## Summary of the working program of the academic discipline

## «STATE REGISTRATION AND EXPERTISE OF MEDICINES»

General Educational Program of higher education (specialist's degree programs): 33.05.01 Pharmacy

Department: Management and Economics of Pharmacy and Pharmaceutical Technology

- **1. The purpose of mastering the discipline** participation in forming the following competencies:
  - professional competences (PC-10, PC-11 (11.1)).

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

**2.1.** The discipline refers to the part formed by the participants of educational relations of Block 1 of GEP HE (B1.PER.E.7).

## 3. Deliverables of mastering the academic discipline and metrics of competence acquisition

Mastering the discipline aims at acquiring the following professional (PC) competencies

Ne   tence   code   competence   competence   corits part		Competence	The content of the competence	Code and name of the competence acquisition	As a result of mastering the discipline, the students should:		
carry out measures to control (supervise) licenses for the activities of legal entities and individuals the pharmaceutical activity pharmaceutical icensed for pharmaceutic cal cartivities, to comply with mandatory requirement s  **Software of the activities of legal entities and individuals the procedure established by law regarding the compliance of activities, to compliance of activities, to compliance of activities, to mandatory requirement s  **Software of the procedure of activities, to compliance of activities and on its safety and effectiveness**  **Software of the procedure of activities, to compliance of activities, to one its safety and effectiveness**  **Software of the activities of legal of the activities and individuals who have legislation in the pharmaceutical activity of development, registration and examination of the procedure of the procedure for registration and examination of drugs, taking into account their origin, type and level of novelty; — the structure of the state registration of drugs in order to obtain a registration of male velop documents of male velop drugs in order to obtain a registration of drugs in the framework of the procedure o	№				know	be able to	possess
- principles, of medicinal execution of	1.	PC-10	carry out measures to control (supervise) the activities of legal entities and individuals licensed for pharmaceuti cal activities, to comply with mandatory requirement	the activities of legal entities and individuals who have licenses for pharmaceutical activity PC-10.2. Monitors the procedure established by law regarding the compliance of available medicines for medical use, instructions and data on its safety and	requirements of domestic and foreign legislation in the field of development, registration and examination of drugs;  – key features of the procedure for registration and examination of drugs, taking into account their origin, type and level of novelty;  – the structure of the state register of medicinal products for medical use and other official sources of information in the field of circulation of medicines;  – principles,	program of preclinical and clinical studies for various drugs; — analyze the data of (pre-)clinical trials to assess the quality, efficacy and safety of drugs in order to subsequently develop programs of measures for the registration and examination of drugs in order to obtain a registration certificate or obtain permission to conduct a clinical trial; — develop documents submitted for state registration and examination of medicinal	working with the state register of medicines for medical use;  - skills in working with the state register of issued licenses for the right to manufacture medicines;  - skills in organizing procedures within the framework of pre-registration preparation and in the process of state registration of medicinal products;  - skills in issuing an application for state registration of medicinal products;  - skills in the development and

procedure for	formation of a
state registration	registration
of medicinal	dossier in
products;	accordance with
- the procedure	the current
for planning the	legislation;
preparatory	- skills of
stages of the state	examination of
registration of	documentation
medicinal	included in the
products;	registration
- the structure	dossier of the
and procedure for	medicinal
the formation of a	product;
registration	- skills in issuing
dossier for	an expert report
various drugs;	on the results of
- domestic and	examinations
foreign	within the
requirements for	framework of
conducting and	state registration;
presenting the	– skills in
results of the	obtaining a
study of	marketing
bioequivalence	authorization for
and biosimilarity	a medicinal
of drugs;	product for
- requirements	medical use
for the execution	
of an application	
for state	
registration of	
medicinal	
products;	
- the procedure	
for examination	
within the	
framework of the	
state registration	
of medicinal	
products;	
- the procedure	
for making	
changes to the	
dossiers of	
registered	
medicinal	
products;	
- the procedure	
for suspending	
and canceling the	
state registration	
of medicinal	
products;	
– basic	
principles and	
procedure for	

