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

BANK OF ASSESSMENT TOOLS FOR DISCIPLINE

STATE CONTROL AND SUPERVISION IN THE FIELD OF CIRCULATION OF MEDICINES

Training program (specialty): **33.05.01 PHARMACY**

Department: **MANAGEMENT AND ECONOMICS OF PHARMACY AND PHARMACEUTICAL TECHNOLOGY**

Mode of study: **FULL-TIME**

Nizhny Novgorod
2021

1. Bank of assessment tools for the current monitoring of academic performance, mid-term assessment of students in the discipline

This Bank of Assessment Tools (BAT) for the discipline "State control and supervision in the field of circulation of medicines" is an integral appendix to the working program of the discipline "State control and supervision in the field of circulation of medicines". All the details of the approval submitted in the WPD for this discipline apply to this BAT.

2. List of assessment tools

The following assessment tools are used to determine the quality of mastering the academic material by students in the discipline:

No.	Assessment tool	Brief description of the assessment tool	Presentation of the assessment tool in the BAT
1	Test	A system of standardized tasks that allows you to automate the procedure of measuring the level of knowledge and skills of a student	Bank of test tasks
2	Case-task	A problem task in which the student is offered to comprehend a real professionally-oriented situation necessary to solve this problem.	Tasks for solving cases
3	Colloquium	A tool of controlling the mastering of study materials of a topic, section or sections of a discipline, organized as a class in the form of an interview between a teacher and students.	Questions on topics/sections of the discipline
4	Workbook	A didactic complex designed for independent work of the student and allowing to assess the level of mastering study materials	Workbook sample

3. A list of competencies indicating the stages of their formation in the process of mastering the educational program and the types of evaluation tools

Code and formulation of competence	Stage of competence formation	Controlled sections of the discipline	Assessment tools
PC-4 Able to participate in monitoring the quality, effectiveness and safety of medicines and medicinal plant raw materials	Entry, Current, Mid-term	**Section 1.** State control and supervision in the field of circulation of medicines	Tests Case-tasks Colloquiums Workbooks
PC-5 Able to take part in planning and organizing the resource provision of a pharmaceutical organization	Entry, Current, Mid-term	**Section 1.** State control and supervision in the field of circulation of medicines	Tests Case-tasks Colloquiums Workbooks
PC-10 Able to carry out measures to control (supervise) the activities of	Entry, Current, Mid-term	**Section 1.** State control and supervision in the field of circulation of medicines	Tests Case-tasks Colloquiums

legal entities and individuals licensed for pharmaceutical activities, to comply with mandatory requirements			Workbooks

4. The content of the assessment tools of entry, current control

Entry /current control is carried out by the discipline teacher when conducting classes in the form of: test control, organization of a discussion, colloquium.

Assessment tools for current control.

4.1. Bank of test tasks

Choose one correct answer:

№	Test tasks with multiple answers	The code of the competence for the formation of which the test task is aimed
1.	THE AFFILIATION OF THE DRUG TO THE OVER-THE-COUNTER IS DETERMINED BY information provided in the instructions for use of the drug and on the packaging of the drug list of medicines approved by the Order of the Ministry of Health of the Russian Federation Government of the Russian Federation pharmacist during the release of drugs	PC-4 PC-5 PC-10
2.	MEDICINES FOR MEDICAL USE, DISPENSED WITHOUT A DOCTOR'S PRESCRIPTION, ARE NOT SUBJECT TO SALE THROUGH Veterinary pharmacies Pharmacy Pharmacies Pharmacy kiosks	PC-4 PC-5 PC-10
3.	THE DOCUMENT, WHICH IS THE BASIS FOR DISPENSING MEDICINES TO THE DEPARTMENTS OF A MEDICAL ORGANIZATION, IS Requirement-invoice of a medical organization Order-application prescription internal movement consignment note	PC-4 PC-5 PC-10
4.	PHARMACEUTICAL EXAMINATION OF THE PRESCRIPTION IS CARRIED OUT BY pharmacist (pharmacist) Doctor paramedic Clinical Pharmacologist	PC-4 PC-5 PC-10
5.	PRESCRIPTIONS FOR DRUGS CONTAINING NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES INCLUDED IN LIST II OF THE LIST OF NS, PV AND THEIR PRECURSORS SUBJECT TO CONTROL IN THE RUSSIAN FEDERATION ARE VALID FOR	PC-4 PC-5 PC-10

	15 days 5 days 1 month 2 months	
6.	NARCOTIC AND PSYCHOTROPIC DRUGS OF LIST II OF THE LIST OF NS, PV AND THEIR PRECURSORS SUBJECT TO CONTROL IN THE RUSSIAN FEDERATION ARE RELEASED TO THE PATIENT OR THE PERSON REPRESENTING HIM, UPON PRESENTATION identity document a document confirming the right to state social assistance certificate confirming the right to receive a set of social services medical record of an outpatient	PC-4 PC-5 PC-10
7.	INCORRECTLY WRITTEN PRESCRIPTIONS IN THE PHARMACY ORGANIZATION ARE REPAID stamp "prescription invalid" and returned to the patient through tearing and return to the patient stamp "prescription invalid" and remain in the organization stamp "the prescription is invalid" and remain in the organization, and the signature is returned to the patient instead of the prescription	PC-4 PC-5 PC-10
8.	THE SHELF LIFE OF PRESCRIPTIONS FOR DRUGS WITH ANABOLIC ACTIVITY IS IN THE PHARMACY ORGANIZATION (YEARS) 3 1 5 10	PC-4 PC-5 PC-10
9.	TO ENSURE THE TREATMENT AND DIAGNOSTIC PROCESS, MEDICAL ORGANIZATIONS RECEIVE DRUGS FROM PHARMACY ORGANIZATIONS FOR invoice requirements Overhead invoices for the internal movement of goods Recipes	PC-4 PC-5 PC-10
10.	ADMISSION OF PERSONS TO WORK WITH NARCOTIC DRUGS, PSYCHOTROPIC SUBSTANCES AND PRECURSORS OF LIST IV OF THE LIST OF NS, PV AND THEIR PRECURSORS SUBJECT TO CONTROL IN THE RUSSIAN FEDERATION DOES NOT PROVIDE FOR certification of knowledge of the legislation of the Russian Federation on narcotic drugs, psychotropic substances and their precursors familiarization of persons with the legislation of the Russian Federation on narcotic drugs, psychotropic substances and their precursors conclusion of an employment contract with the inclusion of mutual obligations of the organization and the person associated with the circulation of narcotic drugs, psychotropic substances and their precursors conducting a psychiatric examination	PC-4 PC-5 PC-10
11.	PERSONS ARE NOT ALLOWED TO WORK WITH NARCOTIC DRUGS, PSYCHOTROPIC SUBSTANCES patients with drug addiction, substance abuse and chronic alcoholism who have reached the age of 18 who do not have outstanding or unexpunged convictions for crimes of medium gravity, serious crimes, especially serious crimes Those who have reached retirement age	PC-4 PC-5 PC-10

12.	FOR PATIENTS WITH CHRONIC DISEASES, PRESCRIPTIONS FOR A COURSE OF TREATMENT UP TO 60 DAYS ARE NOT ISSUED FOR Clonidine table. LPs with anabolic activity Derivatives of barbituric acid combined drugs containing codeine (its salts)	PC-4 PC-5 PC-10
13.	THE LIST OF DRUGS FOR PROVIDING CITIZENS ENTITLED TO RECEIVE DRUGS FREE OF CHARGE (AT THE EXPENSE OF THE FEDERAL BUDGET) IS APPROVED Government of the Russian Federation Ministry of Health of the Russian Federation Federal Compulsory Medical Insurance Fund the health care management body of the constituent entity of the Russian Federation	PC-4 PC-5 PC-10
14.	FROM THE MOMENT THE PATIENT APPLIES TO THE PHARMACY ORGANIZATION, THE SERVICE PERIOD FOR PRESCRIPTIONS FOR DRUGS PRESCRIBED BY THE DECISION OF THE MEDICAL COMMISSION FOR OUTPATIENT TREATMENT OF CITIZENS AS PART OF THE PROVISION OF STATE SOCIAL ASSISTANCE SHOULD NOT EXCEED (WORKING DAYS) 15 2 5 10	PC-4 PC-5 PC-10
15.	THE BASIS FOR DISPENSING PRESCRIPTION DRUGS FROM PHARMACY ORGANIZATIONS TO A PATIENT IS Doctor's prescription Sheet of medical prescriptions invoice-requirement of a medical organization "Journal of accounting for wholesale sales and settlements with buyers"	PC-4 PC-5 PC-10
16.	SCHEDULED INSPECTIONS OF COMPLIANCE WITH LICENSING REQUIREMENTS IN THE IMPLEMENTATION OF PHARMACEUTICAL ACTIVITIES IN PHARMACY ORGANIZATIONS ARE CARRIED OUT no more than 1 time per year no more than 1 time in 2 years at intervals established by the relevant licensing authority no more than 1 time in 3 years	PC-4 PC-5 PC-10
17.	SCHEDULED INSPECTIONS OF COMPLIANCE WITH LICENSING REQUIREMENTS IN THE IMPLEMENTATION OF PHARMACEUTICAL ACTIVITIES IN DRUG WHOLESALERS ARE CARRIED OUT no more than 1 time in 2 years no more than 1 time per year at intervals established by the relevant licensing authority no more than 1 time in 3 years	PC-4 PC-5 PC-10
18.	ON THE CONDUCT OF A SCHEDULED INSPECTION OF LEGAL ENTITIES, INDIVIDUAL ENTREPRENEURS ARE NOTIFIED BY THE STATE SUPERVISION BODY BEFORE THE START OF ITS CONDUCT NO LATER THAN 3 working days 2 working days 2 calendar days	PC-4 PC-5 PC-10

