Federal State Budgetary Educational Institution of Higher Education "Privolzhsky Research Medical University" Ministry of Health of the Russian Federation



WORKING PROGRAM

Name of the academic discipline: Pharmaceutical manufacturing technology

Specialty: 33.05.01 PHARMACY

Qualification: PHARMACIST

Department: Pharmaceutical Chemistry and Pharmacognosy

Mode of study: full-time

Labor intensity of the academic discipline: 288 academic hours

Nizhny Novgorod 2021 The working program has been developed in accordance with the Federal State Educational Standard for the specialty 33.05.01_"Pharmacy", approved by the order of the Ministry of Science and Higher Education of the Russian Federation dated March 27, 2018 N 219 (Registered in the Ministry of Justice of Russia on April 16, 2018 N 50789).

Developers of the working program:

Associate Professor of the Department of Pharmaceutical Chemistry and Pharmacognosy, Ph.D. Volkov A.A.

The program was reviewed and approved at the department meeting (protocol No. 1 of 08/29/2021)

Head of the Department, ON Ph.D. Zhukova O.V.

29 August 2021

AGREED Deputy Head of EMA ph.d. of biology

Br Lovtsova L.V.

(signature)

29 August 2021

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1. The purpose and objectives of mastering the academic discipline Pharmaceutical manufacturing technology

- 1.1. The purpose of mastering the discipline:
- universal competencies (UC 1 (1.1.-1.4.))
- general professional competencies (GPC-1 (1.3., 1.4), GPC -6 (6.2., 6.3.);
- professional competencies (PC-7 (7.1.-7.5.); PC-11 (11.1-11.3.)).

1.2. Tasks of the discipline - As a result of completing the discipline, the student should: Know:

- requirements for maintaining subject-quantitative accounting of medicines
- requirements for maintaining reporting documentation in pharmaceutical organizations, professional office work
- classification of narcotic drugs, psychotropic, toxic chemicals, biological agents, radioactive substances and their physical and chemical characteristics;
- technology of dosage forms obtained under the conditions of pharmaceutical production: powders, collections, granules, capsules, microgranules, microcapsules, dragees, tablets, aqueous solutions for internal and external use, solutions in viscous and volatile solvents, syrups, aromatic waters, tinctures, extracts, ophthalmic dosage forms, solutions for injections and infusions, suspensions for enteral and parenteral use, emulsions for enteral and parenteral use, ointments, suppositories, patches, pencils, films, aerosols;
- technology for the manufacture of medicines in a pharmacy: powders, aqueous solutions for internal and external use, solutions in viscous and volatile solvents, ophthalmic dosage forms, solutions for injections and infusions, suspensions for entheal and parenteral use, emulsions, aqueous extracts from medicinal plant materials, complex combined preparations with a liquid dispersion medium, ointments, suppositories;
- normative documentation regulating the production and quality of medicines in pharmacies and pharmaceutical enterprises;
- nomenclature of modern excipients, their properties, purpose;
- theoretical foundations of biopharmacy, pharmaceutical factors influencing the therapeutic effect in the extemporaneous and industrial production of dosage forms
- arrangement and principles of operation of modern laboratory and production equipment;
- analysis methods used in drug quality control and described in the State Pharmacopoeia
- normative documentation regulating the manufacture, production and quality of medicines at pharmaceutical enterprises;
- technology of dosage forms obtained in the conditions of pharmaceutical production Be able to:
- maintain reporting documentation in accordance with established requirements
- register data on manufactured drugs
- draw up basic technological and instrumental schemes for the production of finished medicines
- draw up a material balance and carry out calculations taking into account the consumption rates of the entire technological process by stages
- draw up a technological section of the industrial regulation for the production of finished dosage forms

- carry out step-by-step control at the stages of manufacturing the finished product and during dispensing; as well as standardize the dosage form for technological and biopharmaceutical indicators in accordance with the current regulatory documents
- make fragments of ND on LF
- work independently with educational and reference literature;
- ensure compliance with the rules of industrial hygiene, environmental protection, labor, safety
 - **Possess:**
- the skills of conducting subject-quantitative accounting of certain groups of drugs and other substances subject to such accounting
- skills in maintaining reporting documentation in the prescribed manner
- skills in maintaining registration of data on the manufacture of medicinal products (filling out a written control passport; in the case of using in the manufacture of drugs that are subject to quantitative accounting, registration of the reverse side of the prescription)
- basic information transformation technologies: text, spreadsheet editors; technique of working on the Internet for professional activities;
- 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;
- develop an accounting policy, keep records of inventory items: cash and settlements, prepare reports for internal and external users of accounting information

2. Position of the academic discipline in the structure of the General Educational Program of Higher Education (GEP HE) of the organization.

