Appendix to the working program

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

BANK OF ASSESSMENT TOOLS FOR

PRACTICE IN PHARMACEUTICAL TECHNOLOGY

Name of discipline: **PRACTICE IN PHARMACEUTICAL TECHNOLOGY**

Speciality: 33.05.01 PHARMACY

Qualification: PHARMACIST

Department: MANAGEMENT AND ECONOMY OF PHARMACY AND PHARMACEUTICAL TECHNOLOGY

Form of study: FULL-TIME

2021

1. BANK OF ASSESSMENT TOOLS IN PRACTICE IN PHARMACEUTICAL TECHNOLOGY

No. p/n	Controlled Sections (themes), modules disciplines	Controlled competency code	Learning outcomes by discipline	Name appraisal facilities	
				view	quantity
1	Pharmaceutical technology practice	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)	***Know:*** • requirements for maintaining subject-quantitative accounting of medicines • requirements for maintaining reporting documentation in pharmaceutical organizations, • professional record keeping • classification of narcotic drugs, psychotropic, toxic chemicals, biological agents, radioactive substances and their physical and chemical–characteristics; • technology of dosage forms obtained in 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, plasters, sticks, 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 enteral 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 that have–influence on the therapeutic effect in the extemporaneous and industrial production of dosage forms • device and principles of operation of a 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:***	Test tasks Control questions Situational tasks	40 40 5

			• 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 the holiday; • as well as to standardize DF in terms of 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 ***Own:*** • 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 use 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. EVALUATION TOOLS

(full list of evaluation tools)

2.1. Test tasks by discipline

Choose one correct answer:

No.	Test tasks with answer options	The code of the competency to which the test task is directed
1.	MEDICINES THAT REQUIRE PROTECTION FROM MOISTURE ARE STORED *1) in accordance with the storage requirements indicated on the secondary packaging 2) on the rack under normal conditions 3) in a place protected from natural and artificial lighting 4) in a separate closet or isolated room	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
2.	STERILE VESSELS USED FOR THE PREPARATION AND PACKAGING OF MEDICINES UNDER ASEPTIC CONDITIONS IS SHELF LIFE (IN HOURS) *1)24 2)12 3)72 4)6	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
3.	STORAGE MODE "IN A COLD PLACE" CORRESPOND TO THE TEMPERATURE RANGE (°C) *1)2 to 8 2)from 0 to 5 3) from - 20 to 0 4) below 0	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
4.	WHEN STORING AND MANUFACTURING MEDICINES, IT IS NECESSARY TO CONSIDER THAT AIR CAN DESTROY THE QUALITY *1) aminophylline 2) riboflavin 3) boric acid 4) anesthetic	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)

5.	WATER FOR INJECTION IS SHELF LIFE IN PHARMACY IS (HOUR) *1)24 2)48 3)12 4)72	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
6.	STORAGE AT TEMPERATURE NOT HIGHER THAN 25 °C CORRESPOND TO THE TEMPERATURE INTERVAL (°C) *1)2 to 25 2) from 0 to 25 3)20 to 25 4) from any value up to 25	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
7.	THE TERM "EXCIENT" CORRESPONSES *1) purified water 2) diphenhydramine 3) liquid extract 4) riboflavin	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
8.	LABEL SIGNAL COLOR "HEART" *1) orange background with white font 2) red background with white font 3) blue background with white font 4) white background with green font	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
9.	EUPHILLIN IN POWDERS FORMS NON-DAMPING MIXTURES WITH *1)sugar 2) glucose 3) ascorbic acid 4) diphenhydramine	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
10.	PRODUCTS OF THE PHARMACY RANGE ARE MEDICINES AND *1)Medical products	GPC-1 (1.1-1.4), OPK - 2 (2.2),