	3 calendar days	
19.	A MEDICINAL PRODUCT ACCOMPANIED BY FALSE INFORMATION ABOUT THE COMPOSITION AND (OR) MANUFACTURER OF THE MEDICINAL PRODUCT IS falsified medicinal product patented medicine narcotic drug psychotropic substance	PC-4 PC-5 PC-10
20.	TO DETERMINE THE QUANTITATIVE INFLUENCE OF VARIOUS FACTORS ON THE MAGNITUDE OF DEMAND FOR DRUGS, THE COEFFICIENTS SHOULD BE CALCULATED correlation and elasticity Risk Magazines speed of implementation Liquidity	PC-4 PC-5 PC-10
21.	DEMAND CAN BE CONSIDERED ELASTIC IF A slight decrease in price significantly increases demand With a significant reduction in price, demand increases slightly price changes demand does not change With a slight decrease in supply, demand increases sharply	PC-4 PC-5 PC-10
22.	THE MAIN TASK OF THE PHARMACY OF A MEDICAL ORGANIZATION IS provision of departments of a medical organization with medicines and medical products Making a profit provision of outpatients with medicines providing patients with information on responsible self-medication	PC-4 PC-5 PC-10
23.	THE PROCEDURE FOR KEEPING RECORDS OF DRUGS WITH A LIMITED SHELF LIFE IN A PHARMACY ORGANIZATION IS ESTABLISHED the head of the organization by the licensing authority executive authority of the constituent entity of the Russian Federation Decree of the Government of the Russian Federation	PC-4 PC-5 PC-10
24.	PERSONS RESPONSIBLE FOR THE STORAGE OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES SHALL BE APPOINTED BY ORDER OF THE HEAD Organization of the licensing authority Federal Drug Control Service Federal Service for Surveillance in Healthcare	PC-4 PC-5 PC-10
25.	THE REQUIREMENTS FOR THE REGISTRATION OF THE REGISTER OF TRANSACTIONS RELATED TO THE CIRCULATION OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES DO NOT INCLUDE THE FACT THAT THE JOURNAL MUST BE certified by the head of the Ministry of Internal Affairs Numbered Corded certified by the seal of the legal entity	PC-4 PC-5 PC-10
26.	SUBJECT-QUANTITATIVE STUDY OF NARCOTIC DRUGS AND PSYCHOTROPIC	PC-4

	SUBSTANCES IN PHARMACY ORGANIZATIONS IS CARRIED OUT IN Journal of registration of transactions related to the circulation of narcotic drugs and psychotropic substances Journal of registration of operations in which the number of precursors of narcotic drugs and psychotropic substances changes Journal of operations related to the circulation of medicines for medical use Narcotic Medicines Accounting Book	PC-5 PC-10
27.	SUBJECT-QUANTITATIVE ACCOUNTING OF PRECURSORS OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES IN PHARMACY ORGANIZATIONS IS CARRIED OUT IN Journal of registration of operations in which the number of precursors of narcotic drugs and psychotropic substances changes Journal of registration of transactions related to the circulation of narcotic drugs and psychotropic substances Journal of operations related to the circulation of medicines for medical use Narcotic Medicines Accounting Book	PC-4 PC-5 PC-10
28.	LOGS OF OPERATIONS IN WHICH THE NUMBER OF PRECURSORS OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES CHANGES ARE STORED IN metal cabinet (safe) a metal cabinet in a technically fortified room safe in a technically fortified room the desktop of the head of the organization	PC-4 PC-5 PC-10
29.	COMPLETED REGISTERS OF OPERATIONS IN WHICH THE NUMBER OF PRECURSORS OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES CHANGES ARE STORED IN THE PHARMACY ORGANIZATION (YEARS) 10 1 3 5	PC-4 PC-5 PC-10
30.	INVENTORY OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES IN A PHARMACY ORGANIZATION IS CARRIED OUT monthly Quarterly annually with a frequency determined by the head of the organization	PC-4 PC-5 PC-10
31.	FOR MEDICINES SUBJECT TO SUBJECT-QUANTITATIVE ACCOUNTING, THE NORMS OF NATURAL LOSS ARE SET IN % OF THE VALUE flow rate in natural meters receipts in the monetary meter receipts in natural meters book residue in natural meters	PC-4 PC-5 PC-10
32.	THE LIST OF MEDICINES SUBJECT TO SUBJECT-QUANTITATIVE ACCOUNTING SHALL BE APPROVED Ministry of Health of the Russian Federation Ministry of Health of the Constituent Entities of the Russian Federation The Ministry of Health of the Russian Federation together with Roszdravnadzor	PC-4 PC-5 PC-10

	Roszdravnadzor	
33.	IN ACCORDANCE WITH THE LAW OF THE RUSSIAN FEDERATION "ON PROTECTION OF CONSUMER RIGHTS", THE CONSUMER IS a citizen who intends to order or purchase goods (works, services) exclusively for personal, family, household and other needs a citizen intending to order or purchase goods (works, services) for business purposes a legal entity intending to order or purchase goods (works, services) exclusively for personal, family, household and other needs Those who use the product for its intended purpose	PC-4 PC-5 PC-10
34.	THE MANUFACTURER IS OBLIGED TO ENSURE THE SAFETY OF THE GOODS DURING the established service life or shelf life of the goods or within 10 years after transfer to the consumer, if the service life is not established a period of at least 10 years from the date of manufacture the period established by the contract shelf life of the goods	PC-4 PC-5 PC-10
35.	GLUCOMETER (PROVIDED THAT THE CONSUMER HAS NO COMPLAINTS ABOUT ITS QUALITY DECLARED BY THE MANUFACTURER) PURCHASED FROM A PHARMACY ORGANIZATION Exchange and non-refundable Can be exchanged during the service life can be exchanged during the warranty period can be exchanged within 14 days if the receipt is preserved and the goods were not in use	PC-4 PC-5 PC-10
36.	THE RULES FOR THE STORAGE OF DRUGS ARE APPROVED Ministry of Health of the Russian Federation The Federal Service for Surveillance in Healthcare or its territorial body (Roszdravnadzor) The Federal Service for Supervision of Consumer Rights Protection and Human Welfare or its territorial body (Rospotrebnadzor) The executive authority in the field of health care of the constituent entity of the Russian Federation	PC-4 PC-5 PC-10
37.	DESTRUCTION OF DRUGS IS NOT CARRIED OUT owners of drugs licensed to carry out pharmaceutical activities organizations that have the appropriate license at specially equipped sites, landfills in specially equipped rooms	PC-4 PC-5 PC-10
38.	THERMOMETERS AND HYGROMETERS IN THE DRUG STORAGE ROOM MUST BE AT A DISTANCE OF AT LEAST (M) FROM DOORS, WINDOWS AND HEATING DEVICES 3 1 2 4	PC-4 PC-5 PC-10
39.	WHEN PLACING DRUGS IN STORAGE ROOMS, IT IS NOT TAKEN INTO ACCOUNT drug supplier Pharmacological group Mode of application physical and chemical properties of drugs	PC-4 PC-5 PC-10
40.	THE DOSAGE FORM GIVES THE DRUG OR MEDICINAL PLANT RAW MATERIALS A CONVENIENT STATE FOR USE, IN WHICH IT IS ACHIEVED Therapeutic effect Geometric shape	PC-4 PC-5 PC-10