2.1. The discipline **Pharmaceutical manufacturing technology** refers to the core of Block 1 of GEP HE (Academic discipline index).

The discipline is taught in the 8th and 9th semesters.

2.2. The following knowledge, skills and abilities formed by previous academic disciplines are required for mastering the discipline:

- general chemistry
- physical chemistry
- pharmaceutical technology
- pharmaceutical chemistry
- pharmacology
- clinical pharmacology with the basics of pharmacotherapy
- management and economics of pharmacy

2.3. Mastering the discipline is required for forming the following knowledge, skills and abilities for subsequent academic disciplines:

- practice in general pharmaceutical technology (manufacturing practice)

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

N⁰	Compe-	The content of the competence (or its	Code and name of the competence ac-	As a result of mastering the discipline, the students should:		
	tence code	part)	quisition metric	know	be able to	

						possess
1.	UC-1.	Able to realize critical anal- ysis of problem sit- uations based on a systematic ap- proach, develop strategy actions	UC-1.1. Analyzes the problem situation as a system identifying its com- ponents and connec- tions between the- mUC-1.2. Identifies gaps in the infor- mation needed to solve a problem situ- ation, and designs processes for their elimination UC-1.3. Critically assesses reliability of information sources, works with conflict- ing information from different sources UC-1.4. Develops and meaningfully argues the strategy of solving the prob- lem situations based on the system and interdisciplinary ap- proaches	 methodology of abstract thinking for systematiza- tion of processes and construction of cause-and- effect relation- ships; modern theoret- ical and experi- mental methods for the imple- mentation of own and borrowed results of scien- tific research into practice. 	 abstract, analyze and synthe- size the infor- mation received; highlight and to systematize the essential properties and connections of objects, to identi- fy the main pat- terns of the ob- jects 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 require- ments 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.	GPC-1.	Able to use basic biological, physical- chemical, chemical, mathematical meth- ods for the develop- ment, research and examination of med- icines, the manufac- ture of medicinal products	GPC-1.3. Applies the basic methods of physical-chemical analysis in the manu- facture of medicinal products GPC-1.4. Applies mathematical meth- ods and performs mathematical pro- cessing of data ob- tained during the de- velopment of medi- cines, as well as re- search and examina- tion 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, physico-chemical and other methods; • pharmacopocial methods of analysis used in the analysis of metabolicant. 	• apply chemical, biological, physi- co-chemical and other methods of analysis during the examination of medicines.	 ensuring the process of quality control of medicines with equipment and con- sumables; basic chemical, biological, physico- chemical and other methods of analysis during the examina- tion of medicines.

3.	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 nec- essary to solve the tasks of professional activity using legal reference systems and professional pharmaceutical data- bases GPC-6.3. Uses spe- cialized software for mathematical pro- cessing of observa- tional and experi- mental data in solv- ing problems of pro- fessional activity	dicinal products using chemical, biological, physi- cochemical and other methods. modern means of computing technology	use modern computer tech- nology and basic office ap- plications And graphic packag- es; evaluate way of imple- menting infor- mation systems and devices for solving task	methods of practical use modern computers to search information pro- cessing and funda- mentals numerical methods for solving applied tasks
4.	PC-7.	Able to carry out operations related to the technological process in the pro- duction of medicines and their control	PC-7.1. Ensures the level of proper pro- duction in accord- ance with the appli- cable rules and regu- lations PC-7.2. Participates in all technological operations carried out in the production of medicines at pharmaceutical en- terprises PC-7.3. Monitors compliance with the requirements of the technological regula- tions of production in order to comply with the norms of the technological process PC-7.4. Monitors compliance of the equipment and con- trol and measuring equipment used in production with the requirements of technological docu- mentation PC-7.5. Monitors the	requirements of regulatory docu- mentation for the raw materials and auxiliary materi- als used	carry out phar- macopoeial anal- ysis of raw mate- rials and auxilia- ry materials used	methods of quality control of raw mate- rials and auxiliary materials used