	2) food 3) household chemicals 4)organic solvents	GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
11.	RIBOFLAVIN BELONG TO A GROUP OF MEDICINAL SUBSTANCES *1) coloring 2)poisonous 3) difficult to grind 4)general list	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
12.	ACCORDING TO ORDER No. 751N DATED 10/26/2015, CONTROL WHEN THE DOSAGE FORM IS DISPOSED FROM THE PHARMACY *1) compliance of the doses of narcotic drugs, psychotropic, potent substances indicated in the prescription or requirement with the age of the patient 2) absence of mechanical inclusions 3) the total volume or mass of the dosage form 4) weight deviation	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
13.	ACCORDING TO ORDER No. 751N DATED 10/26/2015, LABELS FOR EYE DROPS AND EYE OINTMENTS SHOULD BE PRINTED A WARNING SIGN *1) "Store in a cool and dark place" 2) "Keep away from children" 3) "Store in a cool place" 4) "Keep in a place protected from light"	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
14.	SIGNAL COLOR FOR NEWBORN LABEL *1) green background with white font 2) white background with red font 3) red background with white font 4) white background with green font	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
15.	AN EXTERNAL MANIFESTATION OF PHYSICO-CHEMICAL INCOMPATIBILITY OF MEDICINE IN-GREDIENTS IS *1) Humidification of the powder mass 2) bundle	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-

	3) gas evolution 4) precipitate formation	1.4), PC-7 (7.1-7.4)
16.	THE CAUSE OF PHARMACEUTICAL INCOMPATIBILITY WHEN COMBINING HEXAMETHYLENTETRAMINE WITH ACETYLSALICYLIC ACID IN POWDERS IS *1) increased sorption of water vapor 2) the formation of a eutectic mixture 3) lowering the melting point of the mixture 4) solid-phase interactions	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
17.	IS *1) pharmacopoeial monograph 2)GMP standard 3) specification for a medicinal product 4)industrial regulation	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
18.	EXTERNAL MANIFESTATION OF CHEMICAL INCOMPATIBILITY OF MEDICINAL INGREDIENTS IS *1) color change 2) emulsion separation 3) immiscibility of ingredients 4) eutectic formation	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
19.	THE CAUSE OF PHARMACEUTICAL INCOMPATIBILITY WHEN COMBINING EUPHILLIN WITH ASCORBIC ACID IN POWDERS IS *1) water vapor sorption 2) lowering the melting point of the mixture 3) the formation of a eutectic mixture 4) sorption of carbon dioxide	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
20.	THE DOSAGE OF THE MEDICINE IS *1) the content of one or more active substances in quantitative terms per dose unit, or volume unit, or mass unit in the preparation 2) the number of doses of the drug during the day 3) the amount of a medicinal substance once introduced into the body 4) the number of units of dosed medicines in the package	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)

21.	HIGHER SINGLE DOSES OF POISONOUS AND POTENT SUBSTANCES IN RECIPES MAY BE EXCEEDED *1) when writing the dose of this substance in words with an exclamation point 2) by 10% 3)50% 4) in no case	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
22.	EMULSION IS A DOSAGE FORM CONSISTING OF *1) finely dispersed, immiscible liquids 2)multiple liquids 3) macromolecules and macroions distributed in a liquid 4) micelles in a liquid dispersion medium	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
23.	WHEN AN EMERGENCY DISCOUNT OF A MEDICINE IS NECESSARY, THE PHYSICIAN SHOULD *1) put on the recipe the designations "cito" or "statim" 2) call the pharmacy 3) at the top of the recipe, write with a red pencil "emergency!" 4) use a special form of prescription form	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
24	ON THE LABEL OF SOLUTIONS FOR INFUSIONS, UNLIKE OTHER INJECTION SOLUTIONS, INDICATED *1) solution osmolarity 2) series and analysis number 3) name of the solution 4) application method	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
25	ACCORDING TO THE REGULATIONS FOR THE USE OF PHARMACOPEIAN ARTICLES, "WARM" IS MEANING TEMPERATURE (°C) *1)40-50 2)35-37 3)18-20 4)36-38	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
26	LABEL AND WARNING INSTRUCTIONS, WHICH ARE MADE IN PHARMACIES FOR EYE DROPS MANUFACTURED IN ASEPTIC CONDITIONS WITHOUT FINISH-	GPC-1 (1.1-1.4), OPK - 2 (2.2),