	State of aggregation Diagnostic action	
41.	IF IT IS NECESSARY TO DISPENSE THE MEDICINAL PRODUCT IN AN EMERGENCY, THE DOCTOR MUST: Put the designations "Cito" or "Statim" on the recipe Call the pharmacy At the top of the recipe, write in red pencil "Urgent!" Use a special form of prescription form	PC-4 PC-5 PC-10
42.	THE COLLECTION OF MANDATORY NATIONAL STANDARDS AND REGULATIONS REGULATING THE QUALITY OF MEDICINES, EXCIPIENTS, DOSAGE FORMS AND PREPARATIONS IS State Pharmacopoeia Order of the Ministry of Health for quality control of medicines GUEST GMP	PC-4 PC-5 PC-10
43.	ORDER No. 706N ESTABLISHES THE REQUIREMENTS FOR premises for storage of medicines decoration of the trading floor storage of promotional products equipment of a medical organization	PC-4 PC-5 PC-10
44.	ACCORDING TO THE RULES FOR THE USE OF PHARMACOPOEIA MONOGRAPHS, "WARM" MEANS TEMPERATURE (°C) 40 to 50 35 to 37 from 18 to 20 from 36 to 38	PC-4 PC-5 PC-10
45.	AN ODOROUS MEDICINAL SUBSTANCE IS thymol riboflavin folic acid Methylene blue	PC-4 PC-5 PC-10
46.	THE COLORING PROPERTIES ASSOCIATED WITH HIGH SORPTION CAPACITY ARE POSSESSED BY potassium permanganate folic acid dry thermopsis extract sulfur	PC-4 PC-5 PC-10
47.	VOLATILE SOLVENTS USED IN PHARMACY PRACTICE INCLUDE ethanol glycerin olive oil Vaseline oil	PC-4 PC-5 PC-10
48.	MEDICINAL SUBSTANCES WITH THE LOWER LIMIT OF MOISTURE CONTENT ESTABLISHED BY REGULATORY DOCUMENTATION INCLUDE: crystalline hydrates Amorphous Volatile lipophilic	PC-4 PC-5 PC-10
49.	DEVICES FOR RECORDING AIR PARAMETERS MUST BE LOCATED FROM THE FLOOR AT A HEIGHT (M) 1,5-1,7	PC-4 PC-5 PC-10

	3 0,2 not higher than 1.7	
50.	THE STATE ATTACHED TO THE DRUG OR MEDICINAL PLANT RAW MATERIALS THAT IS CONVENIENT FOR USE, IN WHICH THE NECESSARY THERAPEUTIC EFFECT IS ACHIEVED, IS dosage form Medicine A medicinal product medicament	PC-4 PC-5 PC-10
51.	THE PHARMACOLOGICAL AGENT IS a substance or mixture of substances with established pharmacological activity that is the subject of clinical trials medicinal product in the form of a certain dosage form additional substance necessary for the manufacture of the drug a medicinal product that is an individual chemical compound or biological substance	PC-4 PC-5 PC-10
52.	TARE WITH POTENT SUBSTANCES ARE DECORATED WITH A LABEL WITH THE INSCRIPTION LETTERS red on a white background white on a black background black on a white background white on a red background	PC-4 PC-5 PC-10
53.	DISPERSOLOGICAL CLASSIFICATION OF DOSAGE FORMS TAKES INTO ACCOUNT THE NATURE OF Relationships between the dispersed phase and the dispersion medium dispersed phase dispersion medium Bonds in homogeneous systems	PC-4 PC-5 PC-10
54.	ONE OF THE BASIC PRINCIPLES OF HOMEOPATHY A cure like like A cure like the opposite Animal testing of drugs Testing drugs in humans at toxic doses before painful symptoms appear	PC-4 PC-5 PC-10
55.	IN ACCORDANCE WITH THE INSTRUCTIONS FOR THE SANITARY REGIME IN THE PHARMACY, DECORATIVE DESIGN AND LANDSCAPING ARE ALLOWED in non-production premises No Limits in industrial premises with a frequency of cleaning at least 1 time per week	PC-4 PC-5 PC-10
56.	CHANGE OF SANITARY CLOTHING OF THE PHARMACY STAFF SHOULD BE MADE AT LEAST 2 times a week 1 time per shift 1 time in 2 weeks 1 time per month	PC-4 PC-5 PC-10
57.	THE AIR OF THE INDUSTRIAL PREMISES OF PHARMACIES IS DISINFECTED ultraviolet irradiation radiation sterilization treatment of premises with detergents supply and exhaust ventilation	PC-4 PC-5 PC-10
58.	FOR THE TREATMENT OF THE HANDS OF PHARMACY PERSONNEL ENGAGED IN	PC-4

	THE MANUFACTURE OF MEDICINES, AFTER WASHING WITH SOAP AND RINSING WITH WATER, IT IS RECOMMENDED TO USE ETHANOL IN A CONCENTRATION (%) 70 40 95 50	PC-5 PC-10
59.	THE WARNING INSCRIPTION "STORE IN A COOL PLACE" PASTED ON MANUFACTURED MEDICINAL PRODUCTS SHOULD HAVE THE FOLLOWING TEXT AND SIGNAL COLOR white font on a blue background white font on a blue background white font on a green background white font on a red background	PC-4 PC-5 PC-10
60.	THE WARNING INSCRIPTION "STORE IN A DARK PLACE" PASTED ON MANUFACTURED MEDICINAL PRODUCTS MUST HAVE THE FOLLOWING TEXT AND SIGNAL COLOR white font on a blue background white font on a blue background white font on a green background white font on a red background	PC-4 PC-5 PC-10
61.	THE WARNING INSCRIPTION "KEEP AWAY FROM FIRE" PASTED ON MANUFACTURED MEDICINAL PRODUCTS MUST HAVE THE FOLLOWING TEXT AND SIGNAL COLOR white font on a red background white font on a blue background white font on a blue background white font on a green background	PC-4 PC-5 PC-10
62.	THE WARNING INSCRIPTION "FOR NEWBORNS" PASTED ON MANUFACTURED MEDICINAL PRODUCTS SHOULD HAVE THE FOLLOWING TEXT AND SIGNAL COLOR white font on a green background white font on a red background white font on a blue background white font on a blue background	PC-4 PC-5 PC-10
63.	WATER FOR INJECTION IN A PHARMACY IS STORED AT 80-95 °C 24 hours 20 °C 24 hours 20 °C 48 hours 20 °C for 3 days	PC-4 PC-5 PC-10
64.	ON ALL BANKS OR TARE IN WHICH MEDICINES ARE STORED, THE FOLLOWING ARE INDICATED the name of the medicinal product, the date of filling the tare with the medicinal product, the expiration date (best before), the signature of the person who filled in the tare name of the medicinal product, expiration date (valid until ____), signature of the person who filled in the tare name of the medicinal product, signature of the person who filled in the tare the date of filling the tare with the medicinal product, the expiration date (valid until ____), the signature of the person who filled out the tare	PC-4 PC-5 PC-10
65.	IN THE PREMISES OF DRUG STORAGE, THE TEMPERATURE AND HUMIDITY OF THE AIR SHOULD BE CHECKED AT LEAST 1 time per day 1 time per shift	PC-4 PC-5 PC-10

	2 times per shift 2 times a day	
66.	IN THE PREMISES OF DRUG STORAGE, TEMPERATURE AND HUMIDITY INDICATORS ARE RECORDED IN log (map) of registration of air parameters shelving card Journal of operations related to the circulation of drugs for medical use journal of accounting for drugs with a limited shelf life	PC-4 PC-5 PC-10
67.	THE SHELF LIFE IN THE PHARMACY OF WATER FOR INJECTION IS (DAY) 1 3 5 10	PC-4 PC-5 PC-10
68.	EXPLOSIVE SUBSTANCES INCLUDE A DRUG potassium permanganate glycerin Tincture Vegetable oils	PC-4 PC-5 PC-10
69.	DISINFECTANTS SHOULD BE STORED IN isolated room conditions of the refrigerating chamber protected from light, cool place cabinets painted from the inside with oil paint	PC-4 PC-5 PC-10
70.	COLLODION, ETHYL ALCOHOL, TURPENTINE, ETHER ARE STORED IN A TIGHTLY SEALED DURABLE GLASS CONTAINER TO PREVENT evaporation of liquids from vessels ignition explosion The action of air vapor	PC-4 PC-5 PC-10
71.	COMPENSATION FOR HARM TO CITIZENS CAUSED AS A RESULT OF THE USE OF A MEDICINAL PRODUCT THAT HAS BECOME UNUSABLE AS A RESULT OF VIOLATION OF THE RULES FOR ITS STORAGE IN A PHARMACY IS MADE Pharmacy Manufacturer insurance organization the budget of the subject of the Russian Federation	PC-4 PC-5 PC-10
72.	IN RECIPES IN RUSSIAN OR RUSSIAN AND THE NATIONAL LANGUAGE ARE INDICATED: Mode of application Composition of the drug Dosage form the doctor's appeal to the pharmacist about the manufacture	PC-4 PC-5 PC-10
73.	A DOCUMENT OF THE ESTABLISHED FORM, WHICH IS ISSUED BY A MEDICAL OR VETERINARY WORKER WHO HAS THE RIGHT TO DO SO, AND CONTAINS IN WRITING AN INDICATION OF THE PHARMACY ORGANIZATION ON THE RELEASE OF THE MEDICINAL PRODUCT OR ON ITS MANUFACTURE AND ON THE RELEASE TO ENSURE THE TREATMENT PROCESS IN A MEDICAL ORGANIZATION, VETERINARY ORGANIZATION, IS CALLED Requirement Pharmacopoeia Monograph normative document	PC-4 PC-5 PC-10