			compliance of the			
			raw materials and			
			excipients used with			
			the requirements of			
			regulatory documen-			
			tation			
5.	PC-11.	Able to take part in	PC-11.1. Participates	• principles	• analyze	• skills to log-
		measures to ensure	in events, including	of search,	and use the	ically and
		the quality of medi-	the preparation and	processing,	received	consistently
		cines in industrial	verification of doc-	analysis	infor- mation. Ar-	present the material of
		production	uments responsible for the quality of	and sys- tematiza-	gumented	scientific re-
			medicines	tion of sci-	and logical-	search in oral
			PC-11.2. Provides a	entific in-	ly state the	and written
			clear implementation	formation	content of	form.
			and execution of the	• conditions	their own	• skills of col-
			technological	for the cor-	conclusions	lecting, pro-
1			scheme in produc-	rect and	and conclu-	cessing, ana-
1			tion, taking into ac-	productive	sions	lyzing and
			count the verifica-	formulation	• work with	systematizing
			tion of the quality	of prob-	scientific	information
			indicators of the re-	lems and	literature,	on the re-
			ceived drug, includ-	tasks • the most	analyze the information	search topicmethods of
			ing the technological stages	important	received,	statistical
			PC-11.3. Ensures the	stages of	highlight	processing of
			reliability and effec-	develop-	the main	experimental
			tiveness of all types	ment and	points,	results of
			of quality control of	the most	form pri-	physical-
			the received medici-	relevant	mary hy-	chemical,
			nal product, primari-	areas of	potheses on	chemical, bio-
			ly ensuring intra-	research in	the topic of	logical and
			factory control, as	modern	scientific	biopharma-
			well as participation in state and arbitra-	world and	research	ceutical stud-
			tion control	domestic science	• use at least 900	ies; • skills of in-
				basic laws	terminolog-	terpretation of
				of physics	ical units	the calculated
1				and chem-	and termi-	values of
				istry, phys-	nological	thermody-
1				ical and	elements in	namic func-
1				chemical	the frame-	tions and on
1				phenomena	work of	their basis to
1				and regu-	oral and	predict the
1				larities	written .	possibility of
1				used in	communi-	implementa-
1				physical	cation; • inde-	tion and di-
1				and colloi- dal chemis-	• inde- pendently	rection of chemical pro-
1				try;	work with	cesses;
1				• the basic	education-	• the skills of
1				laws under-	al, refer-	conducting
				lying ana-	ence and	scientific re-
1				lytical	scientific	search to es-
L	1	l	1			0

		chemistry;	literature;	tablish the
		• the main	• carry out	relationship
		provisions	elementary	between
		of the theo-	statistical	physical and
		ry of ionic	processing	chemical
		equilibria	of experi-	properties and
		as applied	mental data	pharmacolog-
		to reactions	in physical	ical activity;
		of acid-	and chemi-	• to predict
		base, re-	cal experi-	physical and
		dox, pre-	ments; pro-	chemical
		cipitation	cess, ana-	transfor-
		and com-	lyze and	mations of
		plexomet-	generalize	medicinal
		ric charac-	the results	substances in
		ter;	of physical	the course of
		• scientific	and chemi-	their circula-
		bases of	cal obser-	tion and stor-
		classifica-	vations and	age;
		tion, no-	measure-	• interpret the
		menclature	ments; ap-	results of the
		and isomer-	ply the ac-	analysis, the
		ism of or-	quired	reasons for
		ganic com-	knowledge	the poor qual-
		pounds;	in the study	ity of medi-
		• classifica-	of analyti-	cines, indicate
		tion of nar-	cal, phar-	ways to ex-
		cotic drugs,	maceutical	clude their
		psycho-	chemistry,	possible poor
		tropic, tox-	pharma-	quality;
		ic sub-	cognosy,	• find and use
		stances,	pharmacol-	the necessary
		their physi-	ogy, toxi-	information
		cal and	cology,	to solve syn-
		chemical	drug tech-	thetic prob-
		characteris-	nology;	lems;
		tics;	• calculate	basic infor-
		• normative	absolute	mation trans-
		documenta-	and relative	formation
		tion regu-	errors of	technologies:
		lating the	measure-	text, spread-
		production	ment re-	sheet editors;
		and quality	sults;	technique of
		of medi-	• carry out	working on
		cines in	informa-	the Internet
		pharmacies	tional, edu-	for profes-
		and phar-	cational	sional activi-
		maceutical	and sani-	ties;
		companies;	tary-	develop a
		• nomen-	educational	business plan;
		clature of	work;	• analyze the
		industrial	work,	state of prop-
		prepara-		erty and lia-
		tions;		bilities of a
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• nomen-	pharmaceuti-
clature of	cal organiza-
modern	tion and en-
excipients,	terprise, as-
their prop-	sess the de-
erties, pur-	gree of risk of
pose;	entrepreneur-
• modern	ial activity;
biotechno-	• carry out
logical	segmentation
methods	of the phar-
for obtain-	maceutical
ing drugs:	market and
genetic en-	select target
gineering,	segments;
	• methods for
protein en-	
gineering,	studying de-
engineering	mand, form-
enzymolo-	ing an as-
gy, chro-	sortment and
mosome	forecasting
engineer-	the need for
ing, cell	drugs
engineer-	• health edu-
ing;	cation skills
• main	
trends in	
the devel-	
opment of	
pharmaceu-	
tical tech-	
nology,	
new direc-	
tions in the	
creation of	
modern	
dosage	
forms and	
therapeutic	
-	
systems • theoreti-	
cal founda-	
tions of	
biopharma-	
cy, phar-	
maceutical	
factors in-	
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neous and	
industrial	
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		production of dosage	
		forms	

