METHODOLOGICAL RECOMMENDATIONS IN PREPARATION FOR THE COMPREHENSIVE PRACTICE-ORIENTED QUALIFICATION EXAMINATION IN PHARMACY
MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY

METHODOLOGICAL RECOMMENDATIONS
in preparation for the comprehensive practice-oriented qualification examination in Pharmacy
for applicants for higher education
of field of knowledge 22 Healthcare
in speciality 226 Pharmacy/Pharmacy, Industrial Pharmacy

under the editorship of Professor Alla KOTVITSKA

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The methodological recommendations contain situational tasks for professionally-oriented academic disciplines, carried out for a comprehensive practice-oriented qualification examination in Pharmacy. Issues related to the principles of professional activity of pharmaceutical workers are covered in the form of situational tasks. The tasks have been worked out in accordance with the curricula in Pharmacy Technology of Medicines, Industrial Technology of Medicines, Pharmacognosy, Pharmaceutical Chemistry, Organization and Economics of Pharmacy, Pharmaceutical Marketing and Management, Clinical Pharmacy and Pharmaceutical Care for applicants for higher education with account taken of the necessary professional competencies of general pharmacists.

Methodical recommendations are intended to prepare for a complex practice-oriented qualifying examination in Pharmacy for applicants for higher education in the field of knowledge 22 Healthcarein specialty 226 Pharmacy / Pharmacy, Industrial Pharmacy.
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INTRODUCTION

The modern doctrine of higher education development in Ukraine, implementation of basic principles, rules and regulations with international and European standards, reforming the domestic Healthcare sector require improvement of the existing system of pharmaceutical training, which would meet modern world requirements. Reforming the domestic pharmaceutical sector in the Healthcare sector involves training competitive professionals at a qualitatively new level on the basis of a competency-based approach. This necessitates professional knowledge of Pharmacy, their skillful practical use.

The methodological recommendations provide situational tasks for professionally-oriented academic disciplines, which are submitted for an integrated practically-oriented qualifying exam in Pharmacy. Issues related to the principles of professional activity of pharmaceutical workers are highlighted in the form of situational tasks.

Situational tasks are developed in accordance with the educational and professional program "Pharmacy", training programs in Pharmacy Technology of Drugs, Industrial Technology of Drugs, Pharmacognosy, Pharmaceutical Chemistry, Organization and Economics of Pharmacy, Pharmaceutical Marketing and Management, Clinical Pharmacy and Pharmaceutical Care for higher education with account taken of the necessary professional competencies of general pharmacists.

These methodological recommendations are intended for the certification of applicants for higher education in the field of knowledge 22 Healthcare in speciality 226 Pharmacy / Pharmacy, Industrial Pharmacy in order to prepare for an integrated practically-oriented qualification exam in Pharmacy.

GENERAL INFORMATION

Certification of people obtaining Master's degree in 226 Pharmacy, Industrial Pharmacy is carried out by the examination commission of the National University of Pharmacy, which operates on the basis of the "Regulations on the examination committee at the National University of Pharmacy" (POL A 2.2-26-136).

Certification of applicants for higher education is the establishment of the learning outcomes compliance with the requirements of the educational program and/or the requirements of the program of the unified state qualification examination.

The applicants for higher education who have met all the requirements of the curriculum and training programs in the speciality 226 Pharmacy / Pharmacy, Industrial Pharmacy are admitted to the certification.

During the integrated practice-oriented qualification exam in Pharmacy, the testing and evaluating the quality of the graduates’ professional training, establishing its compliance with the requirements of the educational-professional training program in the speciality 226 Pharmacy / Pharmacy, Industrial Pharmacy are carried out.

The examination paper of the integrated practice-oriented qualification exam in Pharmacy contains the situation and 4 practical tasks adapted to the realities of the future professional activity.

The competencies of applicants for higher education in the integrated practice-oriented qualification exam in Pharmacy are assessed by a separate single assessment of all disciplines that are classified in accordance with the curriculum.
**SITUATIONS AND PRACTICAL TASKS FOR A COMPREHENSIVE PRACTICE-ORIENTED QUALIFICATION EXAM IN PHARMACY**

**Situation 1**

LLC “Research Plant State Research Center of Medicines” received a batch of medicinal plant raw material for medicine “Mucaltin”, tablets 50 mg No. 30, production.

1. Identify medicinal plant raw material by morphological and anatomical features. With the help of identification reactions confirm the presence of the main class of biologically active substances in medicinal plant raw material, propose a method for its quantitative determination.

2. Give appropriate calculations, demonstrate technological operations for the preparation of the mixture (using dry standardized extract-concentrate of Marshmallow root (1:1)) according to the prescription:

   \[
   \text{Rp.:} \quad \begin{align*}
   &\text{Infusi radicis Althaeae } 80 \text{ mL} \\
   &\text{Natrii benzoatis } 2.0 \\
   &\text{Liquoris Ammonii anisati } 3\text{ mL} \\
   &\text{Sirupi simplicis } 5 \text{ mL} \\
   &\text{Misce. Da. Signa: Use } 1 \text{ table spoon } 3 \text{ times a day.}
   \end{align*}
   \]

   Write the front side of the written control passport, perform operations on packaging and labeling.

3. Calculate the amount of vacation payment to pharmacist Ivanova A. A., who works as a head of the prescription and production department of the pharmacy No. 8. Monthly salary of Ivanova A. A. is 6 300 UAH, the sum of bonuses for the year is 8 600 UAH.

4. Propose an algorithm of pharmaceutical care for symptomatic treatment of cough in the patient with a gastrointestinal disorder. Propose a list of effectiveness/safety criteria. Provide an informational and counseling service regarding use of the medicine “Mucaltin”.

**Situation 2**

A visitor turned to your pharmacy with a request for prescription drug «Doxycycline», ordered by a doctor for treatment of mycoplasmal pneumonia:

   \[
   \text{Rp.:} \quad \begin{align*}
   &\text{Tab. Doxycyclini 0.1 No. 10} \\
   &\text{D.S.: } 1 \text{ tablet } 2 \text{ times a day during } 7 \text{ days}
   \end{align*}
   \]

1. Provide pharmaceutical care to a pharmacy visitor considering that at the same time she reported about use of Azithromycin for 7 days before the referral to a pharmacy. Now she complains about discomfort in the gastrointestinal tract, abdominal distention, diarrhea. Provide the substantiated recommendation regarding responsible self-treatment.

2. Give appropriate calculations, demonstrate technological operations for the preparation of the ointment with an antibiotic of the tetracycline group according to the prescription:

   \[
   \text{Rp.:} \quad \begin{align*}
   &\text{Ung. Tetracyclini } 1 \% 10.0 \\
   &\text{D. S. Lubricate the edges of the eyelids } 2 \text{ times a day.}
   \end{align*}
   \]

   Write the front side of the written control passport, perform operations on packaging and labeling.

3. Make a conclusion about the compliance of doxycycline hydrochloride substance with requirements of the EuPh and SPhU monographs (tests for purity), by the specific absorbance. Due to the chemical properties of doxycycline, give background for the risks of its simultaneous use with antacids and iron preparations.

4. Calculate the capacity of the regional pharmaceutical market for Doxycycline (per year), taking into account capabilities of manufacturers and the purchasing capacity of consumers, if marketing research of the regional pharmaceutical market of the medicine “Doxycycline” shows the following data:

   \[
   \begin{align*}
   &\text{Population of region} \quad – 2 \text{ million people} \\
   &\text{Purchasing capacity per 1 person} \quad – 0.4 \text{ pac. a year} \\
   &\text{Firm “A” production} \quad – 0.7 \text{ mil. pac.} \\
   &\text{Firm “B” production} \quad – 1.2 \text{ mil. pac.} \\
   &\text{Arrivals of the medicine from other regions} \quad – 0.3 \text{ mil. pac.} \\
   &\text{Deliveries of the medicine in other regions} \quad – 0.8 \text{ mil. pac.} \\
   &\text{Commodity stocks} \quad – 0.1 \text{ mil. pac.}
   \end{align*}
   \]

   Establish the type of the regional market by results of calculations. Suggest other quantitative market indicators for analysis.
**Situation 3**

PJSC “Liktravy” received a batch of medicinal plant raw material for medicine “Vitamin species No. 2” production.

