academic discipline

« **Biotechnology** »
(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, UC-2), general professional (GPC-1, GPC -3, GPC -6) and professional (PC-7) competencies

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

2.1. The discipline Biotechnology refers to the core part (or the part formed by the participants of educational relations) of Block 1 of GEP HE (Academic discipline index).
The discipline is taught in 8 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 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 evaluation of modern concepts of philosophical and social nature in its subject areas	• 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

2.	UC-2.	Able to manage the project at all stages of its life cycle	UC-2.1. Formulates a project task on the basis of the set problems and a method of its solutions through the implementation of the project management UC-2.2. Develops a project concept within the framework of the designated problem: formulates the purpose, tasks, justifies the relevance, significance, expected results and possible areas of their application UC-2.3. Plans necessary resources, including taking into account their replaceability UC-2.4. Develops a project implementation plan using planning tools UC-2.5. Monitors the progress of the project, corrects deviations, makes additional changes to the project implementation plan, clarifies zones of responsibilities of project participants	principles for developing a project implementation plan in the field of professional activity at all stages of its life cycle	develop a project implementation plan in the field of professional activity at all stages of its life cycle, providing for problem situations and risks	methods of planning and executing projects under conditions of uncertainty, managing the project (supporting the implementation of the project)

3.	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	modern biotechnological methods for obtaining drugs: genetic engineering, protein engineering, engineering enzymology, chromosome engineering, cell engineering; the most important technological processes for the processing of plant and animal raw materials and the production of pharmaceutical products; technologies for the production of medicines based on the vital activity of microorganisms;	ensure the conditions for the aseptic conduct of the biotechnological process and its compliance with modern requirements for the organization of production; ensure compliance with the rules of industrial hygiene, environmental protection, labor, safety; take into account the influence of biotechnological factors on the efficiency of the technological process and maintain optimal conditions for the biosynthesis of the target product;	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; the ability to draw up a material balance and carry out calculations, taking into account the consumption rates of all types of the technological process in the production of various drugs by stages; rules for calculating the optimal technological parameters of fermentation and their correction; technique for carrying out all stages of immobilization and the use of immobilized biological objects;

4	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 for the development, testing and registration of biotechnological medicines	• put into practice the basic principles of the system of quality control and safety of biotechnological medicines in the conditions of pharmaceutical organizations;	• Skills in carrying out preventive measures to ensure the quality of biotechnological medicinal products at the level of their production, transportation and storage.
5	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
	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	basic terms and concepts of biotechnology; theoretical foundations of biopharmaceuticals; device and principles of operation of modern laboratory and production equipment; main trends in the development of pharmaceutical technology, new	draw up a material balance for individual components of the technological process use educational, scientific, popular science literature for professional activities;	the ability to draw up a material balance and make calculations taking into account the consumption rates of all types of technological processes in the production of various drugs by stages

				directions in the creation of modern dosage forms and therapeutic systems		

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

Total labor intensity of the discipline is 4 CU (144 AH)

Type of educational work	Labor intensity (VIII semester)	
	volume in credit units (CU)	volume in academic hours (AH)
classroom work, including	2	66
Lectures (L)	0.6	14
Practicals (P)	1.4	52
Student's individual work (SIW)	1	42
Mid-term assessment		
exam	1	36
TOTAL LABOR INTENSITY	4	144

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

№	Competence code	Section name of the discipline
1.	UC-1, UC-2, GPC-1, GPC -3, GPC -6, PC-7	Theoretical foundations of biotechnological productions
2.	UC-1, UC-2, GPC-1, GPC -3, GPC -6, PC-7	Main processes and devices of biotechnological productions
3.	UC-1, UC-2, GPC-1, GPC -3, GPC -6, PC-7	Fundamentals of technology for cultivating cells and tissues of multicellular organisms. Cellular engineering.
4.	UC-1, UC-2, GPC-1, GPC -3, GPC -6, PC-7	Selection and mutagenesis. Fundamentals of genetic engineering. Genetically engineered drugs.
5.	UC-1, UC-2, GPC-1, GPC -3, GPC -6, PC-7	Medical and pharmaceutical biotechnology.