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

No. p /	Compete nce code	Section name of the discipline	The content of the section in teaching units
<u>p</u> 1.	UC-1 GPC-1 GPC -6 PC-7 PC-11	State regulation of the manufacture and production of medicinal prod- ucts.	State regulation of the manufacture and produc- tion of medicinal products.GMP rules, organi- zation of pharmaceutical production
2.	UC-1 GPC-1 GPC -6 PC-7 PC-11	The main pro- cesses and devices of pharmaceutical technology in the production of soft dosage forms	Ointments, gels, creams, liniments, pastes Rectal and vaginal dosage forms Medical pencils
3.	UC-1 GPC-1 GPC -6 PC-7 PC-11	The main pro- cesses and devices of pharmaceutical technology in the production of transdermal thera- peutic systems (TTS)	Application medicines
4.	UC-1 GPC-1 GPC -6 PC-7 PC-11	The main pro- cesses and devices of pharmaceutical technology in the production of me- dicinal herbal preparations (HRP, phytopreparations).	Medicinal herbal preparations (phytoprepara- tions) Methods and apparatus for extraction extracts Oil extracts, elixirs, balms
5.	UC-1 GPC-1 GPC -6 PC-7 PC-11	The main pro- cesses and equip- ment of pharma- ceutical technology in the production of dosage forms for parenteral use	Injectable dosage forms Production of ampoules and vials for injection dosage forms Stabilization and purification of injection solu- tions in factory production infusion solutions. Emulsions and suspensions for parenteral administration
6.	UC-1	Aerodisperse	Characteristics of aerosol dosage forms. Fea-

	GPC-1 GPC -6 PC-7 PC-11 UC-1 GPC-1	dosage forms The main pro- cesses and equip-	tures of the technology for the manufacture of drugs under pressure. Devices and auxiliary materials in the manufacture of aerosols. New aerosol packages Pills Technological and physico-chemical character-
7.	GPC -6 PC-7 PC-11	ment of pharma- ceutical technology in the production of solid dosage forms.	istics of pressed materials Coated tablets Dragee. Granules Medical capsules Microcapsules and microgranules Fees
8.	UC-1 GPC-1 GPC -6 PC-7 PC-11	Prospects for the creation of new generation dosage forms and thera- peutic systems.	 Ways of search and development of new means. Experimental study and testing of drugs. Ways to improve traditional medicines. Biotechnology of traditional medicines and medicines of the future. Status and development prospects for the production of therapeutic systems. Phytotherapy and ways to improve the production of extraction drugs. The main directions for improving the technology and quality of ointments. The main directions of improvement of suppository drugs. New solid dosage forms of prolonged action

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

Type of educational work	Labor i	Labor intensity		Labor intensity in se-	
	volume	volume	me	sters	
	in credit	in aca-	8	9	
	units	demic			
	(CU)	hours			
		(AH)			
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			

6. Content of the academic discipline

No.	No.	Nome of the costion of the cost domin	Ty	pes o	f educ	ational	work (i	n ACH)
p /	semes	Name of the section of the academic discipline	L	LP	Р	S	SIW	Total
p	ter	discipline						
1.	8	State regulation of the manufacture and production of medicinal prod- ucts.GMP rules, organization of pharmaceutical production	4		10		12	36
2.	8	The main processes and devices of pharmaceutical technology in the pro- duction of soft dosage forms	8		16		12	36
3.	8	The main processes and devices of pharmaceutical technology in the pro- duction of transdermal therapeutic systems (TTS)	8		14		12	36
4.	9	The main processes and devices of pharmaceutical technology in the pro- duction of medicinal herbal prepara- tions (HRP, phytopreparations).	4		16		12	9
5.	9	The main processes and equipment of pharmaceutical technology in the production of dosage forms for paren- teral use	4		14		12	9
6.	9	Aerodisperse dosage forms	4		14		12	43
7.	9	The main processes and equipment of pharmaceutical technology in the production of solid dosage forms.			18		16	74
8.	9	Prospects for the creation of new generation dosage forms and therapeutic systems.	4		10		12	9
9	9	Exam						36
		TOTAL	40		112		100	288

6.1 Sections of the discipline and types of academic work

* - L – lectures; LP – laboratory practicum; P – practicals; S – seminars; SIW – student's individual work.