	Recipe	
74.	AN ORGANIZATION ENGAGED IN WHOLESALE TRADE IN MEDICINES IN ACCORDANCE WITH THE REQUIREMENTS OF THE FEDERAL LAW "ON THE CIRCULATION OF MEDICINES" IS organization of wholesale trade in medicines Pharmacy medical organization pharmacy kiosk	PC-4 PC-5 PC-10
75.	A SPECIAL PERMIT TO CARRY OUT A SPECIFIC TYPE OF ACTIVITY, SUBJECT TO MANDATORY COMPLIANCE WITH LICENSING REQUIREMENTS, ISSUED BY THE LICENSING AUTHORITY TO A LEGAL ENTITY OR INDIVIDUAL ENTREPRENEUR IS License Certificate of accreditation Certificate Patent	PC-4 PC-5 PC-10
76.	PSYCHOTROPIC SUBSTANCES INCLUDED IN LIST III OF THE LIST OF NARCOTIC DRUGS (NS), PSYCHOTROPIC SUBSTANCES (PV) AND THEIR PRECURSORS ARE PRESCRIBED ON THE PRESCRIPTION FORM No. 148-1 / y-88 "Prescription form" 107/y-NP "Special prescription form for NA and PV" 107-1/y "Prescription form" 148-1/y-04 (l) "Prescription form"	PC-4 PC-5 PC-10
77.	THE ASKHOD OF NARCOTIC MEDICINES IS ADDITIONALLY RECORDED IN THE JOURNAL registration of transactions related to the circulation of narcotic drugs and psychotropic substances registration of transactions related to the trafficking of precursors of narcotic drugs and psychotropic substances registration of transactions related to the trafficking of narcotic drugs and psychotropic substances of List II of the List of NA, PV and their precursors accounting for operations related to the circulation of drugs for medical use subject to PKU	PC-4 PC-5 PC-10
78.	IF THE PRESCRIBED DOSE OF NARCOTIC DRUGS IN THE PRESCRIPTION EXCEEDS THE HIGHEST SINGLE DOSE, AND THE PRESCRIPTION IS NOT PROPERLY ISSUED, THEN THE PHARMACIST MUST redeem the prescription with the stamp "Prescription is invalid", register in the journal of incorrectly written prescriptions and return it to the patient release this drug in half the dose that is set as the highest single dose Release in the amounts indicated in the recipe return the prescription to the patient	PC-4 PC-5 PC-10
79.	THE VALIDITY PERIOD OF PRESCRIPTIONS FOR NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES INCLUDED IN LIST II OF THE LIST OF NS, PV AND THEIR PRECURSORS IS (DAYS) 15 10 30 5	PC-4 PC-5 PC-10
80.	ASSESSMENT OF THE COMPLIANCE OF PRESCRIPTIONS RECEIVED BY THE PHARMACY WITH THE CURRENT REGULATIONS ON THE RULES FOR PRESCRIBING PRESCRIPTIONS AND THE PROCEDURE FOR DISPENSING DRUGS IS pharmaceutical expertise of prescriptions Taxation of recipes	PC-4 PC-5 PC-10

	recipe acceptance algorithm Subject-quantitative account	
81.	PRESCRIPTIONS FOR MEDICINES MARKED "CITO" (URGENTLY) ARE SERVED WITHIN A PERIOD NOT EXCEEDING (DAYS) 2 1 5 10	PC-4 PC-5 PC-10
82.	COMPLIANCE OF THE MEDICINAL PRODUCT WITH THE REQUIREMENTS OF THE PHARMACOPOEIA MONOGRAPH OR, IN THE ABSENCE THEREOF, A REGULATORY DOCUMENT OR A REGULATORY DOCUMENT IS: quality of medicines safety of medicines efficacy of medicines circulation of medicines	PC-4 PC-5 PC-10
83.	A DOCUMENT APPROVED BY THE AUTHORIZED FEDERAL EXECUTIVE BODY AND CONTAINING A LIST OF QUALITY INDICATORS AND QUALITY CONTROL METHODS OF A MEDICINAL PRODUCT FOR MEDICAL USE IS Pharmacopoeia article State Pharmacopoeia clinical and pharmacological article Formulary article	PC-4 PC-5 PC-10
84.	FOR VIOLATION OF THE RULES OF SALE, A PHARMACY ORGANIZATION MAY BE HELD LIABLE Administrative Criminal Disciplinary Material	PC-4 PC-5 PC-10
85.	FOR VIOLATION OF LICENSING REQUIREMENTS, A PHARMACY ORGANIZATION MAY BE HELD LIABLE Administrative Criminal Disciplinary Material	PC-4 PC-5 PC-10
86.	THE STATE SUPERVISION BODY THAT MONITORS COMPLIANCE WITH THE LEGISLATION ON THE CIRCULATION OF MEDICINES FOR MEDICAL USE IS Roszdravnadzor Ministry of Health of the Russian Federation Rospotrebnadzor Moa	PC-4 PC-5 PC-10
87.	THE STATE SUPERVISION BODY THAT CARRIES OUT INSPECTIONS OF COMPLIANCE WITH LICENSING REQUIREMENTS IN THE IMPLEMENTATION OF PHARMACEUTICAL ACTIVITIES IN ORGANIZATIONS ENGAGED IN THE WHOLESALE TRADE OF DRUGS FOR MP IS Roszdravnadzor Ministry of Health of the Russian Federation Rospotrebnadzor Moa	PC-4 PC-5 PC-10
88.	IN ACCORDANCE WITH THE FEDERAL LAW OF 26.12.2008 NO. 294-FZ "ON THE PROTECTION OF THE RIGHTS OF LEGAL ENTITIES AND INDIVIDUAL ENTREPRENEURS IN THE IMPLEMENTATION OF STATE CONTROL AND	PC-4 PC-5 PC-10

	MUNICIPAL CONTROL", THE TYPES OF INSPECTIONS DO NOT INCLUDE: Target Planned Cameral Documentary	
89.	SCHEDULED INSPECTIONS OF COMPLIANCE WITH LICENSING REQUIREMENTS IN THE IMPLEMENTATION OF PHARMACEUTICAL ACTIVITIES IN PHARMACY ORGANIZATIONS ARE CARRIED OUT no more than 1 time per year no more than 1 time in 2 years at intervals established by the relevant licensing authority no more than 1 time in 3 years	PC-4 PC-5 PC-10
90.	SCHEDULED INSPECTIONS OF COMPLIANCE WITH LICENSING REQUIREMENTS IN THE IMPLEMENTATION OF PHARMACEUTICAL ACTIVITIES IN DRUG WHOLESALERS ARE CARRIED OUT no more than 1 time in 2 years no more than 1 time per year at intervals established by the relevant licensing authority no more than 1 time in 3 years	PC-4 PC-5 PC-10
91.	ON THE CONDUCT OF A SCHEDULED INSPECTION OF LEGAL ENTITIES, INDIVIDUAL ENTREPRENEURS ARE NOTIFIED BY THE STATE SUPERVISION BODY BEFORE THE START OF ITS CONDUCT NO LATER THAN 3 working days 2 working days 2 calendar days 3 calendar days	PC-4 PC-5 PC-10
92.	WHEN CONDUCTING A SCHEDULED ON-SITE INSPECTION, EMPLOYEES OF THE STATE SUPERVISION BODY DO NOT CHECK measures taken by a legal entity or individual entrepreneur to prevent harm to life, health of citizens, harm to animals, plants, the environment, etc. information contained in the documents of a legal entity, individual Entrepreneur; compliance of employees, premises and equipment with the established Requirements Manufactured and sold goods	PC-4 PC-5 PC-10
93.	LIABILITY IS PROVIDED FOR VIOLATION OF THE LEGISLATION ON THE CIRCULATION OF MEDICINES Administrative Criminal Material Civil	PC-4 PC-5 PC-10
94.	THE VALIDITY PERIOD OF THE REGISTRATION CERTIFICATE FOR A MEDICINAL PRODUCT REGISTERED FOR THE FIRST TIME IN RUSSIA IS (YEARS) 5 7 10 15	PC-4 PC-5 PC-10
95.	THE VALIDITY PERIOD OF THE REGISTRATION CERTIFICATE FOR THE DRUG AFTER CONFIRMATION OF ITS STATE REGISTRATION IS Indefinite period 5 years 10 years	PC-4 PC-5 PC-10

	15 years	
96.	MEDICINAL PRODUCTS ARE NOT SUBJECT TO STATE REGISTRATION manufactured by pharmacy organizations according to doctors' prescriptions and the requirements of medical organizations Original Reproduced New combinations of previously registered medicines	PC-4 PC-5 PC-10
97.	ARE NOT SUBJECT TO STATE REGISTRATION Extemporal drugs Generic drugs Original medicines New combinations of previously registered medicines	PC-4 PC-5 PC-10
98.	ACCORDING TO THE LEGISLATION OF THE RUSSIAN FEDERATION, THE CIRCULATION OF MEDICINES DOES NOT INCLUDE: Drug Distribution development, preclinical studies, clinical trials, expertise, state registration, standardization and quality control production, manufacture, storage transportation, import into the territory of the Russian Federation, export from the territory of the Russian Federation, advertising	PC-4 PC-5 PC-10
99.	STATE REGISTRATION OF MEDICINES, MAINTENANCE OF THE STATE REGISTER OF MEDICINES ARE WITHIN THE POWERS OF Ministry of Health of the Russian Federation Roszdravnadzor Rospotrebnadzor Drug manufacturing organizations	PC-4 PC-5 PC-10
100.	THE STATE SUPERVISION BODY THAT VERIFIES COMPLIANCE WITH LICENSING REQUIREMENTS WHEN CARRYING OUT PHARMACEUTICAL ACTIVITIES IN RETAIL PHARMACEUTICAL ORGANIZATIONS OF PRIVATE OWNERSHIP IS Licensing Authority Ministry of Health of the Russian Federation Roszdravnadzor Rospotrebnadzor	PC-4 PC-5 PC-10

