

**Appendix to the Order of  
the Ministry of Health and  
Social Development of the  
Kyrgyz Republic dated  
"\_\_25\_"\_\_03\_\_ 2021 city  
of  
№\_\_317\_\_**

**COMPETENCE CATALOG  
BY SPECIALTY  
"PHARMACEUTICAL TECHNOLOGY" POSTGRADUATE  
LEVEL**

The catalog of competencies in the specialty "Pharmaceutical Technology " was developed by a working group consisting of:

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The catalog of competencies in the specialty "Pharmaceutical Technology " was discussed by employees of the I. K. Akhunbaev KSMA, specialists of the Ministry of Health and Social Development of the Kyrgyz Republic, The

Department of Medicines and Medical Devices, the CHI Fund under the Ministry of Health of the Kyrgyz Republic, members of the professional association "Pharmaceutical Union of Kyrgyzstan", the Association of manufacturers of Kyrgyzstan and representatives of pharmaceutical organizations.

**The catalog is reviewed:**

- M. K. Abdiev, Deputy Head of the Department of Information Technology. Director of the Department of Medicines and Medical Devices;
- Toktomatova Z. T., Director of LLC "Daniba" Bishkek.

**EXPLANATORY NOTE**

Scientific and technological progress in the twentieth century contributed to the active development of the pharmaceutical industry. Opened opportunities for the development of new technologies for the production of drugs that meet the requirements of quality, safety, a high degree of compatibility with minimal side effects in combination with maximum side-efficiency and easy-to-use by the patient, to implement technologies to improve productivity and efficiency pharmaceutical about enterprises to reduce the amount of waste and by-products, to reduce the burden on the environment and to reduce consumption of energy and raw materials.

Based on the above, it follows that highly qualified specialists should work in the field of development, production, and quality control of medicines, who are well versed in the theoretical foundations of pharmaceutical technology, and have the necessary skills and abilities to work. Pharmaceutical technology as one of the specialized disciplines is of great importance in the system of training pharmaceutical technologists.

According to the Decree of the Government of the Kyrgyz Republic "On Medical postgraduate education in the Kyrgyz Republic" dated July 31, 2007 No. 303, graduates of the Faculty of Pharmacy are provided with postgraduate education (residency) in pharmaceutical specialties, including pharmaceutical technology.

## **1. GENERAL PROVISIONS**

The residency program in the specialty "Pharmaceutical Technology" provides professional training for a specialist who has deep theoretical and practical knowledge and is ready to carry out professional activities. The term of study is 1 year, the form of study is full-time.

**1.1. The purpose of the residency** is to train a qualified pharmacist-technologist who has a system of general and professional competencies, is capable and ready for independent professional activities: production, technological and organizational management.

### **1.2. Residency tasks:**

- to develop in-depth knowledge on various residency issues, forming the competencies of a pharmacist-technologist who is able to successfully solve professional problems;
- prepare a pharmacist-technologist with analytical thinking, capable of managing pharmaceutical organizations and their divisions engaged in the field of drug circulation.
- to form a system of general and specialized knowledge and skills that will allow a pharmacist-technologist to freely navigate the issues of pharmaceutical technology, pharmaceutical development, organization of industrial production and quality control of medicines.

## **2. SPECIALIST COMPETENCIES.**

The competencies of a specialist characterize their potential ability to use the acquired knowledge, skills, and practical experience in professional and public activities.

The Catalog of postgraduate training competencies (residency) in the specialty "Pharmaceutical Technology" (hereinafter referred to as the Catalog) provides a list of specific competencies (knowledge and skills), a list of practical skills that a resident must master during the residency under the guidance of a mentor or independently. When developing the Catalog, we used the recommendations of the World Health Organization (WHO), the International Pharmaceutical Federation (FIP), the experience of foreign countries such as Austria, the United Kingdom, the United States, Switzerland, the Russian Federation, and regulatory

legal acts of the Kyrgyz Republic regulating activities in the field of drug circulation.

**2.1.** In this Catalog, competencies are divided into two groups: general and professional. They must be mastered by a specialist in accordance with the requirements of the Order of the Ministry of Health of the Kyrgyz Republic No. 691 dated 04.10.2018 "On approval of requirements for the structure of the basic professional educational program of postgraduate medical education (Residency of the Republic of Armenia) in the Kyrgyz Republic".

**2.2. General competencies** reflect the needs of society and the individual for the general cultural, social and personal qualities of the graduate, knowledge and ability to apply instrumental competencies upon completion of the residency program.