6.2. Thematic schedule of educational work types:

	0.2.1 Thematic schedule of feetures		
No. p / p	Name of lecture topics		by semes- in AH
p / p			9
1.	State regulation of the manufacture and production of medicinal products.GMP rules, organization of pharma-ceutical production	2	
2.	Ointments, pastes, liniments of industrial production.	2	

6.2.1 Thematic schedule of lectures

3.	Technological equipment for the production of oint-	2	
	ments, pastes, gels, creams and liniments		
4.	Rectal and vaginal dosage forms of industrial production.	2	
	Medical pencils.		
5.	Application medicines of industrial production. Plasters,	2	
	medical adhesives.		
6.	Transdermal therapeutic systems, phytofilms. Types, re-	2	
	quirements, equipment		
7.	The main processes of pharmaceutical technology in the	2	
	production of herbal medicines (HRP, phytoprepara-		
	tions).		
8.	Methods and apparatus for extraction Medicinal herbal	2	
	preparations (phytopreparations) Extracts. Oil extracts,		
	elixirs, balms		
9.	Aerodisperse dosage forms. Aerosols.	2	
10.	Injectable dosage forms. Production of ampoules and vi-	2	
	als for injection dosage forms		
11.	Stabilization and purification of injection solutions in	2	
	factory production		
12.	infusion solutions. Emulsions and suspensions for paren-		2
	teral administration		
13.	Tablets as a dosage form. Classification of tablets. Basic		2
	requirements for tablets. Theoretical foundations of		
	pressing. The main groups of excipients for tableting		
14.	Technological and physico-chemical characteristics of		2
	pressed materials. Tablet technology (Wet granulation		
	Dry granulation)		
15.	Coating of tablets with shells: (Drawing coatings. Film		2
	coatings.		
16.	Trituration tablets. Evaluation of the quality of tablets.		2
	Ways to improve tablets.		
17.	Dragee. Granules		2
18.	Medical capsules		2
19.	Microcapsules. Ways to get. Standardization.		2
	Nomenclature		
20.	Fees		2
21.	Prospects for the creation of new generation dosage		2
	forms and therapeutic systems.		
	TOTAL (40 hours)	20	20
1		· · · ·	

6.2.2. Thematic plan of practicals

No. p / p	Name of topics of practicals	Volume b ters i	5
		8	9

 State regulation of the manufacture and production of 3 medicines. Pharmaceutical development. Regulation of industrial production of drugs. GMP rules. Industrial regulation. Hardware and technological 3 schemes of production. material balance. Industrial production ointments 	
industrial production of drugs. GMP rules. 2. Industrial regulation. Hardware and technological 3 schemes of production. material balance.	
^{2.} Industrial regulation. Hardware and technological 3 schemes of production. material balance.	
schemes of production. material balance.	
schemes of production. material balance.	
4.Liniment industrial production3	
5. The main groups of excipients for the production of 3	
The main groups of exciptents for the production of 5	
ointments, gels, creams, pastes and liniments6.Rectal and vaginal dosage forms3	
iteetai alia vaginai dosage formis	
7. Rectal cansules Production features requirements 3	
Rectal capsules. I foldetion features, requirements	
^{8.} suppositories industrial production. pouring method. 3	
pressing method. Features requirements process	
equipment	
^{9.} The main groups of excipients for the production of sup- 3	
positories and rectal capsules	
^{10.} Industrial medical pencils 3	
^{11.} Application medicinal products of industrial production 3	
^{12.} Plasters. Types, requirements, equipment 3	
^{13.} transdermal therapeutic systems. Types, requirements, 3	
equipment	
^{14.} The main groups of excipients for the production of TTS 3	
 ^{15.} medical adhesives. Types, requirements, equipment 3 	
 ^{16.} Extracts, elixirs, balms 	4
State and dynamic extraction methods and apparatus	4
rumeation of the primary exhaust nom banast sub-	4
stances. Technology of highly purified phytoprepara-	
tions.	
19. Aerodisperse dosage forms. Aerosols	4
^{20.} Injectable dosage forms of industrial production. Produc-	4
tion of ampoules and vials for injection dosage forms	
^{21.} Stabilization and purification of injection solutions in	4
factory production	
^{22.} Infusion solutions for industrial production. Emulsions	4
and suspensions for parenteral administration	
^{23.} Tablets as a dosage form. Theoretical foundations of	4
pressing.	
 ^{24.} The main groups of excipients for tableting 	4
^{25.} Technological and physico-chemical characteristics of	4
pressed materials.	-
	A
Tablet teenhology (wet and dry grandation)	4
Country of tublets with shens. (Drawing countrys. Thin	4
coatings.	
	4
 ^{28.} Trituration tablets. Evaluation of the quality of tablets. Ways to improve tablets. 	

