

**Basic Degree Program  
in Specialty 33.08.03 Pharmaceutical Technology (Level of Top Qualification Personnel Training in  
Residency)**

***Terms, Workload of the Degree Program and Qualification of Graduates***

Name of the Basic Professional Degree Program (BPDP)	Qualification	Term of education according to the BPDP including the holidays provided after the completion of the State Final Certification	Workload (in credits)
BPDP in Residency	Pharmacist-analyst	2 years	120

***Purpose (Mission) of the Degree Program***

The mission of the degree program in 33.08.03 Pharmaceutical Chemistry and Pharmacognosy is training of practice-oriented high-skilled personnel of new formation, who are able to carry out professional activity in the field of development, production and quality control of medicinal products at high professional level in the field of circulation of medicinal products in accordance with the established healthcare requirements and standards.

The basic professional degree program is aimed at the implementation of the following principles, namely: application of the results of theoretical education in professional and pedagogical practices, carrying out of professional activities based on the continuous development and innovation.

***Demand for Graduates***

Graduates of the degree program in 33.08.03 Pharmaceutical Chemistry and Pharmacognosy are in demand with pharmaceutical organizations, pharmaceutical enterprises (public and private), quality supervision centers for medicinal products of the Russian Federation, in particular those in St. Petersburg and the Northwestern Federal District. JSC "St. Petersburg Pharmacies", CJSC "St. Petersburg Institute of Pharmacy", CJSC "BIOCAD", FSUE Saint Petersburg Scientific Research Institute of Vaccines and Serums of the FMBA of Russia, Scientific and Technological Company "POLYSAN" LTD, JSC "PHARMPROJECT", ROSBIO LLC, JSC Ivanovo Pharmaceutical Factory, LLC "GEROPHARM", LLC "Groteks", "SAMSON-MED" LLC and others are among them.

***Requirements for Enrollment in the Degree Program***

The persons with higher pharmaceutical education who have passed entrance examinations in accordance with the Regulations for Admission to Degree Programs, namely residency programs are allowed for enrollment.

***Graduate's Qualification Characteristic***

***Areas of Professional Activity***

The area of professional activity of graduates who have completed the residency program includes circulation of medicinal products.

According to the register of professional standards (the list of types of professional activity approved by Order No. 667n of the Ministry of Labor of Russia dated 29.09.2014), the areas of professional activity and fields of professional activity which the graduates who have completed the residency program (hereinafter referred to as graduates) can be engaged in include:

02 Healthcare (in the field of circulation of medicinal products and other pharmacy goods).

Graduates can be engaged in professional activity in other areas and (or) fields of professional activity if their education level and acquired competences correspond to the employee's qualification.

***Objects of Professional Activity***

The objects of professional activity of graduates of the degree program in 33.08.03 Pharmaceutical Chemistry and Pharmacognosy are:  
medicinal products;

a set of facilities and technologies aimed at creating conditions for development, manufacturing, quality control, circulation of medicinal products as well as control in the field of circulation of medicinal products according to the established healthcare requirements and standards.

### ***Types of Professional Activity***

Types of professional activity which graduates of the residency program are prepared for:

engineering and manufacturing;

control and permission;

organizational and managerial.

### ***Tasks of Professional Activity***

The graduate who has completed the residency program is ready to carry out the following job tasks:

#### **Engineering and manufacturing activities:**

- carrying out of medicinal product expertise;
- carrying out of chemico-toxicological expertise;

#### **Control and permission activities:**

- carrying out of control and permission procedures related to circulation of medicinal products and ensuring the quality of medicinal products;

#### **Organizational and managerial activities:**

- organization of control and permission procedures related to circulation of medicinal products;
- organization and implementation of measures for storage, transportation, seizure and destruction of medicinal products;
- maintenance of accounts and records in a pharmaceutical organization;
- management of personnel labor in pharmaceutical organizations and (or) their structural units proceeding from the health and safety requirements;
- compliance with the basic requirements of information security.

### ***List of Professional Standards Corresponding to the Professional Activity of Graduates Who Have Completed the Degree Program***

Item No.	Code of professional standard	Name of areas of professional activity. Name of professional standard
02 Healthcare		
2.	02.015	Pharmacist-analyst

### ***General Characteristic of the Degree Program***

#### ***Planned results of completing of the degree program (competences) and indicators of their achievement***

In accordance with the aims of the degree program and types of tasks of professional activity, the graduate of the degree program in 33.08.03 Pharmaceutical Chemistry and Pharmacognosy shall have the following competences characterized by the indicators of their achievement (Table 1)

**Table 1**

Codes	Competences, indicators of competence achievement
<b>UC-1</b>	<b>Readiness to think abstractly, analyze, synthesize</b>
UC-1.1	Develops and substantively argues a problem situation solving strategy based on system and interdisciplinary approaches