**Professional competencies** reflect the demands of the labor market regarding the readiness of a specialist to perform professional tasks and related labor functions from professional standards (if any) for the appropriate level of professional qualification.

The results of mastering the residency program are determined by the competencies acquired by the specialist, i.e. his ability to apply knowledge, skills and personal qualities in accordance with the tasks of professional activity.

### **2.3. Purpose of the document.**

This one The catalog should become normative part of the regulations for postgraduate training and, therefore, be valid for all postgraduate study programs of the residency program in the specialty "Pharmaceutical Technology".

### **2.4. Based on this Catalog:**

#### **Defined by:**

- Purpose and content of postgraduate training in residency in the specialty
- levels of professional competencies, knowledge, and practical skills of a specialist.

#### **Being developed:**

- Work programs
- Criteria for evaluating the quality of specialist training
- Standard requirements for certification of a specialist
- Standards of professional activity of a specialist
- **Being organized:**
- professional orientation of medical university graduates; - postgraduate training;
- Held:**
- Attestation of internships .

**2.5. The main users of this Catalog are:** - medical educational organizations that implement programs of higher postgraduate pharmaceutical education;

- pharmaceutical organizations that have licenses for pharmaceutical activities;
- professional pharmaceutical associations;
- internships;
- authorized body of executive power that performs the functions of developing state policy and regulatory regulation in the field of healthcare;
- other

### **3.            REGION                            PROFESSIONAL                            ACTIVITY**

#### **PHARMACIST-TECHNOLOGIST.**

The areas of professional activity of a pharmaceutical technologist who has completed a residency program are::

- healthcare (in the sphere of circulation of medicines, medical devices, and other pharmacy products));
- production and technological activities (in the sphere of circulation of medicines);
- education and science (in the field of scientific research);
- other areas of activity related to health protection.

#### **3.1. Types of professional activities for which graduates of the internships program in the specialty "Pharmaceutical technology" are prepared»:**

- production and technological infrastructure;
- organizational and managerial information.

### **3.2. Tasks of professional activity of a graduate of the residency program in the specialty "Pharmaceutical technology" in the field of: production and technological activities:**

- readiness to implement technological processes in the production and manufacture of medicines (PC-1); - readiness to ensure the quality of medicines in their production and manufacture (PC-2);
- readiness to use specialized equipment intended for use in the professional sphere (PC-3);

#### **organizational and managerial activities:**

- readiness to use basic economic and legal knowledge in professional activities (PC-4);
- readiness to apply the basic principles of management in the professional sphere (PC-5);
- readiness to organize technological processes in the production and manufacture of medicines (PC-6)

### **4. REQUIREMENTS FOR THE PLANNED RESULTS OF MASTERING THE EDUCATIONAL PROGRAM PROGRAMS PROVIDED BY THE DISCIPLINES AND PRACTICES OF THE RESIDENCY PROGRAM.**

As a result of mastering the residency program, the graduate should develop general and professional competencies: - readiness for abstract thinking, analysis, synthesis (**OK-1**);

- readiness to manage a team, to tolerate social, ethnic, confessional and cultural differences (**OK-2**);-readiness to participate in teaching activities in secondary and higher pharmaceutical education programs, as well as in additional professional programs for persons with secondary professional or higher pharmaceutical education (**OK-3**).
- #### **production and technological activities:**
- readiness to implement technological processes in the production and manufacture of medicines (PC-1);
  - readiness to ensure the quality of medicines in their production and manufacture (PC-2);
  - readiness to use specialized equipment intended for use in the professional sphere (PC-3);
- #### **organizational and managerial activities:**

- readiness to use the basics of economic and legal knowledge in professional activities (PC-4);
- readiness to apply basic principles management principles in the following areas:  
professional sphere (PC-5);
- readiness to organize technological processes in the production and manufacture of medicines (PC-6).

**To indicate the level of competence that needs to be achieved by the end of training in this discipline, the following gradation is used::**

**Level 1**-indicates that the specialist can independently carryout pharmaceutical activities in the field of production technology and organizational and managerial to solve professional problems.

**Level 2**-indicates that the specialist is well-versed in matters of professional activity and can perform certain functions.