4.2. Bank of case-tasks for solving cases

№	Case-task	The code of the competence for the formation of which the case-task is aimed
1.	**When checking the activities of the pharmacy kiosk of the municipal unitary enterprise "Pharmacy No. 1", the control and supervisory organization found the following. Onthe showcase are exhibited drugs: almagel-A susp. 170 ml, Corinfar** table. p / o 10mg No. 30, panangin table. p / o No. 50, **lidaza (**lyophilisate for the preparation of the solution d / in. 64 UE, 5 ml No. 10**), cerucal** table. 10mg No. 50, **Levomekol 40g, tincture of peony evading 50ml, formic alcohol 50ml, Fotil ch. cap. 20/5mg 5ml, mercazolil table. 5mg No. 50, diphenhydramine table. 50mg No. 10, No-shpa table. 40mg No. 20, no-shpa r-r d / in. 20mg/ml 2ml No. 5, grass celandine 75g, etc. When checking the storage conditions, the absence of a refrigerator was found, the temperature at the place of storage of the medicine was 23 ° C. When asked to present documents confirming the quality**	PC-4 PC-5 PC-10

	of the drugs, the kiosk pharmacist replied that they exist, but are stored in the pharmacy. The answer to the requirement to present a license for pharmaceutical activities and a specialist certificate was the same. When checking the documents in the pharmacy, it turned out that the pharmacist did not have a specialist certificate, she was hired under a contract agreement. 1) Conduct an audit analysis: comment on the results and identify violations. What licensing requirements were violated? 2) What forms of state control (supervision), municipal control, according to the Federal Law of the Russian Federation of 26.12.2008 No. 294-FZ "On the Protection of the Rights of Legal Entities and Individual Entrepreneurs in the Exercise of State Control (Supervision) and Municipal Control", exist? Describe the procedure for their implementation. 3) What rights do legal entities and individual entrepreneurs have in the exercise of state control (supervision), municipal control? 4) Who has the right to carry out the process of licensing pharmaceutical activities? What is the procedure for obtaining the above licenses? 5) Violation of what requirements are classified as gross and non-gross violations? When answering each of the questions, it is necessary to make references to the relevant regulatory legal documents.	
2.	**Pharmacy N is municipally owned, serves the population and medical organizations. It has 3 departments: production, department of stocks and dispensing of medicines of the Ministry of Defense, department of dispensing medicines to the population. In addition, the pharmacy received a license to work with narcotic drugs and psychotropic substances (NA and PV). In the pharmacy at night there was a theft of goods. Actions of the manager in this situation.** 1) How should the safety of goods be ensured? 2) With which organizations does this pharmacy have the right to conclude a security contract? 3) What types of liability are there? 4) List the stages of conducting and documenting the verification of compliance of the actual availability of goods with accounting data. 5) What will be the composition of the inventory commission in this case? 6) What will be the procedure for compensation for damage to the pharmacy in the event of a shortage of goods based on the results of the inventory and its documentation? 7) Who has the right to work with NA and PV? 8) How should the storage room for HC and PV be organized in this pharmacy? Argue the answer with the relevant regulatory legal documentation.	PC-4 PC-5 PC-10
3.	**On November 15, 2012, the municipal unitary enterprise "CRA No. 5" from the Moscow Region received requirements for finished medicines, including a solution *of morphine hydrochloride 1.0 N50*. The pharmacy has a license for pharmaceutical activities with the right to work with narcotic drugs and psychotropic substances (NA and PV), issued by the Commission for Licensing of Pharmaceutical Activities of the Constituent Entity of the Russian Federation on January 10, 2012.** 1) Does the pharmacy have the right to fulfill the application of a medical organization (MO) in this situation? 2) Do all pharmacies have the right to work with NA and PV? How is the permit for the right to work of a pharmacy with NA and PV documented? 3) What types of work include activities for the turnover of NA and PV? 4) What are the licensing requirements for obtaining a license for the right to work with NA and PV? 5) How is the process of applying for NA and PV carried out in this pharmacy organization?	PC-4 PC-5 PC-10

	6) What documents reflecting the transactions on the turnover of NA and PV should be available in the pharmacy organization? 7) What documents need to be checked when accepting NA and PV at the pharmacy? 8) How is the process of storing NA and PV in the MO carried out? Argue the answer with the relevant regulatory documentation.	
4.	**The licensing authority sent a commission for a routine inspection of compliance with licensing requirements to the pharmacy of PharmPlus LLC. As a result of the inspection, it was established: prescription drugs are stored in the windows, the pharmacist of the JSC has expired the validity of the specialist's certificate, at the time of the inspection, the temperature regime in the refrigerator where the LP "Grippferon" was stored (on the packaging of the drug it is indicated "Store at a temperature of 2** 0 C **to 8** 0 C**", "Dispensing without a prescription"), was violated (15^{0}C).** 1. What are the licensing requirements for the implementation of pharmaceutical activities by a pharmacy organization? 2. Who has the right to engage in pharmaceutical activities? 3. How long can the verification of licensing requirements last? 4. What violations are gross violations of licensing requirements? 5. Can a decision be made to suspend the license, by whom and for how long? 6. Can this JSC be held administratively liable (which one)? 7. Can LP Grippferon be put on display?	PC-4 PC-5 PC-10
5.	**When checking the activities of the pharmacy, the licensing commission established the following: drugs of the List of SD and poisonous are stored on racks; prescriptions for diphenhydramine (table) are left in the pharmacy and stored for 1 month; there are no duly executed price tags for medicines and other goods allowed for release from pharmacies (only the price is indicated);phenobarbital for a course of treatment for up to 1 month is often dispensed by prescription with the inscription "For special purposes", signed and personal seal of the doctor; The pharmacist-analyst has not improved his qualifications for 6 years. The director explained the latter by the fact that the employee has reached retirement age and it is inappropriate to send him to advanced training courses at the expense of the pharmacy. In addition, there was no instruction on the procedure for registering the collection of information on the side effects of the drug, adverse reactions during its use, on the facts and circumstances that pose a threat to the life and health of citizens and medical workers and the transfer of information about them to Roszdravnadzor.** 1) Who has the right to inspect pharmaceutical organizations? 2) What types of inspections of legal entities are there? Give them a brief description. 3) What is the peculiarity of conducting a prosecutor's check of a pharmaceutical organization? 4) What is the procedure for checking licensing requirements and conditions? 5) List the basic rights of legal entities in the implementation of their verification. 6) Conduct a validation analysis; comment on the results; Identify violations. 7) Which violations of licensing requirements can be classified as gross and which as non-gross. 8) Who in the pharmacy organization is obliged to collect information about the side effects of the drug, adverse reactions when it is used, about the facts and circumstances that pose a threat to the life and health of citizens and medical workers and transmit information about them to Roszdravnadzor? What other information must be transmitted to the specified structure? Argue the answer with the relevant regulatory documentation.	PC-4 PC-5 PC-10
6.	**As a result of the inspection of the pharmacy organization conducted by the Federal Antimonopoly Service, a violation of pricing for medicines included in the list of vital and essential drugs was revealed. The violation consisted in the**	PC-4 PC-5 PC-10