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				conducting		
				examinations in		
				the process of		
				state registration		
				of medicinal		
				products;		
				- the procedure		
				for inclusion in		
				the state register		
				of pharmaceutical		
				substances;		
				– rules for		
				registration of		
				medicinal		
				products in		
				accordance with		
				the requirements		
1				of the Eurasian		
1				Economic Union.		
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2.	PC-11	Able to take	PC-11.1. Participates	- current	– develop a	- skills in
		part in	in events, including	requirements of	program of	working with the
		measures to	the preparation and	domestic and	preclinical and	state register of
		ensure the	verification of	foreign	clinical studies	medicines for
		quality of	documents	legislation in the	for various drugs;	medical use;
		medicines in	responsible for the	field of	<ul> <li>analyze the</li> </ul>	<ul><li>skills in</li></ul>
		industrial	quality of medicines	development,	data of (pre-	working with the
		production		registration and	)clinical trials to	state register of
				examination of	assess the quality,	issued licenses
				drugs;	efficacy and	for the right to
				<ul><li>key features of</li></ul>	safety of drugs in	manufacture
				the procedure for	order to	medicines;
				registration and	subsequently	- skills in
				examination of		
					develop programs	organizing
				drugs, taking into	of measures for	procedures within
				account their	the registration	the framework of
				origin, type and	and examination	pre-registration
				level of novelty;	of drugs in order	preparation and
				- the structure of	to obtain a	in the process of
				the state register	registration	state registration
				of medicinal	certificate or	of medicinal
				products for	obtain permission	products;
1				medical use and	to conduct a	<ul><li>skills in issuing</li></ul>
1				other official	clinical trial;	an application for
1				sources of	– develop	state registration
1				information in the	documents	of medicinal
1				field of	submitted for	products;
1				circulation of	state registration	- skills in the
1				medicines;	and examination	
1				· ·	of medicinal	development and
1				– principles,		execution of
1				rules and	products.	documents for the
1				procedure for		formation of a
1				state registration		registration
1				of medicinal		dossier in
1				products;		accordance with
				- the procedure		the current
1				for planning the		legislation;
				preparatory		,
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stages of the state	- skills of
registration of	examination of
medicinal	documentation
products;	included in the
- the structure	registration
and procedure for	dossier of the
the formation of a	medicinal
registration	product;
dossier for	- skills in issuing
various drugs;	an expert report
- domestic and	on the results of
foreign	examinations
requirements for	within the
conducting and	framework of
presenting the	state registration;
results of the	– skills in
study of	obtaining a
bioequivalence	marketing
and biosimilarity	authorization for
of drugs;	a medicinal
- requirements	product for
for the execution	medical use
of an application	Interior was
for state	
registration of	
medicinal	
products;	
- the procedure	
for examination	
within the	
framework of the	
state registration	
of medicinal	
products;	
- the procedure	
for making	
changes to the	
dossiers of	
registered	
medicinal	
products;	
- the procedure	
for suspending	
and canceling the	
state registration	
of medicinal	
products;	
- basic	
principles and	
procedure for	
conducting	
examinations in	
the process of	
state registration	
of medicinal	
products;	
- the procedure	
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	for inclusion in	
	the state register	
	of pharmaceutical	
	substances;	
	– rules for	
	registration of	
	medicinal	
	products in	
	accordance with	
	the requirements	
	of the Eurasian	
	Economic Union.	

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

	Labor	Labor intensity		
Type of educational work	volume in	volume in	(AH) in	
Type of educational work	credit units	academic	semesters	
	(CU)	hours (AH)	9	
Classroom work, including	0,61	22	22	
Lectures (L)	0,17	6	6	
Laboratory practicum (LP)*	Laboratory practicums are not stipulated			
Practicals (P)	0,44	16	16	
Seminars (S)	Seminars are not stipulated			
Student's individual work (SIW)	0,39	14	14	
Mid-term assessment				
credit/exam (specify the type)			credit	
TOTAL LABOR INTENSITY	1	36	1	

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

№	Compete nce code	Section name of the discipline	The content of the section in teaching units
1	PC-10 PC-11	State registration and expertise of medicines	Fundamentals of the state policy in the field of drug provision to the population. General characteristics of the drug supply system of the Russian Federation. Organization and provision of drug care in the Russian Federation. Programs to improve drug supply based on the list of essential medicines. State regulation of pricing for medicines. Problems and prospects for the development of the pharmaceutical industry of the Russian Federation.  Legislative basis of drug provision to the population.  Regulatory and legal framework in the field of organization of drug provision to the population at the present stage. Federal
			Regulations "On the Circulation of Medicines", "On Licensing certain types of activities", "On Narcotic Drugs and Psychotropic Substances", "On the Basics of Protecting the Health of Citizens in the Russian Federation"  The system of drug supply to the population in the Russian Federation. Medical and pharmaceutical organizations in the system of drug provision. Types of consumers. Characteristics of types of medical care and types of medical organizations.

Types and characteristics of pharmaceutical organizations in the system of drug provision. Types and characteristics of consumers of medicines.

Organization of drug provision to end users. Organization of drug provision in outpatient and polyclinic treatment. Organization of work of pharmacies. Organization of drug provision for citizens who have the right to receive drugs free of charge or on preferential terms for outpatient treatment. Programs and state guarantees of free medical care for citizens. Procedure for providing citizens with the necessary medicines.

Organization of drug provision for medical organizations. The procedure for drug provision of inpatients. Fundamentals of the formulary system in the health care of the Russian Federation. Modern models of drug provision for inpatient patients. The appointment of drugs in the provision of medical care in stationary conditions. The procedure for the release of goods from the pharmacy to the departments and offices of the Ministry of Defense. Accounting for released goods.

Pharmacoeconomic aspects of providing drug care to the population. Characteristics of drug consumption. Methods for determining the need for medicines. Types of demand for medicines. Concepts of need, demand, consumption. Types of consumption and factors affecting the consumption of medicines. Methods for determining the need for medicines. Types of demand. Types of demand.