**Thematic cycles of residency in the specialty "Pharmaceutical technology»**

<b>n/a number</b>	<b>Cycle names</b>	<b>Duration (week)</b>
1.	Technology of medicines.	20
2.	Pharmaceutical management and Marketing	4
3.	Medical and pharmaceutical commodity	science 4
4.	Biopharmaceutical	4
5.	Clinical pharmacology and fundamentals of pharmaceutical consulting	4
6.	Drug development	5
7.	Pedagogy and Psychology	3
8.	Checkpoint	2
9.	Credit	2
	<b>Total:</b>	<b>48</b>

**5. LIST OF MANIPULATIONS/SKILLS**

A graduate resident in the specialty " Pharmaceutical Technology "(position – pharmacist-technologist) must have the following skills (to work out during the internship in healthcare institutions and pharmaceutical organizations licensed for the production/manufacture of medicines):

	<b>Skills</b>	<b>Number of tasks completed together with the mentor</b>	<b>The number of tasks performed independently, but under the following conditions:</b>
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			<b>under the supervision of a mentor</b>
1.	Organize рабочее the workplace of a pharmacist-technologist	1	
2.	Conduct mandatory types of intra-apical monitoring	2	1
3.	Draw up written control certificates for the manufacture of extemporal dosage forms	2	1
4.	Choose storage conditions and types of packaging to maintain the stability of dosage forms	1	1
5.	Analyze purified water in a pharmacy	1	1
6.	Perform internal calibration of scales (production) with data recording (recording)	2	2
7.	Set/assign product series	2	
8.	Carry out weighing of raw materials with proper registration of documents (weighing protocols)	4	

9.	Perform cleaning of scales with data fixation (recording)	2	2
10.	Carry out grinding of raw materials with subsequent sieving with data recording (records)	2	2 (laboratory)
11.	Carry out cleaning of the equipment for grinding with data fixation (recording)	1	1
12.	Perform mixing of raw materials with recording of data (records)	3	2 (laboratory)
13.	Clean mixing equipment with	a 1	1 fix

	data (records)		
14.	Conduct the preparation of a humidifier-starch paste with the recording of data (records)	2	2 (laboratory)
15.	Conduct the preparation of a humidifier – povidone solution with data recording (records)	2	2 (laboratory)
16.	Carry out cleaning of the equipment for preparation of the humidifier with fixing of data (records)	1	1
17.	Carry out wet granulation of the mixture with data recording (records)	4	2 (laboratory)
18.	Perform cleaning of the granulator with data fixation (recording)	1	1
19.	Carry out drying of the wet mass with recording of data (records)	2	2 (laboratory)
20.	Carry out cleaning of the drying cabinet with recording of data (records)	1	1

21.	Carry out powdering of dry granulate with recording of data (records)	2	2 (laboratory)
22.	Submit an application for testing (quality control) of an intermediate product	2	
23.	Carry out cleaning equipment for dusting with data fixation (recording)	1	1
24.	Perform tableting of the tablet mass with data fixation (records)	2	2 (laboratory)
25.	Perform cleaning of the tablet press with data fixation (recording)	1	1
26.	Carry out encapsulation of a mixture of powders/granules in a manual capsulator with data recording (records)	2	2 (laboratory)

27.	Perform cleaning of the manual capsulator with data fixation (recording)	1	1
28.	Carry out encapsulation of a mixture of powders/granules in an automatic capsulator with data recording (recording)	1	1
29.	Perform cleaning of the automatic capsulator with data fixation (recording)	1	1
30.	Carry out primary packaging of tablets on strip packaging equipment with data recording (recording)	2	
31.	Perform cleaning of equipment on a strip package with data fixation (recording)	1	

32.	Carry out primary packaging of tablets on the equipment using a blister pack with data recording (recording)	2	
33.	Carry out cleaning of equipment according to the blister pack with data fixation (recording)	1	
34.	Carry out secondary packaging of tablets on cardboard equipment with data recording (recording)	2	
35.	Prepare the material balance of the production series	2	2 (laboratory)
36.	Draw up production protocols and packaging protocols for the manufactured series of products (tablets and capsules)	4	
37.	Apply for testing (quality control) of the finished product	4	

38.	Draw up documents for quality assessment (certification) of the released batch of the finished product	2	
39.	Manage the plant for obtaining water purified by reverse osmosis	1	
40.	Carry out work on the preparation of syrups/suspensions	1	
41.	Perform cleaning of syrup/suspension preparation equipment	1	
42.	Carry работы out filling operations out filling operations for syrups/suspensions	1	