1. Identify medicinal plant raw material by morphological and anatomical features. Suggest methods of qualitative analysis and quantify ascorbic acid in medicinal plant raw material.

2. Prepare 100.0 g of simple sugar syrup, on the basis of which medicinal syrup “Cholosas” which contains an extract from rose hips is made. Name features of technology of medicinal syrups and excipients used in their production.

3. Offer a set of marketing communications to promote the vitamin species – herbal tea of a pharmaceutical company. Make a plan for an advertising campaign for herbal tea.

4. Substantiate a reasonability of using the medicine containing Rose Hips (Rosa Canina fruits) by the patient with the following diagnosis: Chronic persistent hepatitis with cholestasis occurrence. Propose a list of effectiveness/safety criteria for use of the medicine. Provide an informational and counseling service regarding the use of the medicine “Cholosas”.

**Situation 4**

A woman turned to your pharmacy with the prescription for «Lisinopril», ordered by a doctor for treatment of essential arterial hypertension:

Rp.: Tab. Lisinopril 0.01 No. 30
D.S.: 1 tablet per day

1. Provide pharmaceutical care to a pharmacy visitor considering that at the same time she asked for advice on the medicine to treat dry cough. Provide the substantiated recommendation. Provide an informational and counseling service regarding use of the medicine “Lisinopril”.

2. Determine the friability of tablets “Lisinopril” 0.01 № 30 according to the SPhU. Make a conclusion about the compliance of the degree of grinding of this raw material to requirements of the SPhU. Justify what factors affect this indicator of tablet quality.

3. Carry out identification and tests for purity of lisinopril substance by the test “Specific optical rotation” and estimate the result.

4. Calculate how many units of the medicine must be sold be the wholesale pharmaceutical company to maintain profits at the same level, if they buy the medicine “Lisinopril” at a price of 79.00 UAH per package and sold at a price of 95.00 UAH. Weekly sales volume is 400 units. Marketing department recommends reducing the price by 10 % for one week.

**Situation 5**

Arterium Corporation received a batch of medicinal plant raw material for medicine “Recutan” production.

1. Identify medicinal plant raw material by morphological and anatomical features. Suggest a method of obtaining essential oil from this medicinal plant raw material. Perform an organoleptic analysis and determine main physical indicators of the quality of essential oil.

2. Carry out a sieve (fractional) analysis of vegetable raw materials - chamomile flowers and make a conclusion about the compliance of the degree of grinding of this raw material to requirements of the SPhU regarding its use for production of extraction medicines.

3. Describe actions of the authorized person, if during the entrance control of goods received at the pharmacy (“Recutan”, liquid in a glass bottle, 100 mL of Arterium Corporation), found a mismatch of the batch number on the package and in the manufacturer’s quality certificate.

4. Compose an algorithm of pharmaceutical care for symptomatic treatment of sore throat in the young woman with type I diabetes mellitus in her medical history. Propose a list of effectiveness/safety criteria of the treatment. Provide an informational and counseling service regarding the use of the medicine “Recutan”.
**Situation 6**

A visitor turned to your pharmacy. You know this patient very good – he regularly buys «Verapamil», which is ordered to him by a doctor in complex treatment of essential arterial hypertension:

Rp.: Tab. Verapamili 0.08 No. 20
D.S.: 1 tablet 3 times a day

1. Provide pharmaceutical care to a pharmacy visitor considering that at the same time he asked for a medicine to treat a headache. During questioning, a pharmacy visitor reported that he takes Verapamil irregularly, only in case of high blood pressure. Provide the substantiated recommendation.

2. Determine the disintegration time of Verapamil film-coated tablets according to the SPhU. Make a conclusion about the compliance of obtained results with requirements of the SPhU.

3. Identify by morphological features medicinal plant raw material that has a laxative effect. Suggest methods of analysis of the main class of biologically active substances in medicinal plant raw material. Name medicines, their use in the health care.

4. Calculate the real cost of advertising and give recommendations on the appropriateness of placing an advertising text about a medicine for constipation elimination in specialized and popular science magazines, if in order to promote this medicine in the pharmaceutical market, the manufacturer plans to place the advertising in a specialized magazine “Practitioner” and the popular science magazine “Science and Life”. At the same time, specialists of marketing research department found that the cost of an advertisement in magazine “Practitioner” is 20 thousand, in magazine “Science and Life” is 30 thousand UAH. Circulation is 30.000 copies for magazine “Practitioner”, for magazine “Science and Life” is 80.000 copies. The real audience (established by marketing research) is: for magazine “Practitioner” – 90 %, for magazine “Science and Life” – 20 %.

**Situation 7**

About Company

PJSC SIC “Borschchahivskiy CPP” received a batch of medicinal plant raw material for medicine “Digoxin” production.

1. Identify medicinal plant raw material by morphological and anatomical features. With the help of identification reactions confirm the presence of the main class of biologically active substances in medicinal plant raw material, propose a method for its quantitative determination.

2. Give appropriate calculations, demonstrate technological operations for the preparation of the infusion (using dry standardized extract-concentrate of Foxglove leaves (1:1)) according to the prescription:

Rp.: Infusi foliorum Digitalis ex 0.25 100 mL
Da. Signa: Use 1 table spoon 3 times a day.

Write the front side of the written control passport, perform operations on packaging and labeling.

3. Prepare financial statements (balance sheet) on the basis of accounting data, if final balances on the accounts are:

- equity – 179 920 000 UAH;
- non-current assets (residual value) – 123 000 000 UAH;
- goods (commodity) – 60 400 000 UAH;
- cash on hand – 170 000 UAH;
- cash in bank (money on the current account) – 40 000 000 UAH;
- debt of employees to the company – 20 000 UAH;
- company’s debt to the budget – 270 000 UAH;
- company’s debt to suppliers – 40 000 000 UAH;
- company’s debt to employees – 1 600 000 UAH;
- company’s debt to the bank – 1 800 000 UAH.

4. Provide pharmaceutical care to the patient with chronic health failure (Functional class III) in the process of dispensing by the prescription the medicine “Digoxin”. Describe clinical and pharmaceutical characteristics of cardiac glycosides and propose a list of effectiveness/safety criteria of the chronic health failure treatment.
Situation 8
A woman turned to your pharmacy with the prescription for «Amoxicillin», ordered her by a doctor for the treatment of acute pyelonephritis of her 6-years old son:
Rp.: Tab. Amoxicillini 0.25 No. 10
D. S. 1 tab. 2 times a day during 7 days

1. Provide pharmaceutical care to a pharmacy visitor considering that at the same time she asked for advice on the medicines for symptomatic treatment allowed for use in children. Provide the substantiated recommendation.
2. Give appropriate calculations, demonstrate technological operations for the preparation of suppositories with an antibiotic of the penicillin group according to the prescription:
Rp.: Benzylpenicillini-natrii 100000 U
Olei Cacao q. s.
Misce, fiat suppositoriorum
Da tales doses No. 3
Signa: Use 1 suppository per night.

Write the front side of the written control passport, perform operations on packaging and labeling.
3. Identify by morphological features medicinal plant raw material that has a diuretic effect. Suggest methods of analysis of the main class of biologically active substances in medicinal plant raw material.
4. Calculate the profitability of the pharmacy, if the average level of trading imposing is 28 %, the amount of expenses is 1 056 000 UAH, total commodity circulation (turnover) is 5 234 000 UAH.

Situation 9
The CPL of Pharmaceutical company “Zdorovye” carries out certification of a batch of the medicine “Cordiaminum-Zdorovye” solution for injections 250 mg/mL, ampoule 2 mL, blisters, pack, No. 10.