	ING THERMAL STERILIZATION, *1) "Eye drops", "Aseptically prepared" 2) "External", "Cooked aseptically" 3) "External", "Prepared without heat sterilization" 4) "Eye drops", "Contents not sterilized"	GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
27	STORAGE LIFE OF WATER EXTRACTIONS FROM MARSH ROOTS IS (DAYS) *1)1 2)2 3)3 4)10	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
28	FORMS A SEDIT IN SOLUTIONS WITH ACIDS AND ACID SUBSTANCES *1) sodium thiosulfate 2) sodium bromide 3) glucose 4) novocaine	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
29	PROTECTION AGAINST VOLATILATION AND DRY-ING IS REQUIRED DURING STORAGE *1) sodium bicarbonate 2) sodium chloride 3) silver nitrate 4) boric acid	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
thirty	FOR THE STORAGE OF PHARMACEUTICAL SUB-STANCES PARTICULARLY SENSITIVE TO LIGHT *1) glass containers are pasted over with black opaque paper 2) glass containers are pasted over with reflective aluminum foil 3) use metal containers 4) use a red lantern to illuminate the room	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
31	FOR THE STORAGE OF PHARMACEUTICAL SUB-STANCES PARTICULARLY SENSITIVE TO LIGHT *1) glass containers are pasted over with black opaque paper 2) glass containers are pasted over with reflective aluminum foil 3) use metal containers	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-

	4) use a red lantern to illuminate the room	7.4)
32	FOR THE STORAGE OF PHARMACEUTICAL SUB-STANCES PARTICULARLY SENSITIVE TO LIGHT *1) glass containers are pasted over with black opaque paper 2) glass containers are pasted over with reflective aluminum foil 3) use metal containers 4) use a red lantern to illuminate the room	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
33	SOLUTION *1)ammonia 2) iodine 3) protargola 4)glycerin	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
34	A MEDICINAL SUBSTANCE PARTICULARLY SENSI-TIVE TO LIGHT IS *1)silver nitrate 2)zinc oxide 3) eucalyptus essential oil 4)menthol	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
35	STORAGE MODE "IN A COOL PLACE" CORRESPOND-ING TO THE TEMPERATURE RANGE (°C) *1)8 to 15 2)from 0 to 8 3) from 0 and below 4)from 2 to 8	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
36	IN THE PROCESS OF STORAGE, THE FORMATION OF A MINOR SEDIMENT OF BALLAST SUBSTANCES IS ALLOWED IN *1)tinctures 2) solutions 3) emulsions 4) syrups	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
37	SHELF LIFE OF WATER EXTRACTS IS NOT MORE THAN (DAYS)	GPC-1 (1.1-1.4), OPK - 2

	*1)2 2)0.5 3)5 4)10	(2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
39	THE PROCESS OCCURRED DURING THE STORAGE OF HYGROSCOPIC MEDICINAL SUBSTANCES IS *1)moisture absorption 2) absorption of carbon dioxide 3)oxidation 4) saponification	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)
40	SUBSTANCES OF INORGANIC OR ORGANIC ORIGIN USED IN THE PROCESS OF MANUFACTURING, MANUFACTURING MEDICINAL PREPARATIONS TO GIVE THEM THE NECESSARY PHYSICAL AND CHEMICAL PROPERTIES, ARE CALLED *1) excipients 2) pharmaceutical substances 3) dosage forms 4) drugs	GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)