	fact that the audited organization calculated the retail price from the actual selling price of the manufacturer with VAT. The pharmacy organization itself is on the general taxation system. 1) Describe the scheme of formation of retail (selling price) for finished medicines. Specify the peculiarity of pricing for vital and essential medicines. 2) Analyze the result of the inspection. Who is right in this situation? 3) Calculate the wholesale and retail cost of the drug "X" (for the pharmacy organization of Nizhny Novgorod), if it is known that the actual release of the manufacturer without VAT = 150 rubles, with VAT = 165 rubles, the organization of wholesale trade is also on the general system of taxation. 4) How would the retail price for this drug be calculated if the pharmacy organization were a payer of a single tax on imputed income (imputed income)? 5) Which organizations can pay imputed? The procedure for paying this type of tax. 6) What other control and supervisory organizations, in addition to the FAS, have the right to verify the correctness of pricing in pharmaceutical organizations?	
7.	**The patient turned to the pharmacy with a request to let him go without a prescription package of Solpadein tablets No. 12 (8 mg of codeine per 1 tablet), 2 packs of Nurofen Plus tablets table. p / o No. 12 (10 mg of codeine per 1 tablet), Tempalgin table. p / o No. 20, No-shpy table. 40mg No. 6 and Baralgetas table. 500mg No. 10. The pharmacist did not release all the drugs, referring to the current vacation rules. Another visitor demanded a refund for an over-the-counter drug sold the day before in the same pharmacy, arguing that after reading the instructions for the drug again, he realized that it was not suitable for him. The pharmacist refused to return.** 1) Did the pharmacist do the right thing in the first case? Which of the following drugs can be dispensed without a prescription? How do you explain the refusal of vacation to the patient? 2) What are the conditions and procedure for storing these drugs? Requirements for storage facilities. 3) What are the rules for prescribing and dispensing these drugs? 4) List the goods that the pharmacy organization has the right to sell. For the sale of what goods should it obtain additional permission and in what form? 5) Did the pharmacist do the right thing in the second case? 6) What is the consumer entitled to, according to the Federal Law of the Russian Federation of 07.02.1992 No. 2300-1 "On Protection of Consumer Rights"? Argue the answer with the relevant regulatory documents.	PC-4 PC-5 PC-10
8.	**The prescription prescribes a solution of atropine sulfate for oral administration. The prescription is certified by the signature and personal seal of the doctor. The highest single dose is exceeded 100 times. Taking a prescription, the pharmacist noticed that today this is the third prescription incorrectly written by this doctor.** 1) What is the pharmaceutical examination of a prescription? 2) What group of drugs does atropine sulfate belong to and what other lists of drugs exist? 3) How should a prescription be issued if a doctor prescribes a drug in a dose exceeding the highest single dose. 4) What types of prescription forms are there? List for each of them: basic and additional details, validity and storage. 5) What drugs can be prescribed on each prescription form? 6) What are the specifics of prescriptions for medical devices? 7) How is it necessary to organize the process of storing drugs in a pharmacy organization? Argue the answer with the relevant regulatory documentation.	PC-4 PC-5 PC-10
9.	**On the 10th day of the current month, goods packed in boxes were delivered to the pharmacy by road of a wholesale pharmaceutical organization. When accepting the goods in terms of the number of units and quality, a shortage of 5**	PC-4 PC-5 PC-10

	packages of the D / in solution was found. 50mg 2ml No. 10 "Pipolfen" at a price of 563 rubles. At the same time, the pharmacy received a batch of narcotic drugs and psychotropic substances (HC and PV), during the inspection of which no violations were found. Laying out these drugs in their storage areas, the pharmacist accidentally dropped one package on the floor, breaking one ampoule, which he immediately reported to the head of the pharmacy. 1) How are the economic ties between the pharmacy and the wholesale pharmaceutical organization formalized? 2) How and by whom should the goods be accepted at the time of receipt? 3) What are the indicators of acceptance quality control of incoming medicines? 4) Your actions, as a materially responsible person, in case of discrepancies in the acceptance of goods, documentation. 5) In what documents, and in what expression (meter) should the received goods be capitalized? 6) Where should the received medicines be stored? 7) List the actions of the head of the pharmacy in case of detection of battle, damage to medicines related to NA and PV. 8) How is the process of write-off and destruction of various categories of medicines in a pharmaceutical organization? Argue the answer with the relevant regulatory documents.	
10.	**The pharmacy of the regional clinical hospital, serving 1400 beds, received a requirement for ethyl alcohol from the surgical department for January of this year. The estimated number of patients for the current year in this department is 1100 people. The approximate standard for the consumption of ethyl alcohol for the surgical department per 1 treated patient (per year) is 225 g.** 1) Determine the approximate consumption rate of the surgical department in ethyl alcohol for the year and January of this year. 2) What are the norms for the release of ethyl alcohol from the pharmacy to the departments of a medical organization? Argue the answer with the relevant regulatory documentation. 3) What are the rules for prescribing requirements for medicines and other pharmaceutical products to the pharmacy of a medical organization. 4) What are the requirements for the organization of the storage room for ethyl alcohol? Argue the answer with the relevant regulatory documentation. 5) List the safety requirements when working with ethyl alcohol. 6) What is the responsibility of pharmacy officials for the safety of ethyl alcohol? Argue the answer with the relevant regulatory documentation. 7) List all the main accounting documents on the turnover of ethyl alcohol in the pharmacy organization. Name the employees responsible for their registration. Argue the answer with the relevant regulatory documentation.	PC-4 PC-5 PC-10
11.	**In April of this year, the pharmacy released to the population on preferential prescriptions of medicines in the amount of 45.5 thousand rubles, which amounted to 16% of the total turnover.** 1) Which pharmacies have the right to dispense medicines on preferential prescriptions? 2) How is the preferential leave financed? How is the pharmacy paid for drugs released on preferential prescriptions? 3) List the population groups and categories of diseases, in the outpatient treatment of which drugs are released on preferential terms. 4) What about thespecifics of prescribing preferential prescriptions, the procedure for their registration and shelf life in a pharmacy? 5) How should the process of storing different groups of preferential drugs be organized? 6) How is the wholesale and retail price of drugs included in the list of vital and essential drugs formed? Argue the answer with the relevant regulatory documentation.	PC-4 PC-5 PC-10

12.	**Pharmacist Ivanova A.N., who is 3 months pregnant, went on another paid vacation for two weeks. After a week of vacation, she was asked to go to work in connection with a routine inventory at the pharmacy. At the same time, it was assumed that the inventory would take place at night.** 1) How legitimate is this situation? What could the pharmacist do in this case, based on the current labor legislation? 2) Does the manager, in case of refusal of the pharmacist to go to work, have the right to apply any punishment to him? 3) Which organizations monitor the observance of employee rights in the Russian Federation? 4) What is night work? What are the features of its payment? 5) What are the normal working hours? What other types of working time are there? 6) What is "inventory"? What are its tasks, types, and timing? Imagine an inventory algorithm. 7) List the documents to be processed in the inventory process.	PC-4 PC-5 PC-10
13.	**The pharmacist, who resigned at his own request, was delayed by the director of the pharmacy "Medicines for You" the issuance of a work book, since upon dismissal he did not return the gown issued to him.** 1) Is the head of the pharmacy right in this situation? What documents should be filed and stored in a pharmaceutical organization for each of the employees? Their shelf life. 2) Terms of issuance of the work book, calculation of dismissal. 3) The procedure for terminating an employment contract at the initiative of the employee (at his own request). 4) The employee's right to withdraw his application. What day is considered the day of dismissal? 5) What should the employer do if the employee was absent from work on the day of dismissal? 6) What is the responsibility of the employer (pharmacy) to the pharmacist in this situation? 7) Can the director of a pharmacy be held financially liable? Foundation. 8) What are the norms for issuing and accounting for sanitary clothing in a pharmacy. Argue the answer with the relevant regulatory documents.	PC-4 PC-5 PC-10
14.	**The accountant of the pharmacy accrued wear and tear on the equipment used for sterilization of medicines as of 01.01.2015 after 2 years of its operation, using the linear method, while taking the initial cost as a basis.** 1) What was the main mistake made by the accountant? 2) By what criteria will the property be classified as fixed assets? 3) What other methods of calculating depreciation of fixed assets are used in pharmacies? 4) What is the classification of pharmacy household products? 5) List the measures for labor protection in pharmacies, paying special attention to the operation of pressure devices. 6) The procedure for investigating accidents in a pharmacy organization.	PC-4 PC-5 PC-10
15.	**Evaluate the legitimacy of the administration's actions in each of the situations below from the standpoint of the Labor Code of the Russian Federation and give answers to questions.** **a) When hiring a pharmacist, the director of the pharmacy "Cherry Orchard" asked her to write her autobiography, then found out that she had a child of 2 years old and refused to hire her, although the pharmacy had a vacant pharmacist rate.** **б) The director of the pharmacy hired a pharmacist for taking prescriptions and dispensing medicines with a probationary period of 1 month. From the first days of work, it became clear that the pharmacist did not know the basic requirements of the current documents regulating the procedure for taking prescriptions and dispensing medicines, and was rude to visitors and**	PC-4 PC-5 PC-10