1. Carry out quantitative determination of nikethamide in the dosage form by refractometric method. Make a conclusion about the compliance of obtained results with requirements of the QCT.
2. Check the sealing of ampoules of cordiaminum solution for tightness; make a conclusion about quality of sealing. Name other methods of quality control of solutions for injection in ampoules according to requirements of the SPhU.
3. Determine the social-psychological management style of the general director of the pharmaceutical company, who independently solves all issues of the future existence of the organization, he has limited contact with subordinates. He is resolute, authoritative, strong-willed, tough in relation to others; he does not accept objections. In the communicative process he uses business, brief instructions. His praise and reproach of employees are extremely subjective, emotions of subordinates and colleagues are not taken into account. The organization is characterized by strategic planning with only immediate goals for each employee. The leader's voice is decisive, and his position is outside the group. Justify your answer according to the characteristic.
4. Compose a list of main symptoms and syndromes of chronic health failure, define approaches to its treatment. Propose a list of effectiveness/safety criteria of the chronic health failure treatment. Substantiate the reasonability of using inhibitors of ACE enzymes in the therapy of chronic health failure.

Situation 10
A woman addressed to your pharmacy with the prescription for «Celecoxib», ordered to her by a doctor for the rheumatoid arthritis treatment:
Rp.: Caps. “Celecoxib” 0.2 No. 10
D.S.: 1 caps. per day

1. Provide pharmaceutical care to a pharmacy visitor considering that at the same time she asked for an ointment containing Methyl salicylate that she uses regularly to treat joint pain. During the conversation, a woman asked to talk louder because she hears poorly due to the noise in the ears appearing for the last week. Provide the substantiated recommendation.
2. Determine the average weight of encapsulated content of Celecoxib capsules -0.2 and the deviation from it according to the SPhU. Make a conclusion about the compliance of obtained results with requirements
of the SPhU.
3. Identify by morphological characteristics medicinal plant raw material containing menthol, which is a component of “Bengay ointment”. Suggest a method of obtaining the main class of biologically active substances from medicinal plant raw material and indicators that characterize its quality. Name medicines, their use in the health care.
4. Identify communication barriers that may arise in the process of communication between the pharmacist and the visitor and recommend ways to eliminate them.

Situation 11
In the laboratory for quality control of medicines the analysis of extemporaneous medicine is carried out according to the prescription:
Take: Sol. Riboflavini 0.02 % 10 mL
Natrii chloridi 0.09
M.D.S.: 2 drops in both eyes

1. Carry out quantitative determination of riboflavin in the dosage form by photocolorimetric method. Make a conclusion about the compliance of obtained results with requirements of the Order of the Ministry of Health of Ukraine No. 812 dated 17.10.2012. Explain what changes may occur with this dosage form if stored incorrectly or when storage term is exceeded.
2. Give appropriate calculations, demonstrate technological operations for the preparation of ophthalmic drops according to the above prescription, write the front side of the written control passport, perform operations on packaging and labeling.
3. Fill in the cash book and indicate primary documents for accounting of expenditure and income cash transactions. Calculate the cash balance at the end of the day:
   • cash balance at the beginning of the day – 2 128 UAH;
   • revenue of pharmacy – 36 500 UAH;
   • revenue of the pharmacy point No. 1 – 22 000 UAH;
   • revenue of the pharmacy point No. 2 – 34 000 UAH;
   • money issued under the report (for business trips) – 150 UAH;
   • received from the bank to advance payment – 26 000 UAH;
   • advance paid to pharmacy employees – 26 000 UAH;
   • revenue handed over to the bank – ? UAH.
4. Explain to a pharmacy visitor the reasonability of prophylaxis of vitamin deficiency in the period of the seasonal prevalence of acute respiratory viral infections. Compose an algorithm of pharmaceutical care for dispensing the vitamins and minerals complex medicines for prophylaxis of seasonal hypovitaminosis.
departments – prescription-and-production and ready-made medicines. Formulate an indicative list of professional qualities and skills that pharmacy network managers should have, depending on management levels.

**Situation 13**
The CPL of “JSC Kyiv Vitamin Plant” carries out incoming control of glutamic acid substance, which will be used for the production of tablets.

1. Carry out identification and tests for purity of glutamic acid substance by polarimetric method. Make a conclusion about the compliance of obtained results with requirements of the SPhU. Give background for the use of polarimetry to identify and determine the purity of amino acids.
2. Determine the bulk density of glutamic acid substance. Draw conclusions from the result. Justify the purpose for which this test is conducted.
3. Make a conclusion, which method of sale should be used by the supplier of the substance of glutamic acid to the manufacturing pharmaceutical company. Recommend and make a scheme for this substance of possible distribution by degree of intensity.
4. Check for “threatening” symptoms by questioning a pharmacy visitor with anxiety. If responsible self-treatment is possible, propose the medicine for treatment of anxiety. Explain advantages and rules of the use of proposed medicine.

**Situation 14**
Pharmaceutical company “Merkle GmbH” (Germany) produces medicine in gelatin capsules “Actiferin”.

1. Determine the average weight of capsules and deviation from it according to requirements of the SPhU. Make a conclusion about obtained results.
2. Carry out identification of ferrous sulfate heptahydrate substance by the reaction for iron and sulfates according to the monograph of the EuPh and SPhU.
3. Schematically illustrate possible sales channels of the medicine. Determine the rating of the wholesale pharmaceutical companies and choose the optimal supplier of the medicine.

<table>
<thead>
<tr>
<th>Selection criterion</th>
<th>Weight of the criterion</th>
<th>Evaluation of the supplier of medicines, points</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Supplier A</td>
</tr>
<tr>
<td>Completeness of the range</td>
<td>0.3</td>
<td>5</td>
</tr>
<tr>
<td>Prices, discounts, payment terms</td>
<td>0.5</td>
<td>5</td>
</tr>
<tr>
<td>Level of service</td>
<td>0.1</td>
<td>3</td>
</tr>
<tr>
<td>Reliability</td>
<td>0.1</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1.0</strong></td>
<td></td>
</tr>
</tbody>
</table>

4. Explain to a pharmacy visitor clinical and pharmaceutical features of using iron medicines. Propose effectiveness and safety criteria of their use for prophylaxis as well as for therapy of iron-deficiency conditions.

**Situation 15**
The CPL of PC “Darnytsia” carries out incoming control of theophylline-ethylenediamine substance, intended for the production of solution for injections.

1. Carry out the assay of ethylenediamine in theophylline-ethylenediamine substance by acidimetric titration. Make a conclusion about the compliance of the substance with the EuPh and SPhU requirements by this parameter.
2. Control the injection solution of euphylline 2.4 % in 5 mL ampoules relative to the filling norms according to the SPhU. Draw conclusions about the compliance of obtained results with requirements of the SPhU. For what purpose this quality indicator is monitored? What factors does it depend on?
3. Carry out an economic analysis of the costs (charges) of the company “Darnytsia”, if the turnover in the base year was 1 134 000 000 UAH, and the absolute amount of expenses was 470 100 000 UAH. In the reporting year the turnover was 1 197 000 000 UAH, and the absolute amount of expenses was 555 610 000 UAH.

4. Compose a list of main symptoms of bronchoobstruction syndrome and early signs of bronchial asthma. Explain to a patient with bronchial asthma clinical and pharmacological features of medicines with Theophylline. Propose a list of effectiveness/safety criteria for their use.

**Situation 16**

Pharmaceutical company “GlaxoSmithKline” (Belgium) produces powder “Coldrex” for oral solution containing following active pharmaceutical ingredients: paracetamol, ascorbic acid and phenylephrine hydrochloride.

1. Analyze fractional composition of active ingredients. Explain the purpose of this test and what particle size of active ingredients in the oral powder should be.

2. Determine the pH of an aqueous solution of ascorbic acid substance and make a conclusion about the compliance with requirements of the EuPh and SPhU. Explain due to the chemical properties of ascorbic acid risks of its simultaneous use with sulfanilamides.