UC-1.2	Logically analyzes, systematizes and summarizes information, uses methods and techniques of argumentation culture in communication
<b>UC-2</b>	<b>Readiness to manage a team, perceive social, ethnic, religious and cultural differences in a non-judgmental manner</b>
UC-2.1	Develops a collaborative strategy and, on its basis, arranges the selection of team members to achieve the set goal, assigning roles in the team
UC-2.2	Settles conflicts and contradictions in business communication proceeding from the interests of all parties
<b>UC-3</b>	<b>Readiness to participate in teaching activities under programs of secondary and higher medical education or secondary and higher pharmaceutical education, as well as under additional training programs for persons with secondary vocational or higher education, according to the procedure prescribed by the federal executive body responsible for the development of public policy and statutory regulation in the field of healthcare</b>
UC-3.1	Participates in the development and update of working programs, learning and teaching materials for programs of secondary and higher pharmaceutical education based on the requirements of federal and local regulatory legal acts regulating activity in the field of secondary vocational and higher education
UC-3.2	Makes educational process for students with different forms of disability taking into account their needs and capabilities based on the application of technologies and teaching aids of inclusive education;
UC-3.3	Creates electronic educational-methodical resources in accordance with the principles of doing electronic learning, applying distance learning technology
<b>PC-1</b>	<b>Readiness to carry out the medicinal product expertise using chemical, biological, physical and chemical and other methods</b>
PC-1.1	Performs sampling for a specific analysis technique and applies standard techniques, guided by regulatory documentation in carrying out the analysis by various methods
PC-1.2	Interprets the results of the analysis by various chemical, biological, physical and chemical methods and formalizes the results of the analysis by filling out the relevant documentation.
<b>PC-2</b>	<b>Readiness to carry out the expertise provided for during the state registration of medicinal products</b>
PC-2.1	Uses the regulatory documentation which governs the carrying out of state registration of medicinal products
PC-2.2	Analyzes the data on the composition and quality of the medicinal product presented in the registration dossier of the medicinal product.
<b>PC-3</b>	<b>Readiness to carry out chemico-toxicological expertise and interpret its results</b>
PC-3.1	Performs chemico-toxicological analysis of biological objects on the preanalytical and analytical stages of the study
PC-3.2	Interprets the results of forensic chemical and chemico-toxicological expertise
PC-3.3	Arranges for the storage of biological samples, documents and stores the results of research
<b>PC-4</b>	<b>Readiness to apply special-purpose equipment intended for use in the professional sphere</b>

PC-4.1	Follows the operating rules for laboratory and technical equipment intended for laboratories dealing with quality control of medicinal products
PC-4.2	Selects and uses special-purpose equipment necessary for the implementation of the analysis technique.
<b>PC-5</b>	<b>Readiness to ensure the conditions of storage and transportation of medicinal products</b>
PC-5.1	Ensures the observance of storage conditions of medicinal products and medicinal plant raw material
PC-5.2	Ensures the observance of transportation conditions of medicinal products and medicinal plant raw material
<b>PC-6</b>	<b>Readiness to carry out the quality control of medicinal products in the conditions of pharmaceutical organizations</b>
PC-6.1	Performs sampling for quality control of medicinal products in the conditions of pharmaceutical organizations
PC-6.2	Reasonably selects the analysis method for quality control of medicinal products in the conditions of pharmaceutical organizations.
PC-6.3	Applies standard techniques, guided by regulatory documentation in carrying out the pharmaceutical analysis in the conditions of pharmaceutical organization.
<b>PC-7</b>	<b>Readiness to carry out procedures of import of medicinal products into the Russian Federation and export of medicinal products from the Russian Federation</b>
PC-7.1	Applies current regulatory documentation when carrying out procedures of import of medicinal products into the Russian Federation and export of medicinal products from the Russian Federation.
PC-7.2	Draws up the permits for import and export of medicinal products
PC-7.3	Communicates for business using a foreign language
<b>PC-8</b>	<b>Readiness to organize the quality control of medicinal products in the conditions of pharmaceutical organizations</b>
PC-8.1	Draws up standard operating procedures (SOP) when organizing the quality control of medicinal products in the conditions of pharmaceutical organization
PC-8.2	Applies standard operating procedures at various stages of quality control of medicinal products, including registration and assessment of analysis results
<b>PC-9</b>	<b>Readiness to use the basics of economic and legal knowledge in the professional activity</b>
PC-9.1	Applies state standards in the field of quality assessment of medicinal products, including State Pharmacopoeia
PC-9.2	Applies regulatory documents governing the general requirements for the competence of testing and calibration laboratories and in the field of good manufacturing practices
PC-9.3	Applies economic knowledge in solving tasks of professional activity
<b>PC-10</b>	<b>Readiness to apply basic management principles in the professional sphere</b>
PC-10.1	Applies basic principles of organization and HR design when planning the activities of a structural unit
PC-10.2	Manages the quality of the current performance of the structural unit
<b>PC-11</b>	<b>Readiness to carry out procedures of withdrawal of falsified, substandard and counterfeit medicinal products from civil circulation and their destruction</b>