	colleagues. After 2 weeks (in agreement with the trade union organization of the pharmacy), she was dismissed. Did the director of pharmacies have the right to dismiss an employee before the end of the probationary period. List the categories of workers who, in accordance with the Labor Code of the Russian Federation, are prohibited from establishing a probationary period when hiring. 1) What documents are required when applying for a job? 2) What are the qualification requirements for a pharmacist? 3) Does the employer have the right to dismiss an employee before the end of the probationary period? 4) What are the grounds for dismissal of the employee? 5) List the categories of workers who are prohibited from establishing a probationary period when hiring. 6) Does a transfer to another workplace apply to transfers to another position? **7)** Can it be carried out without the consent of the employee?	
16.	**During the inspection of the activities of the pharmacy kiosk of the municipal unitary enterprise "Apteka 1", conducted jointly by the Inspectorate for the Protection of Consumer Rights, the Labor Inspectorate, the Commission for Licensing of Pharmaceutical Activities and the Tax Inspectorate, the following was established:** 1) The following drugs were exhibited in the showcase: Almagel A, Nikodin, Corinfar, Panangin, Saridon, Lidase, Cerucal, Lorinden-A ointment, peony tincture, formic alcohol, otipax, Maerkazolil, diphenhydramine in table., No-shpa in table. and ampoules, grass celandine, etc. 2) When checking the storage conditions, the absence of a refrigerator was found, the temperature at the place of storage of the drug is 230C. 3) A pharmacist was working at the kiosk that day. When asked to present documents confirming the quality of the drugs, the kiosk pharmacist replied that they exist, but are stored in the pharmacy. On the proposal to present a license for pharmaceutical activities and a specialist certificate, the answer was the same. 4) When checking the documents in the pharmacy, it turned out that the pharmacist did not have a specialist certificate, she was hired under a contract agreement. 5) At the time of the inspection, the electricity was turned off, and the pharmacist dispensed medicines without punching checks on the cash register.	PC-4 PC-5 PC-10
17.	**The management of the pharmaceutical organizationN decided to conduct an advertising campaign in order to stimulate the sale of products. The turnover of the organization in the pre-advertising period amounted to 60 thousand rubles The advertising department justified the need for five publications in a pharmaceutical newspaper and four broadcasts of a radio commercial in the amount of 3 thousand rubles As a result, 2 thousand rubles were allocated, the money was used for 3 broadcasts and 3 publications. After carrying out promotional activities, the turnover amounted to 66 thousand rubles.** 1) Give a description of the concept of "pharmaceutical advertising". What is its purpose? 2) What should not be contained in the advertising of medicines? 3) Give a classification of the means of advertising. Give them a brief description. 4) How is the phased planning of the budget of advertising and information activities in a pharmaceutical organization carried out? 5) What expenditure items does the advertising budget contain? 6) How is the effectiveness of information and advertising activities of pharmaceutical organizations assessed? 7) What liability is provided for by the legislation of the Russian Federation for violations in the field of advertising, consumer protection and rules for the sale of certain types of goods?	PC-4 PC-5 PC-10

	Argue the answer with the relevant regulatory documentation.	
18.	**A fine was imposed on one of the pharmacies of the "Your Doctor" network for the fact that the pharmacist of this pharmacy took a sample of the drug from the medical representative of the pharmaceutical company X. In another pharmacy of the same network, the manager made a remark to a visitor who photographed the windows.** 1) Is it legal to impose a fine on the first pharmacy? 2) Is the head of the second pharmacy right? 3) List the rights of the consumer in the field of obtaining proper information about the pharmaceutical organization and the product sold by it. 4) What are the rights of consumers when dispensing drugs from a pharmacy organization? 5) What is the liability for violation of these rights? 6) What restrictions are imposed by the legislation of the Russian Federation in the field of advertising of medicines? 7) Give examples of outdoor and indoor advertising in a pharmacy organization. Argue the answer with the relevant regulatory documentation.	PC-4 PC-5 PC-10
19.	**The administration of the pharmacy decided to form a closed joint-stock company on its basis and began to prepare constituent documents, the pharmacy staff was not informed about this. Rumors began to spread around the pharmacy about the sale of the pharmacy to unknown people and the dismissal of all employees. Finally, a delegation of employees led by an informal leader - the head of one of the departments of the department - came to the director of the pharmacy with a threat to start a strike. Head. The pharmacy was surprised, and then explained to the employees the benefits of the changes, that they would all be the owners of the pharmacy, and denied the rumors. The conflict was avoided.** 1) What is the mistake in the behavior of the pharmacy administration? 2) Reveal the essence of the concepts of "Formal" and "Informal" structure of the organization. 3) What are some examples of sources of conflict in pharmaceutical organizations? 4) What measures can be taken to prevent them? 5) What are the requirements for management decisions? 6) Stages of development of management decisions?	PC-4 PC-5 PC-10
20.	**A pharmacist was hired at the Municipal Unitary Enterprise "Apteka" to carry out information work from August 1 of this year with a probationary period of 1 month. On September 3 of this year, the employee was dismissed under Art. 71 of the Labor Code of the Russian Federation, as he did not pass the test. In November of this year, the district court of N ruled to reinstate the pharmacist at work with the payment of average earnings for the entire period of forced absenteeism and with compensation to the employee for monetary compensation for moral damage in the amount of 5 thousand rubles.** 1) What is the violation of the labor legislation of the head of the pharmacy? 2) Testing when applying for a job: the purpose of the test, its duration, design. 3) Categories of workers for whom the test is not established. Test result. 4) then compensates for the damage caused to the employee? What is it? 5) What financial responsibility is imposed in this case on the manager? Foundation. 6) Information activities of the pharmacy. Consumers of pharmaceutical information, methods of working with different groups of consumers of pharmaceutical information. 7) List the responsibilities of the pharmacist for information work.	PC-4 PC-5 PC-10
21.	**An advertisement for the dietary supplement "Fulflex" was placed in the television space. The advertiser recommended treatment for gout. The FAS banned the broadcast of the video and fined the manufacturer's company.**	PC-4 PC-5 PC-10

	1) Give the concept of unfair competition. 2) What inconsistencies with the Federal Law "On Advertising" were identified by the FAS in this case? 3) What types of unfair competition are found in the pharmaceutical market? 4) Terms of advertising for prescription and over-the-counter drugs. 5) What additional inscriptions when advertising dietary supplements should be on the screene?	
22.	**In the manufacture of chloramphenicol alcohol solution 1% 25 ml, the pharmacist found that in the tare with the label "Laevomycetinum", which had just arrived from the material room, there was, in his opinion, another substance that resembled anestezinin in appearance and taste.** 1) What should a pharmacist do in this situation? 2) What kind of control must be subjected to medicines coming from the material room to the assistant room, and who should carry out this control? How is it documented and how should the tare be issued? 3) What types of intra-pharmacy control are you required to own as a pharmacist for quality control of medicines in a pharmacy? 4) How and where should the workplace of a pharmacist-technologist and a pharmacist-analyst be organized? 5) What types of control can be subjected to medicines manufactured in a pharmacy, including injectables, purified water, medicinal plant materials? 6) What preventive measures are you required to carry out in the pharmacy to ensure the quality of medicines prepared in the pharmacy? 7) At the expense of what indicators in the pharmacy are the costs of quality control of medicines written off?	PC-4 PC-5 PC-10
23.	**As a result of the inspection carried out by the inspector of Roszdravnadzor in the wholesale pharmaceutical organization, it was found that a batch of the drug "Herceptin, lyophilized powder for the preparation of solution for infusions of 440 mg (fl.) was prepared for sale. / complete with solvent series N3555 / B2055 (on the packages the manufacturer is indicated F. Hoffman-La Roche Ltd., Switzerland, Jenentek Inc., USA), in respect of which the Federal Service for Surveillance in Health and Social Development reported by letter as falsified. The drug in the amount of 10 packages was seized and destroyed in the presence of the inspector.** **Conduct a full legal analysis of this situation and answer the questions posed with references to the relevant legislation:** 1) What types of violations and in what area of legislation took place? 2) What legal consequences can occur for a wholesale organization? 3) What is the procedure for the destruction of drugs in this situation? 4) What liability can the perpetrators incur? 5) Rights of legal entities and individual entrepreneurs in the exercise of state control and supervision.	PC-4 PC-5 PC-10
24.	**The head of the pharmacy of the health care facility has work experience in this specialty, general experience and 10 years of continuous work experience in health care institutions, expressed a desire to be certified for the assignment of a qualification category.** 1) What regulatory document approved the Regulation on the certification of pharmacists? 2) Where should the pharmacist go? What documents do I need to prepare? 3) In what specialties is the certification of pharmacists, pharmacists carried out? 4) Who is allowed to be certified for the assignment of a qualification category, the procedure for its implementation? 5) What category can be assigned to the head of the pharmacy? 6) The procedure for drug provision of LLU in modern conditions. **7)** Modern problems of drug provision for inpatients.	PC-4 PC-5 PC-10
25.	**A patient came to the pharmacy with a prescription form No. 148-1 / y-88,**	PC-4

	on which Alprazolam and Escitalopram were prescribed. The recipe has all the required and additional details. The pharmacist refused to leave. The patient appealed to the head of the pharmacy with a demand to release the drugs prescribed by the doctor. 1) Is the pharmacist right? Justify the answer. How was the doctor supposed to prescribe these drugs so that the pharmacy could dispense them? 2) What is the procedure for accounting in the pharmacy of Alprazolam? 3) If the doctor needs to prescribe the drug Escitalopram to a patient for a period of treatment of 6 months, how should the prescription be issued? 4) How is the retail price for these drugs formed if they are included in the list of vital and essential drugs? **5)** What marks should a pharmacy employee make on a prescription when dispensing a drug?	PC-5 PC-10

4.3. Questions for colloquiums

1) Retail link in the system of promotion of pharmacy products. Nomenclature of pharmacy organizations, tasks and functions. Forms of ownership and organizational and legal forms of pharmacy organizations.

2) Nomenclature of full-time positions of pharmacy workers. Options for the organizational structure of the pharmacy. The composition of the premises of pharmacy organizations, depending on the functions performed.

3) Legislation of the Russian Federation in the field of licensing of pharmaceutical activities. The procedure for opening and licensing a pharmacy organization.