3. According to the table, draw a graph of compliance with the production and sale of the medicine “Coldrex Hotrem Lemon”. Define and describe the stage of the product life cycle and tasks of marketing at this stage:

<table>
<thead>
<tr>
<th>Years</th>
<th>Production volumes (million units)</th>
<th>Sales volumes (million units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.3</td>
<td>0.18</td>
</tr>
<tr>
<td>2</td>
<td>0.6</td>
<td>0.32</td>
</tr>
<tr>
<td>3</td>
<td>0.8</td>
<td>0.48</td>
</tr>
<tr>
<td>4</td>
<td>0.4</td>
<td>0.26</td>
</tr>
<tr>
<td>5</td>
<td>0.4</td>
<td>0.24</td>
</tr>
<tr>
<td>6</td>
<td>0.4</td>
<td>0.25</td>
</tr>
</tbody>
</table>

4. Compose an algorithm of pharmaceutical care for cold treatment for the patient working as an air-traffic controller. Explain clinical and pharmaceutical features of the use of combined cold medicines. Provide an informational and counseling service regarding the use of the medicine “Coldrex”.

**Situation 17**

The CPL of “JSC Lubnypharm” carries out certification of a batch of “Acetylsalicylic acid”, tabl. 500 mg.

1. Carry out the assay of acetylsalicylic acid in tablets by alkalimetric titration. Make a conclusion about the compliance with requirements of the QCT.

2. Check acetylsalicylic acid tablets, 500 mg (ø = 7 mm) for compressibility by their mechanical strength according to the SPhU. Make a conclusion about quality of studied tablets. Justify what factors affect the compressibility of the tablet mass.

3. Draw a graph by given digital values of sales volumes of the medicine “Acetylsalicylic acid”, tablets 0.5 No. 10 and define its life cycle stage:

<table>
<thead>
<tr>
<th>Volume of sales, million units</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year 2 year 3 year 4 year 5 year 6 year 7 year 8 year</td>
</tr>
<tr>
<td>0.5 1.0 2.8 3.2 3.3 3.4 3.5 3.5</td>
</tr>
</tbody>
</table>

Propose a marketing strategy for the medicine at this stage. Justify features of marketing activities of pharmaceutical companies at each stage of the product life cycle.

Situation 18
Pharmaceutical companies (PJSC “Kyivmedpreparaty”, PJSC “Halychpharm”, etc.) produce “Paracetamol”, tablets 500 mg No. 10 in primary blister packs.

1. Determine friability of these tablets according to requirements of the SPhU. Make a conclusion of the compliance of obtained results to requirements of the SPhU. Name factors that affect this quality indicator of tablets.

2. Carry out identification of paracetamol substance by IR spectrophotometry (according to the monograph of the EuPh and SPhU) and by the reaction for phenolic hydroxyl. Name the main pathways of paracetamol metabolism and explain its possible hepatotoxicity.

3. Assess the effectiveness of marketing communications of pharmaceutical companies Kyivmedpreparaty and Halychpharm. In order to promote Paracetamol tablets, they allocated funds for the organization of scientific and practical conferences (8.800 UAH and 30.300 UAH respectively), and for advertising (16.400 UAH and 24.200 UAH respectively). These marketing activities brought Kyivmedpreparaty a profit of 56.000 UAH and Halychpharm – 262.000 UAH.

4. Compose an algorithm of pharmaceutical care for symptomatic treatment of a tension headache in a student in the period of preparing for graduate exams. Explain clinical and pharmaceutical features of using combined analgesics. Provide an informational and counseling service regarding the use of the medicine “Paracetamol”.

Situation 19
The CPL of PJSC PP “Viola” carries out certification of a batch of magnesium sulfate substance intended for the production of the powder for internal use.

1. Carry out the test for chlorides and iron in the substance according to the EuPh and SPhU monographs. Make a conclusion about the compliance of obtained results with requirements of the EuPh and SPhU.

2. Give appropriate calculations, demonstrate technological operations for the preparation of 50 mL of 10 % concentrated solution of magnesium sulfate in pharmaceutical conditions, register this solution for the use.

3. Analyze the structure of pharmacy’s commodity circulation (determine the share (%) of retail and wholesale turnover), if during the month following business transactions were carried out:
   • medicines were dispensed free of charge – 6 000 UAH;
   • medicines and goods were sold to the city hospital No. 1 – 127 000 UAH;
   • revenue of the pharmacy – 158 000 UAH;
   • revenue of the prescription department – 570 000 UAH;
   • revenue of the non-prescription department – 862 000 UAH;
   • goods were sold to the kindergarten No. 17 – 1 900 UAH.

4. Compose an algorithm of pharmaceutical care for symptomatic treatment of constipation in a patient with ischemic heart disease that takes for a long time the complex therapy (isosorbide dinitrate, verapamil, clopidogrel, atorvastatin). Recommend a medicine to treat constipation and counsel the patient on its use.

Situation 20
“Kyiv Vitamin Plant” produces “Vitamin A” in soft gelatin capsules.

1. Determine disintegration time of capsules and make a conclusion about its compliance with requirements of the SPhU. Name a method used to produce medicine “Vitamin A” in capsules.

2. Identify by morphological features medicinal plant raw material – flowers that contain carotenoids. Suggest methods of analysis of carotenoids in medicinal plant raw material. Name medicines, their use in the health care.

3. Calculate the coefficient of elasticity of demand for the medicine “Vitamin A” (in soft capsules of 100.000 IU No. 50) and determine the type of elasticity of demand. Specialists of marketing department of the pharmaceutical company found that at the price of 42 UAH the demand for the medicine is 265.000 units, and at the price of 36 UAH the demand increases to 320.000 units.

**Situation 21**

Pharmacy No. 7 of Pharm Life LLC was approached by a patient with a prescription for “Glibenclamide”, tablets No. 30, that was prescribed by a doctor. When the medicine was released, the pharmacist informed the patient about rules of administration, methods of use and side effects of the medicine.

1. Make a diagram of the model of communication process between the pharmacist and the patient, applying knowledge about main stages and elements of the communication process.
2. Determine the disintegration time of “Glibenclamide” tablets according to the SPhU. Make a conclusion about the compliance of obtained results with requirements of the SPhU. Name factors that affect the rate of tablets disintegration.
3. Identify by morphological features medicinal plant raw material – leaves that have a hypoglycemic effect. Suggest methods of analysis of the main class of biologically active substances in medicinal plant raw material. Name medicines, their use in the health care.
4. Advise the young physician-intern regarding the possibility to prescribe the antihypertensive medicines of the first choice (“first line”) to a patient with both arterial hypertension and diabetes mellitus. Provide an informational and counseling service regarding the use of the medicine “Glibenclamide” and propose a list of effectiveness/safety criteria of its use.

**Situation 22**

A visitor turned to the pharmacy No. 1 with a request to recommend a cold medicine. The visitor complained about sore throat and runny nose. The pharmacist gave a consultation, released the appropriate over-the-counter medicine, and informed the visitor about rules of admission, methods of application, side effects of the medicine.

1. Identify the type of communication, possible obstacles that may arise in organizational communications and recommend ways to overcome them.
2. Give appropriate calculations, demonstrate technological operations for the preparation of nasal drops with Protargol according to the prescription:
   
   **Rp.:** Sol. Protargoli 1 % 10 mL
   
   Da. Signa: Use 3 drops in the nose 3 times a day.

   Write the front side of the written control passport, perform operations on packaging and labeling.
3. Identify by morphological features medicinal plant raw material from which the essential oil is obtained, the main component of which is 1,8-cineole, which is a part of medicine “Ingalipt”. Suggest a method of obtaining the main class of biologically active substances from medicinal plant raw material and indicators that characterize its quality. Name medicines, their use in the health care.
4. Check for “threatening” symptoms in a patient with a sore throat and runny nose. Compose an algorithm of pharmaceutical care for symptomatic treatment of runny nose in a patient with arterial hypertension (Stage II, 150/100 mm Hg). Explain features of using topical dosage forms for treatment of cold symptoms.

**Situation 23**

Pharmaceutical company OJSC “Ternopil Pharmaceutical Factory” produces Lily of the Valley tincture.

1. Carry out preliminary calculations and load the percolator with vegetable raw materials and extractant to obtain 150 mL of this tincture. Describe presented method of tincture obtaining.
2. Identify by morphological features medicinal plant raw material from which Lily of the Valley tincture is obtained. Suggest methods of analysis of the main class of biologically active substances in medicinal plant raw material. Name medicines, their use in the health care.
3. At the enterprise Open Joint-Stock Company “Ternopil Pharmaceutical Factory” an audit of the correctness of accounting for fixed assets. Determine the monthly depreciation deductions for equipment if:
- cost of equipment on the invoice – 360 000 UAH
- cost of delivery and installation – 7 500 UAH
- cost of dismantling after use – 8 500 UAH
- cost of equipment after the end of exploitation – 38 000 UAH
- exploitation life – 10 years.