PC-11.1	Performs a procedure for analysis of a specific medicinal product with justification of the chemical, physical and chemical or biological method of analysis and interprets the analysis results to confirm its quality
PC-11.2	Based on the current regulatory documentation, performs the procedure for preparation of falsified, substandard, counterfeit medicinal products, medicinal products that have become unusable, products with expired shelf life for withdrawal from circulation and subsequent destruction

*Mandatory part (name, workload, final discipline assessment)*

1. Business Communication Conflict Resolution Studies – 3 credits (108 hours), in-class work – 28 hours, pass-fail test
  2. Pedagogy – 3 credits (108 hours), in-class work – 28 hours, pass-fail test
  3. Logic and Theory of Argumentation – 3 credits (108 hours), in-class work – 30 hours, pass-fail test
  4. Pharmacy Innovation Management – 3 credits (108 hours), in-class work – 36 hours, pass-fail test, course project.
  5. Corporate Management – 3 credits (108 hours), in-class work – 32 hours, graded test
  6. Application of Current Methods in Pharmaceutical Analysis of Medicinal Products – 6 credits (216 hours), in-class work – 58 hours, examination
  7. Good Practices in Quality Control of Medicinal Products – 6 credits (216 hours), in-class work – 58 hours, examination
  8. Methodology for Detecting Falsified and Counterfeit Medicinal Products – 3 credits (108 hours), in-class work – 22 hours, pass-fail test
  9. Quality Management System in a Pharmaceutical Organization – 3 credits (108 hours), in-class work – 32 hours, pass-fail test
  10. Organization of Chemico-Toxicological Expertise – 3 credits (108 hours), in-class work – 32 hours, graded test
  11. Foreign Language – 3 credits (108 hours), in-class work – 28 hours, pass-fail test
  12. Current Approaches to Standardization of Medicinal Plant Raw Material and Herbal Formulations – 3 credits (108 hours), in-class work – 32 hours, pass-fail test
- Elective disciplines (name, workload, final discipline assessment)*
13. Standardization and Confirmation of Conformity of Medicinal Products – 3 credits (108 hours), in-class work – 30 hours, pass-fail test
  14. Environmental Safety of Medicinal Plant Raw Material – 3 credits (108 hours), in-class work – 30 hours, pass-fail test
- Optional subjects (name, workload, final discipline assessment)*
15. Implementation of GSP Principles in the Conditions of Pharmaceutical Organization – 2 credits (72 hours), in-class work – 20 hours, pass-fail test
  16. Current Methods of Separation of Substances in Phytochemical Analysis – 2 credits (72 hours), in-class work – 20 hours, pass-fail test
- Practices (name, workload, final assessment)*
17. Practice in Quality Control of Medicinal Products – 60 credits (2,160 hours), in-class work – 68 hours, graded test.
  18. Pedagogical Practice – 3 credits (108 hours), in-class work – 8 hours, pass-fail test
  19. Practice in Chemical Expertise – 3 credits (108 hours), in-class work – 5 hours, pass-fail test
  20. Practice in Medicinal Plant Cultivation – 3 credits (108 hours), in-class work – 5 hours, pass-fail test
- Elective disciplines (name, workload, final discipline assessment)*
21. Practice in High-Performance Liquid Chromatography of Medicinal Products – 3 credits (108 hours), in-class work – 5 hours, pass-fail test
  22. Practice in Quality Control of Medicinal Plant Raw Material and Herbal Formulations – 3 credits (108 hours), in-class work – 5 hours, pass-fail test
- State final certification*
23. Preparation for and Passing of State Examination – 3 credits (108 hours), in-class work – 6 hours, examination

***Resources Provision of the Degree Program***

The degree program is provided with learning and teaching documentation, as well as materials in all disciplines (modules) and practices, including electronic educational-methodical complexes posted in electronic information and educational environment of the University.

The University has facilities and resources that are in compliance with applicable fire safety rules and regulations and ensure all types of the disciplinary and interdisciplinary preparation, practical and scientific research works of students, provided for by the curriculum.

The list of facilities and resources, learning and teaching support, required for implementation of the degree program, includes the following: special rooms in the form of classrooms for conducting lecture-type activities, seminar-type activities, course work development (course work execution), group and individual tutorials, current control and midterm assessment. There are also rooms for independent work and rooms for storage and preventative maintenance of training equipment. Special rooms are equipped with designated furniture and teaching aids intended for presentation of teaching information to a large audience. Laboratories are equipped with laboratory equipment depending on the degree of complexity. Sets of demonstration equipment and illustrative study guides providing for topic-based illustrations and corresponding to discipline (module) programs, working educational programs of disciplines (modules), are offered for lecture-type activities.