2.2. Pharmaceutical Technology Practice Exam Questions (33.05.01. Pharmacy)

1. Prospects and tasks for the development of pharmaceutical technology in the framework of the strategy "Pharma - 2030".
2. Rules of Good Manufacturing Practice of the Eurasian Economic Union, their purpose, structure. Good manufacturing practice as part of quality management, its main requirements.
3. Quality risk management, principles, overall management process.
4. Manufacture of herbal medicinal products in accordance with the rules of good manufacturing practice.
5. Life cycle of medicines. Peculiarities of pharmaceutical development of a reference and reproduced medicinal product.
6. Ethical aspects in conducting clinical and preclinical studies of drugs.
7. Problems of the use of excipients in the production of drugs.
8. Auxiliary substances based on polymers. Prospects for their use.
9. Polymorphism of pharmaceutical substances, its importance in the development, production of medicines, research in accordance with the Global Philosophy XIV ed. OFS "Polymorphism".
10. Correction of dosage forms. The main directions of correction. Features of correction of liquid and solid drugs.
11. Water treatment. Organization of the work of the water treatment plant. Storage and circulation of purified water and water for injection in a pharmaceutical plant.
12. Obtaining purified water at an industrial enterprise by demineralization, reverse osmosis. Characteristics of the devices. principle of operation.
13. Prevention of cross-contamination in the production of medicines, contaminants. Technical and organizational measures to prevent cross-contamination.
14. Cleaning of technological equipment, cleaning program, cleaning in place (SIP). Equipment and washing stations, detergents. Evaluation of cleaning efficiency, cleaning validation.
15. Aerosols and sprays, their definition, characteristics as dosage forms and dispersed systems. Comparative characteristics of aerosols and sprays.
16. Auxiliary substances in the technology of aerosols and sprays. Their nomenclature and purpose. Propellants, their classification, characteristics, prospects for application.
17. Production of aerosols. Characteristics of the technological stages of the production process. Safety precautions in the production of aerosols.
18. Tests of aerosols and sprays. Nomenclature of aerosols and sprays.
19. Medical pencils. Classification. Auxiliary substances in the production of medical pencils. Technological schemes for obtaining. Tests.
20. Lozenges: characteristics as a dosage form. Auxiliary substances in the production of lollipops. Technological scheme for the production of lozenges with medicinal substances with a brief description of the stages.
21. Medicinal fees. Technological scheme for obtaining medicinal fees. Features of grinding medicinal plant materials. Tests.
22. Industrial powders. Instrumental scheme for obtaining powders. Methods for dosing powders. The choice of primary packaging depending on the method of application of the powder.
23. Modern methods of obtaining tablets, advantages and disadvantages. Features of obtaining tablets using 3D printing, trituration tablets.
24. Multilayer tablets, characteristic. Technology and equipment in the production of multilayer tablets.
25. Effervescent tablets. Requirements for medicinal and excipients. Organization of the technological process for obtaining effervescent tablets. Choice of packaging. Quality control.
26. Solid medical capsules, characteristics. Improving the design of hard capsules. Development of the composition and technology for obtaining capsules on vegetable polymers.
27. Microcapsules, definition and characterization. Methods for obtaining microcapsules. Dosage

forms containing microcapsules.
28. Features of the technology for obtaining soft capsules for pediatric practice. The equipment used, its structure and principle of operation.
29. Solutions of industrial production. Technological scheme for obtaining solutions. Features of obtaining and filtering alcohol solutions, safety precautions.
30. Extractive phytopreparations, their classification. Production of total phytopreparations (tinctures, extracts), technology features, tests. Equipment.
31. Phytopreparations of individual substances. Classification. General technological scheme of obtaining. Methods for isolating and purifying the amount of individual substances.
32. Ointments for industrial production, general technological scheme for obtaining, machines and apparatuses, use at the stages of production, testing of ointments, direction of improvement.
33. Manufacture of sterile medicinal products in accordance with the rules of good manufacturing practice. Principle, general requirements, technological process.
34. Aseptic production of medicines, factors affecting aseptic processing.
35. Modeling of the aseptic process by filling with nutrient media.
36. Dosage forms with modified release. reasons for their development. Classifications.
37. Dosage forms with prolonged release. . Matrix systems, types of matrix, their characteristics, purpose, Tablets of the "Retard" type
38. Oral osmotic systems. Classification, principles of construction and action. Examples.
39. Characteristics, principles of construction, examples of dosage forms with delayed release, with pulsating release, Solutab tablets, floating tablets.
40. The system of drug delivery to the body, goals and objectives. Delivery systems and their design. Nanocarriers of delivery systems, examples of drugs for various delivery systems.

2.3. Approximate situational tasks for the practice exam in pharmaceutical technology (33.05.01. Pharmacy)

Case study 1.
Substantiate the manufacturing technology, carry out the necessary calculations, describe the manufacturing technology of the indicated dosage form with registration for release.
Take: Camphor 0.3
Ephedrine hydrochloride 0.05
Lanolin 5.0
Vaseline 10.0
Mix to make an ointment.
Give. Designate. Ointment for the nose.