**Situation 24**

Pharmaceutical company “Pharm Life”, which operates on the territory of Ukraine, has external service. Medical representatives ensure the implementation of plans to promote the market cough medicine with plantain extract in the form of syrup.

1. Calculate the required number of medical representatives for a pharmaceutical company working with 950 pharmacies, including 50 pharmacies of the type “A” (large pharmacies with high sales potential), 300 pharmacies of the type “B” (medium sized pharmacies with sufficient sales potential); 600 pharmacies of the type “C” (small or average pharmacies with low sales potential). Planned number of visits makes 52, 26, 12 visits a year on each group of pharmacies; one medical representative carries out 14 visits in one working day; working week makes 5 days, 8 weeks a year are necessary for vacations and days of temporary disability. Specify functional responsibilities of medical representatives and indicators of control over their work.

2. Carry out identification and tests for purity of acetylcysteine substance according to the value “Specific optical rotation” and make a conclusion about the compliance of obtained results with requirements of the EuPh and SPhU. Give background for the use of polarimetry method to assess the quality of the drug.

3. Give appropriate calculations, demonstrate technological operations for the preparation of the ointment with Menthol according to the prescription:

   \[ Rp.: \quad \text{Mentholi 0.03} \\
   \text{Lanolini 1.0} \\
   \text{Vaselini 10.0} \\
   \text{Misce, ut fiat unguentum} \]

   \[ \text{Da. Signa: For rubbing when coughing.} \]

   Write the front side of the written control passport, perform operations on packaging and labeling.


**Situation 25**

Pharmaceutical companies (Flora-Pharm LLC, Ukraine; Sandoz, Poland/Slovenia, etc.) produce soft medicines, which include horse chestnut extract with capillary-stabilizing action (“Venoton-cream”, “Venoton-gel-balm”, “Venitan”, etc.).

1. Determine concentration of ethanol in the liquid extract of horse chestnut according to the method of the SPhU. Name other methods for determining concentration of ethanol in liquid extraction medicines and alcohol-containing solutions.

2. Identify by morphological features medicinal plant raw material - seeds, from which extract with capillary-stabilizing action is obtained. Suggest methods of analysis of the main class of biologically active substances in medicinal plant raw material. Name medicines, their use in the health care.
3. Determine the level of monopolization of the domestic pharmaceutical market on the example of venotonic medicines using Herfindahl-Hirschman index:

<table>
<thead>
<tr>
<th>Manufacturing company</th>
<th>Market share ((r)), %</th>
<th>(r^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company A</td>
<td>27.1</td>
<td>734.4</td>
</tr>
<tr>
<td>Company B</td>
<td>24.9</td>
<td>620.0</td>
</tr>
<tr>
<td>Company C</td>
<td>13.6</td>
<td>185.0</td>
</tr>
<tr>
<td>Company D</td>
<td>6.0</td>
<td>36.0</td>
</tr>
<tr>
<td>Company E</td>
<td>6.0</td>
<td>36.0</td>
</tr>
<tr>
<td>Company F</td>
<td>5.4</td>
<td>29.2</td>
</tr>
<tr>
<td>Company G</td>
<td>4.0</td>
<td>16.0</td>
</tr>
<tr>
<td>Company H</td>
<td>2.4</td>
<td>5.8</td>
</tr>
<tr>
<td>Company I</td>
<td>1.4</td>
<td>2.0</td>
</tr>
<tr>
<td>Company G</td>
<td>1.2</td>
<td>1.4</td>
</tr>
<tr>
<td>Other companies</td>
<td></td>
<td>6.2</td>
</tr>
</tbody>
</table>

Note: \(HHI = 0\) – total decentralization of production; \(HHI \leq 1000\) – non-monopolized market; \(1000 < HHI \leq 1800\) – moderately monopolized market; \(HHI \geq 1800\) – monopolized market; \(HHI = 10 000\) – absolute market monopoly.

4. Compose an algorithm of pharmaceutical care for symptomatic treatment of soft tissue injury in a man that has fallen off his bicycle. Explain clinical and pharmaceutical features of choosing medicines with local effects for the treatment of soft tissue injury. Provide an informational and counseling service regarding the use of medicines in topical dosage forms.

**Situation 26**

A diabetic visitor turned to pharmacy No. 1 with a request to recommend a vitamin complex from those presented in the showcase of the pharmacy.

1. Name rules of medicines placement on shelves and showcases of the pharmacy according to basic principles of merchandising.

2. Give appropriate calculations, demonstrate technological operations for the preparation of the powder according to the prescription:

   \[
   \text{Rp.}:
   \begin{align*}
   &\text{Riboflavini } 0.005 \\
   &\text{Acidi ascorbinici } 0.05 \\
   &\text{Glucosi } 0.1 \\
   &\text{Misce, ut fiat pulvis} \\
   &\text{Da tales doses No. 6} \\
   &\text{Signa: Use } 1 \text{ powder } 3 \text{ times a day}
   \end{align*}
   \]

   Write the front side of the written control passport, perform operations on packaging and labeling.

3. Identify by morphological features medicinal plant raw material included in the vitamin species No. 2. Suggest methods of analysis of the main class of biologically active substances in medicinal plant raw material. Name medicines, their use in the health care.

4. Explain to a pharmacy visitor the reasonability of prescribing him by a physician a polyvitamin medicine (vitamins \(B_1 + B_6 + B_{12}\)) as a part of the complex therapy of diabetes mellitus. Propose a list of effectiveness/safety criteria for the therapy of diabetes complications caused by microangiopathy.

**Situation 27**


1. Explain at what stages of technological process violations were committed, if during quality control of ampoules with caffeine-sodium benzoate solution for injection, the controller had noticed a white precipitate that appeared after thermal sterilization. Check ampoules for tightness.

2. Carry out identification of sodium benzoate according to the monograph of the EuPh and SPhU (tests A and B).

3. Calculate the base salary of the head of marketing department of the Private Joint-Stock Company “Pharmaceutical Firm “Darnytsia”” Ivanova V. I. for December, which fully worked a month (the norm of
working days in December is 22), in addition, 1 day was a festive (December 25). The salary for December is 18 600 UAH. Explain the order of calculation on festive days. Calculate mandatory deductions (withholding) from salary.

4. Explain clinical and pharmaceutical features of using non-prescription combined analgesics or cold medicines containing caffeine. Compose a list of precautions concerning their administration for the symptomatic treatment of headache or cold symptoms in some categories of patients.

Situation 28

The pharmacist of the pharmacy No. 7 provided the visitor with a consultation on medicines of hepatoprotectors (in the form of capsules), that he was interested in. The visitor was quite curious and could not decide on the choice. A queue was formed in the pharmacy. After 15 minutes of waiting in a queue, other visitors of the pharmacy began to resent. There was a conflict between the pharmacist and visitors. Pharmacist could not sell the medicine without prior consultation, she explained to visitors that it is necessary to wait a little, but in response she heard their dissatisfied comments.

1. Name the type of the conflict between the pharmacist and pharmacy visitors. Explain main types and causes of conflicts. Suggest ways to prevent and resolve them.
2. Prepare hard gelatin capsules with caps, which are used in the manufacture of hepatoprotector medicine “Silibor Max 140 mg”. Explain the method of hard gelatin capsules production and give the composition of gelatin mass.
3. Identify by morphological features medicinal plant raw material - seeds that have a hepatoprotective effect. Suggest methods of analysis of the main class of biologically active substances in medicinal plant raw material according to the SPhU 2.0. Name medicines, their use in the health care.
4. Explain to a pharmacy visitor clinical and pharmacological features of main groups of medicines with hepatoprotective activity. Propose a list of effectiveness/safety criteria for the therapy of a patient with liver cirrhosis and hepatic encephalopathy occurrence. Provide an informational and counseling service regarding the use of the medicine “Glutargin”.