44.	Perform cleaning of syrup/suspension filling equipment	1	
45.	Draw up production protocols and packaging protocols for the manufactured batch of products (syrups/suspensions)	1	
46.	Make hardware schemes for the production of various dosage forms		2
47.	Draw up technological instructions for the production of a series of medicinal products		2
48.	Prepare preliminary formulations for the pharmaceutical development of a generic medicinal product		2
49.	Use data from the biopharmaceutical classification system to predict biopharmaceutical properties/characteristics of drugs based on preliminary prescriptions		2
50.	Master the basics of setting expiration dates for manufactured medicines		2
51.	Prepare the registration dossier of the medicinal product according to the national procedure	2	
52.	Master the basics of preparing a drug registration dossier according to the EAEU procedures (in the OTD format)		1

53.	Conduct pharmaceutical expertise of the prescription and requirements, including for NS, PV and their precursors;	10	5
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## **Characteristics of post-graduate training institutions/organizations**

### **1. Department of Medicines and Medical Devices Main tasks:**

- implementation of the State policy on providing the population and healthcare organizations with medicines and medical devices;
- organization of a management system and control over the provision of safe, effective, high-quality medicines and medical devices to the population;
- determination of directions and organization of research activities to improve the methods of management, control and standardization of medicines and medical devices.

### **2. Biovit Pharmaceutical Plant (LLC) Bishkek**

- Production of medicines, food and biologically active additives;
- Participation in training of pharmaceutical industry personnel by::  
ensuring that university residents complete their academic/industrial internship on the basis of concluded contracts and within the framework of the Residency Regulations approved by the Decree of the Government of the Kyrgyz Republic dated 31.07.2007 No. 303 "On Medical Postgraduate Education in the Kyrgyz Republic".

### **3. Production pharmacy of BNITSTIO**

- Manufacture of sterile and non-sterile dosage forms in pharmacies;
- Participation in training of pharmaceutical industry personnel by:  
ensuring that university residents complete their academic/industrial internship on the basis of concluded contracts and within the framework of the Residency Regulations approved by the Government decree No. 303 of the Kyrgyz Republic dated 31.07.2007 "On Medical postgraduate education in the Kyrgyz Republic".

Note: due to production needs, as well as as educational organizations conclude contracts with other pharmaceutical organizations, internships are allowed in them.

## **6. REGULATIONS ON THE EXAMINATION/ATTESTATION.**

**The purpose** of the exam / attestation is to determine the level of knowledge and practical skills of residents who have been trained in the specialty

"Pharmaceutical technology" in accordance with the competence catalog.

**Composition of the exam board/Attestation Commission determines the Ministry of Health and Social Development of the Kyrgyz Republic: Tasks of the examination commission/attestation commission:**

1. organization of the exam/attestation;
2. conducting an exam/attestation and communicating the result;
3. review and correct exam questions no as needed if necessary;
4. formation of exam questions and bringing them to residents no later than 1 month before the exam / certification.

**Filing an appeal.** The appeal must be submitted after the exam on the same day.

**Exam structure:**

- 1 Part: computer testing;
- 2 part: a structured oral exam based on a discussion of practical skills with minimal criteria for results determined in advance (from 30 to 60 minutes).

**Admission to the exam.**

Graduate of the postgraduate educational program in the specialty "Pharmaceutical technology".

**Exam/attestation evaluation criteria:**

The assessment of each part of the exam, as well as the final assessment, is given with a note "passed" or "failed". The exam was successful if both parts of the exam were passed.

## **LITERATURE:**

1. Resolution of the Government of the Kyrgyz Republic "On Medical postgraduate education in the Kyrgyz Republic" dated July 31, 2007 No. 303.
2. Order of the Ministry of Health of the Kyrgyz Republic No. 691 dated 04.10.2018 " On approval of requirements for the structure of the basic professional educational program of postgraduate medical education (residency) in the Kyrgyz Republic".
3. Order of the Ministry of Health of the Kyrgyz Republic No. 653 dated 25.08.2020 "Nomenclature of medical and pharmaceutical specialties,

nomenclature of positions and correspondence of medical and pharmaceutical specialties to positions in healthcare organizations of the Kyrgyz Republic»

4. International Standards of the World Federation of Medical Education (WFME) for Improving the Quality of Postgraduate Medical Education (WFME, 2015), the World Health Organization (WHO) and the International Pharmaceutical Federation (IFF).
  5. Development of pharmaceutical practice: focus on the patient. - B.: 2008. -112
- C. City Hope International, Inc.
6. Federal State Educational Standard of Higher Education in Residential Specialties, Russian Federation.

Postgraduate medical education  
About the approval of the catalog of competencies of the  
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