Rooms for students' independent work are equipped with computer hardware with the possibility of connecting to the Internet network and access to electronic information and educational environment of the organization. Furthermore, students' independent work is arranged with the use of electronic resources of the University.

The library fund is provided with the required number of printed publications, moreover, there is an access to electronic library systems.

The University has the necessary licensed software package the composition of which is given in working programs of disciplines (modules) and is subject to annual update.

The students are provided with an access (remote access), including in the event of doing electronic learning, applying distance learning technology, to today's professional databases and inquiry and communications systems the composition of which is determined in working programs of disciplines (modules) and is subject to annual update.

During the whole period of studying every student and a teacher are provided for with an unlimited access (including the remote one) to electronic library systems and to electronic information and educational environment of the University from any place with the available Internet connection.

Electronic information and educational environment of the University provides for:

- the access to curricula, working programs of disciplines (modules), practices, editions of electronic library systems and electronic learning resources specified in working programs;
- recording of progress of the educational process, results of midterm assessment and results of the degree program completion;
- the formation of electronic portfolio of the student, including the preservation of student's works and grades for these works by any participants of the educational process;
- interaction between participants of the educational process, as well as synchronous and (or) asynchronous communication via Internet.

Functioning of electronic information and educational environment complies with the requirements of the legislation of the Russian Federation in the field of education and is provided for with the relevant means of information and communication technologies and qualification of the University employees who use and maintain it.

### ***Staffing of the Degree Program***

Implementation of the residency program is ensured by the senior academic staff of the University, as well as by persons engaged in the implementation of the residency program under the terms of the civil contract.

The percentage of the academic staff (reduced to integer rates) having education that corresponds to the profile of the discipline (module) taught in the total number of the academic staff implementing the residency program is at least 70 %.

The percentage of the academic staff (reduced to integer rates) having a degree and (or) an academic rank in the total number of the academic staff implementing the residency program is at least 65 %.

The percentage of staff (reduced to integer rates) among the heads and employees of organizations whose activities are related to the specialization (profile) of the residency program (having at least 3 years of work experience in this professional field) in the total number of staff implementing the residency program is at least 10%.

### ***Uniqueness and Competitive Advantages of the Top Qualification Personnel Training in Residency in Specialty 33.08.03***

#### ***Pharmaceutical Chemistry and Pharmacognosy***

The degree program is implemented for persons with higher pharmaceutical education. The relevance of this program lies in the training of high-skilled specialists in the field of quality control of medicinal products of intrapharmacy and industrial production.

Employers interested in residency graduates are involved in the educational process during the implementation of the training program: JSC “St. Petersburg Pharmacies”, LLC “Pharmamed”, Scientific and Technological Company “Polysan” LTD, Pharmaceutical Company Werteks and other leading manufacturers of medicinal products actively involved in the training of residents, especially within the manufacturing (clinical) practices.

The training is practice-oriented and is aimed at the formation of the general cultural knowledge and professional competences. High priority is given to the introduction of theoretical and practical aspects of mastering of high-tech methods of control of medicinal products of industrial and intrapharmacy production into the educational process, first of all, introduction of current pharmacopeial chemical and physical and chemical methods of medicinal product analysis, including methods of non-destructive testing of medicines.

The content of the program represents the needs of today’s labor market. Graduates of the residency program are in demand as pharmacists-analysts of industrial pharmacies, as well as pharmacists-analysts and chemists-analysts of quality control departments, quality assurance departments of pharmaceutical enterprises, testing laboratories of quality control centers for medicinal products.

During the manufacturing practice in quality control of medicinal products and during the State Final Certification, representatives of employers, who are heads of practice bases from relevant organizations and members of the State Final Certification, carry out active career guidance counseling, allowing graduates to get involved in the work processes of organizations more quickly.

Objects of professional activity of graduates who have completed the residency program are:

- medicinal products of intrapharmacy and industrial production;
- a set of facilities and technologies aimed at creating conditions for development, manufacturing, quality control, circulation of medicinal products as well as control in the field of circulation of medicinal products according to the established healthcare requirements and standards.

The graduate who has completed the residency program is ready to carry out the following job tasks:

- carrying out of expertise of medicinal product of intrapharmacy and industrial production;
- organization and carrying out of control and permission procedures related to circulation of medicinal products and ensuring the quality of medicinal products;
- organization and implementation of measures for storage, transportation, seizure and destruction of medicinal products;
- maintenance of accounts and records in a pharmaceutical organization.

Upon completion of the program, the graduates are awarded the qualification of “Pharmacist-analyst”.