29.	Dragee. Granules		4
30.	Soft gelatin capsules. Hard gelatin capsules		4
31.	Microcapsules. Ways to get. Standardization. Nomenclature		4
32.	Prospects for the creation of new generation dosage forms and therapeutic systems.		2
	TOTAL (total - 112 hours)	46	66

6.2.4. Types and topics of student's individual work (SIW)

p /	Types and topics of SIW	Volume	by semes-
no.		ters in AF	ł
		8	9
1	Work with literary and other sources of information	22	22
2	Preparation of term papers	20	
3	Preparation of the final qualifying work		26
	TOTAL (total - 100 Ah)	42	58

6.2.5. Research work of the student.

Research work of the student - the implementation of term papers and final qualifying work. Topics of work are approved at the meeting of the department in each new academic year.

7. Types of assessment formats for ongoing monitoring and mid-term assessment

No.		Types	Name of section of	Competence	As	sessment f	formats
p /	Semester	of con-	academic disci-	codes	types	number	number of
p	No.	trol	pline			oftest	test task
_			-			questions	options
1	2	3	4		5	6	7
1.	8	Current	Technological pro- cesses and equip- ment for the manu- facture of dosage forms with a liquid medium.		Test	20	10
2.	8	Current	The main process- es and devices of pharmaceutical technology in the production of me- dicinal herbal preparations (HRP, phytopreparations).		Test	20	10
3.	8	Current	The main process- es and devices of pharmaceutical		Test	20	10

			technology in the			
			production of soft			
			dosage forms			
4.			The main process-	Test	20	10
т.			es and devices of	1030	20	10
			pharmaceutical			
	9	Current	technology in the			
)	Current	production of			
			drugs from animal			
			raw materials.			
5.			Aerodisperse	Test	20	10
5.	9	Current	dosage forms	1050	20	10
6.			The main process-	Test	20	10
0.			es and equipment	1.000		10
			of pharmaceutical			
	9	Current	technology in the			
			production of dos-			
			age forms for par-			
			enteral use			
7.			The main process-	Test	20	10
			es and equipment			
	9	Comment	of pharmaceutical			
	9	Current	technology in the			
			production of solid			
			dosage forms.			
8.			Prospects for the	Exam	3	35
			creation of new			
	9	final	generation dosage			
			forms and thera-			
			peutic systems.			

8. 8. Educational, methodological and informational support for mastering the academic discipline (printed, electronic publications, the Internet and other network resources)

8.1. Key literature references

Ν	Name according to bibliographic requirements	Number o	of copies
0.		At the	In the library
		department	
1.	Pharmaceutical technology: Technology of	4	153
	dosage forms: a textbook for students. higher		
	textbook institutions / I.I. Krasnyuk, S.A.		
	Valevko, G.V. Mikhailova and others; ed. I.I.		
	Krasnyuk, G.V. Mikhailova M.: Publishing		
	Center "Academy", 2006 592 p.		
2.	Workshop on the technology of dosage forms:		153
	study guide I.I. Krasnyuk, G.V. Mikhailova,		
	O.N. Grigorieva and others; ed. I.I. Krasnyuk,		
	G.V. Mikhailova M.: Publishing Center		
	"Academy", 2006 432 p.		
3.	Pharmaceutical technology. Guide to laborato-		220

		ry studies: a study guide. Bykov V.A. 2010		
2	4.	Pharmaceutical technology. Manufacturing of	2	100
		drugs: a textbook. Gavrilov A.S. 2010		

8.2. Further reading

No.	8.2. Further reading	according to bibliographic requirements Number of Number			
INO.	Name according to bibliographic requirements		*		
		At the	In the		
		departm	library		
1.		ent			
1.	Pharmaceutical homeopathy: Proc. allowance for students.	5			
	higher textbook institutions / I.I. Krasnyuk, G.V. Mikhai-				
	lov; Ed. ON THE. Zamarenova M.: Publishing Center				
2	"Academy", 2005 272 p.		.1 • .		
2.	Tutorial. Medical cosmetics/I.I. Krasnyuk, G.V. Mikhailo-	5	thirty		
	va, E.T. Chizhova M.: Publishing Center "Academy",				
2	2006 240p.				
3.	State Pharmacopoeia of the USSR X edition, 1968.	2			
4.	USSR State Pharmacopoeia XI edition, issue 1, 1987; issue	8			
	2, 1990				
5.	State Pharmacopoeia XIIth ed Part 1M: Scientific Cen-	2			
	ter for Expertise of Medicinal Products, 2008704 p.				
6.	State Pharmacopoeia XIIIth ed Volume 1, Volume 2,	2			
	Volume 3M: Scientific Center for Expertise of Medicinal				
	Products, 2015.				
7.	Order of the Ministry of Industry and Trade of the Russian	20			
	Federation No. 916 dated June 14, 2013 "On Approval of				
	the Rules of Good Practice"				
8.	Order of the Ministry of Health of the Russian Federation	20			
	No. 751n dated October 26, 2015 "On approval of the rules				
	for the manufacture and dispensing of drugs for medical				
	use by pharmacy organizations, individual entrepreneurs				
	licensed for pharmaceutical activities"				
9.	Order of the Ministry of Health of the Russian Federation	50			
	No. 309 dated 10/21/97 on the approval of the "Instruc-				
	tions on the sanitary regime of pharmacies";				
10.	Order of the Ministry of Health and Social Development of	20			
	the Russian Federation of August 23, 2010 N 706n				
	"On approval of the Rules for the storage of medicines"				
11.	Order of the Ministry of Health of the Russian Federation				
	No. 1175n dated December 20, 2012 "On approval of the	20			
	procedure for prescribing and prescribing medicines, as				
	well as forms of prescription forms for medicines, the pro-				
	cedure for issuing these forms, their accounting and stor-				
	age"				
12.	Order of the Ministry of Health and Social Development of	50			