4) General principles of organization of storage of drugs in pharmacy organizations.

5) Features of storage of certain groups of goods in a pharmacy warehouse. Receiving, storing and accounting for goods in a pharmacy warehouse, inventory management.

6) Requirements for the design of the trading floor of the pharmacy organization and the design of shop windows. Basic principles of merchandising.

7) Organization of the work of pharmacy organizations for the sale of goods and services. Over-the-counter medication. Organization of workplaces of specialists on the trading floor.

8) Organization of the work of the pharmacy for the reception of prescriptions and dispensing of drugs: pharmaceutical expertise, registration.

9) Registration of primary documentation at the workplace of the pharmacist, technologist.

10) Organization of the manufacture of medicinal products, semi-finished products, intra-pharmacy preparations, production of concentrates and semi-finished products. Taxation of recipes and the procedure for their registration.

11) Intra-pharmacy quality control of medicinal products, drugs dispensed from pharmacy organizations. Equipment of the workplace for quality control of drugs, basic documentation.

12) State regulation of the circulation of controlled groups of drugs. Subject-quantitative accounting in the pharmacy.

13) Features of receipt, storage and accounting of narcotic drugs, psychotropic substances and their precursors.

14) The procedure for licensing a pharmaceutical organization.

15) The procedure for licensing pharmaceutical activities and activities for the circulation of HC, PV and their precursors.

16) State supervision and control of the activities of a pharmaceutical organization. Control procedure.

17) Documentary sources of scientific pharmaceutical information.

18) Marketing methods of research of information needs of subjects of the pharmaceutical market

19) Communication policy in pharmacy: methodological approaches to advertising and promotion of medicines and other pharmacy products.

20) The system of protection of the rights of consumers of pharmaceutical products and services.

4.4. Workbook sample

TOPIC 1 – THE STATE CONTROL (SUPERVISION) IN THE SPHERE OF CIRCULATION OF MEDICINES

1.1. The state control (supervision) in the sphere of circulation of medicines

1) represents the activity of the authorized FEBs aimed at
_____
_____
_____

2) includes the following list of types of control:
а) _____, which consists in _____;
б) _____, which consists in _____;
в) _____, which consists in _____.

1.2. Licensing of activities in the field of circulation of medicines

1) The aim and tasks (purpose) of licensing certain types of activities.
2) Define the following basic concepts in the field of licensing:

Licensing	
License	
Licensingg authorities (e.g.)	
Licensed activity (e.g.)	
License requirements	
License applicant	
Licensee	

3) Describe the procedure for granting a license

_____

_____

1.10. Approval of general pharmacopeia monographs and pharmacopeia monographs and enactment of the State pharmacopeia

1) The State pharmacopoeia – is _____

_____

The structure of the State pharmacopoeia	
... monographs	*... monographs*
definition	*definition*

2) Who develops quality indicators and quality control methods, their expertise and inclusion in the State pharmacopoeia?

_____

_____

_____

3) Which FEB and with what frequency reissues the State pharmacopoeia? How is the quality control of medicines (for which articles have been developed, but not yet included in the State pharmacopoeia) carried out between reprints?

_____

_____

4) What is a reference medicinal product? _____ .

What are the peculiarities of the development and inclusion in the State pharmacopoeia of the pharmacopoeial monograph on the reference MP?

_____ .

What is the purpose of this approach?

_____ .

How is the quality control of a reference MP performed in the absence of pharmacopoeial monograph?

_____ .

1.11. Organization of expert examination of medicines

1) The authorized federal executive body responsible for the expert examination of medicines is –

_____

2) Expertise of medicines is carried out in the following directions:

а) _____

б) _____

в) _____

г) _____

д) _____

5. The content of the assessment tools of mid-term assessment

Mid-term assessment is carried out in the form of a credit.

5.1 The list of control tasks and other materials necessary for the assessment of knowledge, skills and work experience

5.1.1. Questions for the credit in the discipline

1) Retail link in the system of promotion of pharmacy products. Nomenclature of pharmacy organizations, tasks and functions. Forms of ownership and organizational and legal forms of pharmacy organizations.
2) Nomenclature of full-time positions of pharmacy workers. Options for the organizational structure of the pharmacy. The composition of the premises of pharmacy organizations, depending on the functions performed.
3) Legislation of the Russian Federation in the field of licensing of pharmaceutical activities. The procedure for opening and licensing a pharmacy organization.
4) General principles of organization of storage of drugs in pharmacy organizations.
5) Features of storage of certain groups of goods in a pharmacy warehouse. Receiving, storing and accounting for goods in a pharmacy warehouse, inventory management.
6) Requirements for the design of the trading floor of the pharmacy organization and the design of shop windows. Basic principles of merchandising.
7) Organization of the work of pharmacy organizations for the sale of goods and services. Over-the-counter medication. Organization of workplaces of specialists on the trading floor.
8) Organization of the work of the pharmacy for the reception of prescriptions and dispensing of drugs: pharmaceutical expertise, registration.
9) Registration of primary documentation at the workplace of the pharmacist, technologist.
10) Organization of the manufacture of medicinal products, semi-finished products, intra-pharmacy preparations, production of concentrates and semi-finished products. Taxation of recipes and the procedure for their registration.
11) Intra-pharmacy quality control of medicinal products, drugs dispensed from pharmacy organizations. Equipment of the workplace for quality control of drugs, basic documentation.
12) State regulation of the circulation of controlled groups of drugs. Subject-quantitative accounting in the pharmacy.
13) Features of receipt, storage and accounting of narcotic drugs, psychotropic substances and their precursors.
14) The procedure for licensing a pharmaceutical organization.
15) The procedure for licensing pharmaceutical activities and activities for the circulation of HC, PV and their precursors.
16) State supervision and control of the activities of a pharmaceutical organization. Control procedure.
17) Documentary sources of scientific pharmaceutical information.
18) Marketing methods of research of information needs of subjects of the pharmaceutical market
19) Communication policy in pharmacy: methodological approaches to advertising and promotion of medicines and other pharmacy products.
20) The system of protection of the rights of consumers of pharmaceutical products and services.

6. Criteria for evaluating learning outcomes

For the credit:

Learning outcomes	Evaluation criteria	
	Not passed	**Passed**
Completeness of knowledge	The level of knowledge is below the minimum requirements. There were bad mistakes.	The level of knowledge in the volume corresponding to the training program. Minor mistakes may be made
Availability of skills	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes.	Basic skills are demonstrated. Typical tasks have been solved, all tasks have been completed. Minor mistakes may be made.
Availability of skills (possession of experience)	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes.	Basic skills in solving standard tasks are demonstrated. Minor mistakes may be made.
Motivation (personal attitude)	Educational activity and motivation are poorly expressed, there is no willingness to solve the tasks qualitatively	Educational activity and motivation are manifested, readiness to perform assigned tasks is demonstrated.
Characteristics of competence formation*	The competence is not fully formed. The available knowledge and skills are not enough to solve practical (professional) tasks. Repeated training is required	The competence developed meets the requirements. The available knowledge, skills and motivation are generally sufficient to solve practical (professional) tasks.
The level of competence formation	Low	Medium/High

For the exam:

Learning outcomes	Assessment of competence developed			
	unsatisfactory	**satisfactory**	**good**	**excellent**
Completeness of knowledge	The level of knowledge is below the minimum requirements. There were bad mistakes	The minimum acceptable level of knowledge. A lot of light mistakes were made	The level of knowledge in the volume corresponding to the training program. A few light mistakes were made	The level of knowledge in the volume corresponding to the training program, without errors
Availability of skills	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes	Basic skills are demonstrated. Typical problems with light mistakes have been solved. All tasks have been completed, but not in full.	All basic skills are demonstrated. All the main tasks have been solved with light mistakes. All tasks have been completed, in full, but some of them with	All the basic skills were demonstrated, all the main tasks were solved with some minor shortcomings, all the tasks were completed in full

Learning outcomes	Assessment of competence developed			
	unsatisfactory	**satisfactory**	**good**	**excellent**
			shortcomings	
Availability of skills (possession of experience)	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes	There is a minimal set of skills for solving standard tasks with some shortcomings	Basic skills in solving standard tasks with some shortcomings are demonstrated	Skills in solving non-standard tasks without mistakes and shortcomings are demonstrated
Characteristics of competence formation*	The competence is not fully formed. The available knowledge and skills are not enough to solve professional tasks. Repeated training is required	The formation of competence meets the minimum requirements. The available knowledge and abilities are generally sufficient to solve professional tasks, but additional practice is required for most practical tasks	The formation of competence generally meets the requirements, but there are shortcomings. The available knowledge, skills and motivation are generally sufficient to solve professional tasks, but additional practice is required for some professional tasks	The formation of competence fully meets the requirements. The available knowledge, skills and motivation are fully sufficient to solve complex professional tasks
The level of competence formation*	Low	Below average	Intermediate	High

For testing:
Mark "5" (Excellent) - points (100-90%)
Mark "4" (Good) - points (89-80%)
Mark "3" (Satisfactory) - points (79-70%)
Mark "2" (Unsatisfactory) - less than 70%

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