Case study 2.
Justify the manufacturing technology, carry out the necessary calculations, describe the manufacturing technology of the indicated dosage form with its registration for release.
Take: Pilocarpine hydrochloride ointment 2% 10.0
Give. Designate. Eye ointment (at night)

Case study 3.
The preparatory stage of the production of tablets includes the preparation of the initial mixture of medicinal substances. The uniformity of mixing is controlled by quantifying one or more ingredients from different places in the mixture. If the ratio of the ingredients according to the prescription does not match, the mixture is brought to normal. In 100 kg of a powdery mixture of codeine and sodium bicarbonate prepared for granulation, 5.85% of codeine was found. Bring the intermediate to normal if the tablets should contain codeine 0.015g, sodium bicarbonate 0.25g.

Case study 4.
Change management is one of the key processes of the pharmaceutical quality system in the production of medicines.
Description of changes. At the stage of preparation of the solution, a solid pharmaceutical substance was used, which is sensitive to temperature and has corrosive activity, a container for mixing with a jacket with a volume of 350 liters was used. The tank has been replaced with a similar one, 700l to increase the batch size. List and explain the critical quality indicators that are potentially affected by the changes, indicate the recommended actions to implement the changes.

Case study 5.
One of the requirements for hydrophobic suppository bases is the melting point, which should not exceed 370C. Depending on the physicochemical properties of pharmaceutical substances that can affect the melting point of suppository bases, a combination of several bases with different melting points is used, which makes it necessary to calculate their melting points.
Calculate the melting point of the suppository base of the following composition:
Hydrofat with a melting point of 400C - 60%
Hydrofat with a melting point of 360C - 10%
Cocoa butter with a melting point of 340C - 30%
Liquid components will not be added to said base. Specify the temperature limit for fusing components that must not be exceeded and why.

3. INDICATORS AND CRITERIA FOR ASSESSING COMPETENCES

3.1. Criteria and scales for assessing the performance of test tasks

Code competencies	Qualitative assessment of the level of training		Percent correct answers
	score	Grade	
GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4) m	5	Great	90-100%
	4	Fine	80-89%
	3	Satisfactorily	70-79%
	2	unsatisfactory	Less than 70%

3.2. Criteria and scale for assessing students' knowledge

Competency code	Grade 5 "Great"	Grade 4 "Fine"	Grade 3 "satisfactorily"	Grade 2 "unsatisfactory"
GPC-1 (1.1-1.4), OPK - 2 (2.2), GPC - 6 (6.2-6.3); PC-1 (1.1-1.4), PC-7 (7.1-7.4)	Deep assimilation of the program material, its logically coherent presentation, the debatability of this issue, the ability to connect theory with the possibilities of its application in practice, the free solution of problems and the justification of the decision made, knowledge of the methodology and research methods, modeling methods	Solid knowledge of the program material, minor inaccuracies in answering a question are acceptable, the correct application of theoretical provisions in solving questions and problems, the ability to choose specific methods for solving complex problems, using methods for collecting, calculating, analyzing, classifying, interpreting data, independently applying mathematical and statistical apparatus	Knowledge of the basic material, inaccuracies in answering questions are acceptable, violation of the logical sequence in the presentation of the program material, the ability to solve simple problems based on basic knowledge and given algorithms of actions, experience difficulties in solving practical problems	Ignorance of a significant part of the program material, inability even with the help of a teacher to formulate the correct answers to the questions asked, failure to complete practical tasks

3.3. Criteria and scale for assessing the knowledge of students during the intermediate certification in the form of a test

"PASSED" - the student gives answers to questions indicating knowledge and understanding of the main program material; reveals the questions of the Program in the discipline correctly, shows the ability to competently use the data of the mandatory literature to formulate conclusions and recommendations; shows effective skills and abilities; presents the material logically and consistently; the student shows diligence in learning.

"NOT PASSED" - the student gives answers to questions indicating significant gaps in the knowledge of the program material in the discipline; makes gross mistakes when performing tasks or failing to complete tasks; shows complete ignorance of one of the ticket questions, gives a confused answer without conclusions and generalizations; in the learning process, there are missed lectures and classes without good reason, unsatisfactory grades for current performance.