	the Russian Federation No. 110 dated February 12, 2007		
	"On the procedure for prescribing and prescribing medi-		
	cines, medical devices and specialized health food prod-		
	ucts";		
13.	Order of the Ministry of Health of the Russian Federation	50	
	No. 377 dated 11/13/96 on approval of the "Instructions for		
	organizing the storage of various groups of medicines and		
	medical devices in pharmacies" (valid for medical devices)		
14.	Sinev D.Ya., Marchenko L.G., Sineva T.D. Reference	5	
	manual for pharmaceutical technology of drugs St. Pe-		
	tersburg, 1992.		
15.	Mashkovsky M.D. medicines 15th edition, revised, cor-	5	
	rected. and additional - M.: RIA "New Wave", 2007		
	1206 p.		

8.3. Electronic educational resources for teaching academic subjects

Name of the electronic resource	Brief description (content)	Access conditions	Number of users
Internal electronic li- brary system (VEBS)	Proceedings of the faculty of the department: textbooks and teaching aids, mono- graphs, collections of scien- tific papers, scientific arti- cles, dissertations, abstracts of dissertations, patents.	From any computer on the Internet, using an individual login and password	Not limited

8.4.2. Electronic educational resources acquired by the University

Ν	Name of the electronic	Brief description	Access conditions	Number of
0.	resource	(content)	Access conditions	users
1	Electronic database "Student Advisor"	Educational lit- erature + addi- tional materials (audio, video, interactive mate- rials, test tasks) for higher medi- cal and pharma- ceutical educa- tion. Editions are structured by specialties and disciplines in accordance with the current Fed-	From any computer on the Inter- net, using an individual login and password [Electronic resource] - Access mode:http://www.studmedlib.ru/	General subscription of PIMU

		10 51	l	,
		eral State Educa-		
		tional Standards		
		of Higher Pro-		
		fessional Educa-		
		tion.		
2	Electronic library system	Educational and	From any computer located on the	General
	"Bukap"	scientific medi-	Internet by login and password,	subscription
	-	cal literature of	from the computers of the acade-	of PIMU
		Russian publish-	my.	
		ing houses, incl.	Subscribed editions are available	
		translations of	for reading.	
		foreign publica-	[Electronic resource] - Access	
		tions.	mode: http://www.books-up.ru/	
3	"Diblion sight"			Comoral
3	"Bibliopoisk"	Integrated search	For PIMU, access to the demo	General
		service "single	version of the Bibliopoisk search	subscription
		window" for	engine is open:	of PIMU
		electronic cata-	http://bibliosearch.ru/pimu.	
		logs, ELS and		
		full-text data-		
		bases.		
		The results of a		
		single search in		
		the demo version		
		include docu-		
		ments from do-		
		mestic and for-		
		eign electronic		
		libraries and da-		
		tabases available		
		to the university		
		as part of a sub-		
		scription, as well		
		as from open		
		access databases.		
4	Domestic electronic	Periodicals on	From the computers of the Acad-	Not limited
	periodicals	medical topics	emy on the platform of the elec-	
		and higher edu-	tronic library eLIBRARY.RU	
		cation	Access mode: https://elibrary.ru/	
5	International	WebofScience	Free access from PIMU comput-	Free access
	scientometric database	covers materials	ers	from PIMU
	"WebofScienceCoreColle	on natural, tech-	Access	computers
	ction"	nical, social,	mode:http://apps.webofknowledg	Ĩ
		humanities;	e.com	
		takes into ac-		
		count the mutual		
		citation of publi-		
		cations devel-		
		oped and pro-		
		vided by Thom-		
		sonReuters; has		
		built-in search,		
		analysis and		
		management of		
		bibliographic		
L	1	<i>D</i>		1

	information.	