Situation 29

Production department of the pharmacy No. 9 in Kharkiv received a prescription for an extemporaneous medicine:

Rp.: Codeini phosphatis 0.01
Camphorae 0.05
Natrii hydrocarbonatis 0.2
Misce, fiat pulvis
Da tales doses No. 6
Signa: Use 1 powder 3 times a day

1. Give appropriate calculations, demonstrate technological operations for the preparation of this medicine, write the front side of the written control passport, perform operations on packaging and labeling.
2. Identify by morphological features medicinal plant raw material that are the source of camphor. Give Latin names of medicinal plant raw material, plants and families that are sources of natural and semi-synthetic camphor. Name medicines that contain camphor, their use in the health care.
3. Keep records of codeine phosphate (powder) in the “Journal of narcotic, psychotropic substances and precursors in pharmacies”. The balance of this medicinal substance at the beginning of May was 0.8 g; for a month from the warehouse received on the invoice No. 24 from January 4, 2.0 g, issued by the prescription to outpatients on January 2, 9, 11, 15, 19, 24 and 29 for 0.2 g. Calculate the balance of codeine phosphate at the end of the month and natural loss. The rate of write-off of natural loss is 0.95 %.
Situation 30

According to results of the marketing research, it was found that the actual consumption of the medicine – a broad-spectrum antibiotic “Normax” (active substance norfloxacin) eye / ear drops 0.3 %, 5 mL. in recent years (provided full demand) was: 207 thousand packages, 122 thousand packages, 118 thousand packages (in the current year).

1. Calculate the need of the region for the next year in the medicine based on its growth rate, make a conclusion about the trend of demand for the medicine in the region.

2. Determine the average mass of “Norfloxacin” 200 mg capsules and the deviation from it according to the EuPh and SPhU. Make a conclusion about the compliance of this quality parameter with requirements of the EuPh and SPhU.

3. Carry out the test for purity for norfloxacin according to requirements of the QCT (clarity and degree of opalescence of liquids and degree of coloration of liquids). Due to the chemical properties of norfloxacin give background for risks of its simultaneous use with antacids and iron preparations.

4. Substantiate a reasonability of prescribing the fluoroquinolone medicine to a patient with the diagnosis Chronic pyelonephritis. Propose a list of effectiveness/safety criteria for the therapy pyelonephritis by fluoroquinolones, explain the limitations of prescribing this group of medicines to children.

Situation 31

Pharmaceutical production company “Pharma” has introduced to the market a generic hypolipidemic medicine “A” in the form of coated tablets 10 mg No. 30, which contains rosuvastatin.

1. Calculate the market share of the medicine “A” in the market segment and market share relative to the leader in digital sales of rosuvastatin for the previous year:

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Sales volume, thousands of packages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine A</td>
<td>48.5</td>
</tr>
<tr>
<td>Medicine B</td>
<td>43.3</td>
</tr>
<tr>
<td>Medicine C</td>
<td>81.2</td>
</tr>
<tr>
<td>Medicine D</td>
<td>154</td>
</tr>
<tr>
<td>Total</td>
<td>327</td>
</tr>
</tbody>
</table>

2. Determine organoleptic characteristics of rosuvastatin film-coated tablets in the accordance with requirements of the SPhU and draw appropriate conclusions. Name factors that affect the appearance of tablets.

3. Identify by morphological features medicinal plant raw material that has hypocholesterolemic action. Suggest methods of analysis of the main class of biologically active substances in medicinal plant raw material. Name medicines, their use in the health care.

4. Provide an informational and counseling service regarding the use of the medicine “Rosuvastatin”, compose a list of effectiveness/safety criteria for its use, propose measures for adverse effects prevention. Advise the patient on a lifestyle modification.

Situation 32

Production department of the pharmacy No. 11 in Kharkiv received a prescription for an extemporaneous medicine:

Rp.: Dibazoli 0.01
      Papaverini hydrochloridi 0.02
      Sacchari 0.3
      Misce, ut fiat pulvis
      Da tales doses No. 6
      Signa: Use 1 powder 3 times a day

1. Give appropriate calculations, demonstrate technological operations for the preparation of this medicine, write the front side of the written control passport, perform operations on packaging and labeling.

2. Carry out identification of bendazole according to the QCT (reaction with iodine solution and reaction for chlorides).
3. Provide an algorithm for pharmacist’s actions when receiving a prescription and dispensing medicines. Explain features of pricing for extemporaneous medicines. Determine the medicine pricing of a prescription.

4. Inform a physician about the availability of modern antihypertensive medicines for the treatment of a patient with the following diagnosis: \textit{Essential arterial hypertension, stage I (145/95 mm Hg)}. Propose a list of effectiveness/safety criteria for the use of this combination. Advise the patient on a lifestyle modification.

\textbf{Situation 33}

The visitor of the pharmacy, having presented World War II veteran’s certificate, insists that according to the current legislation of Ukraine he has the right to receive free of charge medicines:

- Aspirin Cardio, tab. No. 20
- Clotrimazole cream 1% – 15 g
- Zopiclon, tab.
- Soothing species 50 g
- Tramizol, tab. No. 10
- Diphenhydramine, tab.
- Tincture Leonuri, fl. 25 mL
- Amizon, tab. No. 10
- GIPURAN 1311 (radio pharmaceutical preparation)
- Zopiclon, tab.
- Hexobarbital (for anesthesia)
- Clotrimazole cream 1 %
- Diphenhydramine, tab.
- Tincture Leonuri, fl. 25 mL
- Amizon, tab. No. 10
- GIPURAN 1311 (radio pharmaceutical preparation)
- Zopiclon, tab.
- Hexobarbital (for anesthesia)
- Clotrimazole cream 1 %

1. Describe the algorithm of actions of the pharmacist, explain the procedure on the regulation of free and favorable realization of prescription medicines in Ukraine. Explain the procedure for dispensing each of these medicines, indicate which medicines are not allowed to prescribe in accordance with the current law.

2. Give appropriate calculations, demonstrate technological operations for the preparation of the ointment with Dimedrol according to the prescription:

   \textbf{Rp.}:
   \begin{align*}
   & \text{Dimedroli 0.05} \\
   & \text{Sol. Adrenalini hydrochloridi (1:1000) 1.5 mL} \\
   & \text{Lanolini 5.0} \\
   & \text{Vaselini 10.0} \\
   & \text{Misce, ut fiat unguentum} \\
   & \text{Da. Signa: Ointment for nose}
   \end{align*}

   Write the front side of the written control passport, perform operations on packaging and labeling.

3. Carry out identification of diphenhydramine hydrochloride substance by UV spectrophotometry and reaction for chlorides. Make a conclusion about the compliance of the substance with requirements of the EuPh and SPhU.

4. Substantiate a reasonability of prescribing the medicine “Aspirin Cardio” to a patient with the diagnosis: \textit{Ischemic heart disease: stable stenocardia of effort, functional class II}. Propose a list of effectiveness/safety criteria for treatment by this medicine. Provide an informational and counseling service regarding the use of the medicine “Aspirin Cardio”.

\textbf{Situation 34}

Production department of the pharmacy No. 195 in Kharkiv received a prescription for an extemporaneous medicine for the liquidator of Chernobyl accident:

\textbf{Rp.}:
\begin{align*}
\text{Sol. Acidi hydrochlorici 2 % 100 mL} \\
\text{Pepsini 1.0}
\end{align*}

M. D. S.: Use 1 table spoon 3 times a day

1. Give appropriate calculations, demonstrate technological operations for the preparation of this medicine, write the front side of the written control passport, perform operations on packaging and labeling.

2. Carry out physical control and identification of hydrochloric acid (reaction for chlorides). Make a conclusion about the compliance of obtained results with requirements of the Order of the Ministry of Health of Ukraine No. 812 dated 17.10.2012.

3. Describe the procedure for taking a prescription and realization medicines. Specify required quality control for this dosage form.

4. Substantiate the reasonability of the prescription given to the patient with the following diagnosis: \textit{Chronic atrophic gastritis, remission phase}. Propose concomitant treatment of maldigestion syndrome as well as the list of effectiveness/safety criteria for the use of proposed medicines.
Situation 35
The pharmacy visitor provided the pharmacist with a list of medicines he needed to buy:
- Ampicillin, tab. 250 mg No. 10
- Bronchipret, syrup 50 mL, fl. No. 1
- Sorbex, caps. 0.25 g No. 10
- Caffeine-sodium benzoate, sol. for inject. 10 % - 1 mL amp. No. 10
- Voltaren forte, emulgel 2.32 % 100 g
- Solpadein, caps. No. 12
- Sibazon (diazepam), tab. 5 mg No. 10

1. Name the criteria for non-prescription medicines. Choose medicines that can be dispensed without a prescription from a pharmacy. For each prescription medicine, indicate the form and its required requisites.
2. Give appropriate calculations, demonstrate technological operations for the preparation of the solution of caffeine-sodium benzoate for injections according to the prescription:
   Rp.: Sol. Coffeini-Natrii benzoatis 10 % 50 mL
   Sterilisa!
   D. S.: Use 1 mL subcutaneously 2 times a day
Write the front side of the written control passport, perform operations on packaging and labeling.
3. Identify by morphological features medicinal plant raw material, which extract is a part of medicine “Bronchicum elixir”. Suggest a method of obtaining the main class of biologically active substances from medicinal plant raw material and indicators that characterize its quality. Name other medicines from this medicinal plant raw material, their use in the health care.
4. Substantiate a reasonability of using medicines “Ampicillin” and “Bronchipret” in a patient with the diagnosis Community-acquired focal pneumonia. Propose a list of effectiveness/safety criteria for the use of these medicines. Provide an informational and counseling service regarding rational use of expectorants and antibiotics.

Situation 36
Production department of the pharmacy No. 308 in Kharkiv received a prescription for an extemporaneous medicine:
Rp.: Infusi herbae Thermopsidis ex 0.3 80 mL
   Natrii benzoatis
   Natrii hydrocarbonatis ana 1.0
   Liquoris Ammonii anisati 3 mL
   Misce. Da. Signa: Use 1 table spoon 3 times a day

1. Give appropriate calculations, demonstrate technological operations for the preparation of this medicine (using dry standardized extract-concentrate of Bush Pea herb (1:1)), write the front side of the written control passport, perform operations on packaging and labeling.
2. Identify by morphological features medicinal plant raw material from which the essential oil that is a part of ammonia-anise drops is obtained. Suggest a method of obtaining the main class of biologically active substances from medicinal plant raw material and indicators that characterize its quality. Name medicines, their use in the health care.
3. Determine the amount of income tax in the pharmacy No. 308 based on results of activities in the first quarter of this year:
   - commodity circulation (excluding value added tax) 1 450 900 UAH
   - purchase price of sold goods 1 015 700 UAH
   - expenses (costs) 290 000 UAH
   - depreciation of fixed assets 10 000 UAH
Situation 37

Production department of the pharmacy “Leda” in Kharkiv received a prescription for an extemporaneous medicine:

Rp.: Picis liquidae Betulae
     Xeroformii ana 0.3
     Olei Ricini 10.0

Misce. Da. Signa: Balsamic liniment by Vishnevsky (for bandages)

1. Give appropriate calculations, demonstrate technological operations for the preparation of this medicine, write the front side of the written control passport, perform operations on packaging and labeling.
2. Identify by morphological features of medicinal plant raw material that are the source of castor oil. Suggest a method of obtaining castor oil from medicinal plant raw material. Determine the identity and quality of castor oil. Name medicines that contain castor oil, their use in the health care.
3. Draw a scheme of internal variables of the pharmacy, demonstrate and justify their interconnection; recommend and formulate the purpose and tasks of the pharmacy, detail internal components “structure” and “technology”.
4. Check for “threatening” symptoms in the patient with skin lesions. Compose an algorithm of pharmaceutical care for symptomatic treatment of scratches in a patient with toxic diffuse goiter. Recommend a medicine and provide an informational and counseling service regarding its use.

Situation 38

During the day, the pharmacy received prescriptions for the production of extemporaneous medicines (prescription set No. 1).

1. Select prescriptions, that include controlled medicines, which are subject to registration in pharmacies in the accordance with the Order of the Ministry of Health of Ukraine No. 360.
2. Give appropriate calculations, demonstrate technological operations for the preparation of the powder with Dimedrol according to the prescription:
   
   \[
   Rp.: \quad \text{Dimedrol} \ 0.02 \\
   \text{Sacchari} \ 0.1 \\
   \text{Misce, ut fiat pulvis} \\
   \text{Da tales doses No. 6} \\
   \text{Signa: Use 1 powder 3 times a day}
   \]

   Write the front side of the written control passport, perform operations on packaging and labeling.
3. Carry out organoleptic and physical control of this medicine in the accordance with requirements of the Order of the Ministry of Health of Ukraine No. 812 dated 17.10.2012.
4. While weighing extemporaneous powder a pharmacy assistant accidentally inhaled a substance that caused the development of angioneurotic edema Quince. Compose a list of main clinical manifestations of Quince’s edema and substantiate the reasonability of using H₁-histamine receptors blockers. Propose a list of effectiveness/safety criteria for their use.

Situation 39

Production department of the pharmacy “Leda” in Kharkiv received a prescription for an extemporaneous medicine:

Rp.: Sol. Laevomycetini 0.25 % 20 mL

Misce. Da. Signa: Use 2 drops 6 times a day in the left eye

1. Give appropriate calculations, demonstrate technological operations for the preparation of this medicine, write the front side of the written control passport, perform operations on packaging and labeling.
2. Carry out organoleptic and physical control of the medicine in the accordance with requirements of the Order of the Ministry of Health of Ukraine No. 812 dated 17.10.2012. Give the name of the active substance according to the INN. Explain the possible difference in activity depending on the optical isomerism. Explain how chemical modification of chloramphenicol can improve its organoleptic properties and solubility.
3. Plan a supply of goods on the following year for the pharmacy “Leda” if planned indicators of financial and economic activities are:
• commodity circulation (turnover) – 19 000 000 UAH
• level of trading imposing – 27 %
• days of supply (stock) – 14 days
• rest of commodity supply (based inventory) – 585 000 UAH

4. Explain to a pharmacy visitor basic approaches to the rational antibacterial therapy and the impact of treatment compliance. Give examples of poor compliance during antibacterial therapy. Provide a counseling service regarding the use of a 0.25 % solution of Levomycetin.

Situation 40
The pharmacy No. 302 in Kharkiv received medicines from the warehouse, which are included in the “National List of Essential Medicines”:

<table>
<thead>
<tr>
<th>Name of medicines</th>
<th>Manufacturer</th>
<th>Purchasing price, UAH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for injections 2mL No.10, amp.</td>
<td>“LVIVDIALIK”, Ukraine</td>
<td>14.50</td>
</tr>
<tr>
<td></td>
<td>“PHARMEX GROUP”, Ukraine</td>
<td>30.95</td>
</tr>
<tr>
<td>Atropine sulfate 1 % 5mL, eye drops</td>
<td>Ukraine</td>
<td></td>
</tr>
</tbody>
</table>

1. Form retail prices for medicines to be sold to patients / healthcare facilities.
2. Give appropriate calculations, demonstrate technological operations for the preparation of ophthalmic drops with Atropine sulfate according to the prescription:
   \[ \text{Rp.: Sol. Atropini sulfatis 1 \% 10 mL} \]
   \[ \text{Da. Signa: Use 2 drops in both eyes 3 times a day} \]
   Write the front side of the written control passport, perform operations on packaging and labeling.
3. Carry out identification of atropine sulfate substance according to requirements of the EuPh and SPhU (reactions E, F).
4. Compose a list of main clinical effects of atropine sulfate and explain how to evaluate the similar M-cholinoblocking activity of some groups of other medicines including non-prescription ones. Provide examples.