8.4.3 Open access resources

No.	Name of the electronic re- source	Brief description (content)	Access conditions
1	Federal Electronic Medical	Includes electronic analogues of printed	from any com-
	Library (FEMB)	publications and original electronic publi-	puter on the In-
		cations that have no analogues recorded on	ternet
		other media (dissertations, abstracts,	
		books, magazines, etc.).	
		[Electronic resource] - Access mode:	
		http://neb.rf/	
2	Scientific electronic library	The largest Russian information portal in	from any com-
	eLIBRARY.RU	the field of science, technology, medicine	puter on the In-
		and education, containing abstracts and full	ternet.
		texts of scientific articles and publica-	
		tions.[Electronic resource] - Access mode:	
		https://elibrary.ru/	
3	Scientific electronic library	Full texts of scientific articles with annota-	from any com-
	of open access CyberLenin-	tions published in scientific journals in	puter on the In-
	ka	Russia and neighboring coun-	ternet
		tries.[Electronic resource] - Access mode:	
		https://cyberleninka.ru/	
4	Russian State Library (RSL)	Abstracts for which there are copyright agreements with permission for their open	from any com- puter on the In-
		publication[Electronic resource] - Access mode: http://www.rsl.ru/	ternet
5	Reference and legal system	Federal and regional legislation, judicial	from any com-
	"Consultant Plus"	practice, financial advice, legislative com-	puter on the In-
		ments, etc.	ternet
		[Electronic resource] - Access mode:	
		http://www.consultant.ru/	

9. Material and technical support for mastering an academic discipline

9.1. List of premises for classroom activities for the discipline

1. An audience for lectures and practical classes, equipped with multimedia and other teaching aids that allow the use of simulation technologies, with standard sets of professional models (sets of clinical trial protocols, formulary lists of health care facilities, price lists of distribution companies, sets of quality of life questionnaires), allowing students to master the skills and abilities provided for by professional activity individually.

2.Educational films (multimedia)"Suspensions", "Emulsions", "Ointments", "Suppositories", "Infusions", "Decoctions", "Extracts", "Pills", "GMP"

3. Premises for independent work of students, equipped with computer equipment with the ability to connect to the Internet and provide access to the electronic information and educational environment of the University.

9.2. List of equipment for classroom activities for the discipline

1. Multimedia complex (laptop, projector, screen, TV)

2. Computer class (15 computers) with installed applications and Internet access.

	Software	number	Type of soft	Manufac-	Number	Contract
T4.	Software	number	Type of soft-			
Ite		of li-	ware	turer	in the uni-	No. and date
m		censes			fied regis-	
no.					ter of	
					Russian	
					software	
1	Wtware	100	Thin Client Op-	Kovalev	1960	2471/05-18
			erating System	Andrey Ale-		from
				xandrovich		28.05.2018
2	MyOffice is	220	Office Applica-	LLC "NEW	283	without limi-
	Standard. A		tion	CLOUD		tation, with
	corporate user			TECH-		the right to
	license for edu-			NOLO-		receive up-
	cational organi-			GIES"		dates for 1
	zations, with no					year.
	expiration date,					-
	with the right to					
	receive updates					
	for 1 year.					
3	LibreOffice		Office Applica-	The Docu-	Freely dis-	
			tion	ment Foun-	tributed	
				dation	software	
4	Windows 10	700	Operating sys-	Microsoft	Azure Dev	
	Education		tems		Tools for	
					Teaching	
					Subscrip-	
					tion	
5	Yandex.		Browser	«Yandex»	3722	
2	Browser				3722	
6	Subscription to					23618/HN10
	MS Office Pro					030 LLC
	for 170 PCs for					"Softline
	FGBOU VO					Trade" from
	"PIMU" of the					04.12.2020
	Ministry of					07.12.2020
	Health of Rus-		Office Applica-			
		170		Microsoft		
	sia	170	tion	wherosoft		
	1		1	L	•	1

9.3. A set of licensed and freely distributed software, including domestic production

10. List of changes to the working program (to be filled out by the template)

Federal State Budgetary Educational Institution of Higher Education "Privolzhsky Research Medical University" Ministry of Health of the Russian Federation (FSBEI HE "PRMU" of the Ministry of Health of Russia)

> Department of Name of the department

CHANGE REGISTRATION SHEET

working program for the academic discipline NAME OF THE ACADEMIC DISCIPLINE

Field of study / specialty / scientific specialty:

Training profile:

(name) - for master's degree programs

Position	Number and name of the program section	Contents of the changes made	Effective date of the changes	Contributor's signature
1				

20

Approved at the department meeting Protocol No. of

Head of the Department

department name, academic title

signature

print name

(code, name)