Situation 41
The pharmacy No. 15 in Kharkiv received medicines from the warehouse, which are included in the “National List of Essential Medicines”:

<table>
<thead>
<tr>
<th>Name of medicines</th>
<th>Purchasing price, UAH</th>
</tr>
</thead>
<tbody>
<tr>
<td>VITAMIN C 500 mg No. 30, tab.</td>
<td>20.10</td>
</tr>
<tr>
<td>Water for injections 2 mL No. 10, amp.</td>
<td>12.30</td>
</tr>
</tbody>
</table>

1. Calculate the maximum amount of trade margin on these medicines for the sale to patients.
2. Determine the flowability of ascorbic acid substance, which is a part of tablets “Vitamin C 500” No. 30. Draw a conclusion about results. Justify the purpose for which this test is conducted.
3. Carry out tests for purity for water for injections according to requirements of the EuPh and SPhU (tests for acidity or alkalinity, impurity of sulfates).
4. Check for cold symptoms in a pharmacy visitor by asking questions. Depending on the symptom define the possibility of responsible self-treatment and advise the patient on the non-prescription medicine to treat the symptom. Provide an informational and counseling service regarding the use of the medicine.

Situation 42
Production department of the pharmacy No. 431 in Kharkiv received a prescription for an extemporaneous medicine:

\[ \text{Rp.: Streptocidi 0.3} \]
\[ \text{PEO q.s.} \]
\[ \text{Misce, ut fiat suppositorium} \]
\[ \text{Da tales doses No. 3} \]

1. Give appropriate calculations \((1/E_f \text{ of streptocide} = 0.62)\), demonstrate technological operations for the
preparation of this medicine, write the front side of the written control passport, perform operations on packaging and labeling.

2. Carry out identification of an active substance according to the monograph of the EuPh and SPhU (tests B and D). Give examples of sulfonamide drugs that are prodrugs.

3. Calculate the amount of natural losses in the pharmacy No. 431 according to the inventory of goods, which was carried out before the preparation of annual financial statements. The balance of the goods according to the accounting is 580 100 UAH. The actual balance of the goods according to the inventory results is 579 270 UAH. Stock department in the pharmacy is not allocated. During the inter-inventory period, the cost of individually produced medicines amounted to 9 400 UAH, intra-pharmacy medicines – 2 600 UAH, medicines dispensed in bulk – 1 350 UAH. The rate of natural losses for medicines – 2.15%; medicines dispensed in bulk – 0.65%. Make conclusions from results of the inventory.

4. Explain to a pharmacy visitor modern approaches to choosing antibacterial medicines. Compose a list of advantages and disadvantages of sulfonamides. Counsel the patient on the features of using different dosage forms of sulfonamides (streptocide) that are available in the pharmacy (liniment, tablets, combined aerosol and spray for oral cavity).

**Situation 43**

Pharmacist Shevchenko A. A., who works in the pharmacy No. 9, is pregnant and is planning a vacation in connection with pregnancy and childbirth. Monthly salary of Shevchenko A. A. is 7 200 UAH, the amount of bonuses in this year – 11 400 UAH.

1. Calculate the amount of maternity assistance.

2. Give appropriate calculations, demonstrate technological operations for the preparation of the powder according to the prescription:
   
   \[ \text{Rp.:} \quad \text{Calcii carbonatis} 0.6 \\
   \text{Magnii carbonatis} 0.08 \\
   \text{Misce, ut fiat pulvis} \\
   \text{Da tales doses No. 6} \\
   \text{Signa: Use 1 powder for heartburn} \]

Write the front side of the written control passport, perform operations on packaging and labeling.

3. Carry out identification of magnesium carbonate substance in the accordance with requirements of the EuPh and SPhU (reactions B, C). Give examples of drugs whose bioavailability may decrease in the presence of drugs containing magnesium carbonate. Explain your answer.

4. Compose an algorithm of pharmaceutical care for a pregnant woman that referred to the pharmacy complaining of heartburn. Advise the pregnant woman a non-prescription medicine to treat the symptom, propose safety criteria for the therapy. Provide an informational and counseling service regarding the use of the medicine.

**Situation 44**

PJSC “Chervona zirka” received a batch of medicinal plant raw material for medicine “Licorice root syrup” production.

1. Identify medicinal plant raw material by morphological and anatomical features. With the help of identification reactions confirm the presence of the main class of biologically active substances in medicinal plant raw material, propose a method for its quantitative determination.

2. Determine the moisture content in 200.0 kg of soft licorice extract according to requirements of the SPhU. Make a conclusion about obtained results. How to get a standard product, if specified extract contains 29 % moisture; 15 % moisture?

3. Draw a graph and determine the equilibrium price and the corresponding amount of demand for the medicine “Licorice root syrup”, if PJSC “Chervona zirka” agrees to produce it at a price of 70 UAH – 20 thousand units, at the price of 60 UAH – 18 thousand units, at the price of 50 UAH – 12 thousand units. The conducted marketing research has shown, that demand at such prices will be: 14 thousand units, 17 thousand units, 20 thousand units accordingly. Explain, what characteristic of the market will be – surpluses or deficits if the market price of the medicine is below the equilibrium price.

**Situation 45**

In the pharmacy “Panacea” during the inventory of goods, inventory commission found the following data:

- actual phenobarbital powder residue – 26.5 g;
- phenobarbital residue based on the results of the previous inventory – 25.0 g;
- received during the inter-inventory period – 295.0 g;
- spent during the inter-inventory period – 293.0 g.

The rate of write-off of natural loss – 0.95%.

1. Calculate natural losses and make conclusions about results of the inventory.
2. Give appropriate calculations, demonstrate technological operations for the preparation of the mixture with Phenobarbital according to the prescription:

   \[
   \text{Rp.:} \quad \text{Phenobarbitali 0.2} \\
   \quad \text{Chlorali hydratis} \\
   \quad \text{Natrii bromidi ana 2.0} \\
   \quad \text{Aquaee purificatae 80 mL} \\
   \quad \text{Sirupi simplicis} \\
   \quad \text{Tincturae Valerianae ana 5 mL} \\
   \quad \text{Misce. Da.Signa: Use 1 table spoon 3 times a day}
   \]

   Write the front side of the written control passport, perform operations on packaging and labeling.
3. Carry out identification of phenobarbital substance according to requirements of the EuPh and SPhU (tests B and D). Give the main provisions of the structure-activity relationship for drugs, that are barbituric acid derivatives.
4. Inform an elderly pharmacy visitor about features of combined use of Phenobarbital with other medicines. Provide examples, explain clinical manifestations and propose a list of safety criteria for combined use.

**Situation 46**

Pharmaceutical company “Zdorovye” received a batch of medicinal plant raw material for medicine with an extract of Belladonna leaves “Besalol” production.

1. Identify medicinal plant raw material by morphological and anatomical features. With the help of identification reactions confirm the presence of the main class of biologically active substances in medicinal plant raw material, propose a method for its quantitative determination.
2. Give appropriate calculations, demonstrate technological operations for the preparation of the powder with Belladonna extract according to the prescription:

   \[
   \text{Rp.:} \quad \text{Extracti Belladonnae 0.015} \\
   \quad \text{Papaverini hydrochloridi 0.01} \\
   \quad \text{Sacchari 0.2} \\
   \quad \text{Misce, ut fiat pulvis} \\
   \quad \text{Da tales doses No. 6} \\
   \quad \text{Signa: Use 1 powder 3 times a day}
   \]

   Write the front side of the written control passport, perform operations on packaging and labeling.
3. Determine by analytical or graphical methods the critical sales volume (break-even point) of the medicine “Besalol” tabl. No. 6 produced by the pharmaceutical company “Zdorovye”:

<table>
<thead>
<tr>
<th>№</th>
<th>Indicator</th>
<th>Symbols</th>
<th>Total, UAH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Fixed costs</td>
<td>FC</td>
<td>45 000</td>
</tr>
<tr>
<td>2.</td>
<td>Variable costs</td>
<td>VC</td>
<td>74 000</td>
</tr>
<tr>
<td>3.</td>
<td>Sales volume, units</td>
<td>Q</td>
<td>11 000</td>
</tr>
<tr>
<td>4.</td>
<td>Price per unit, UAH</td>
<td>p</td>
<td>18.0</td>
</tr>
</tbody>
</table>
Justify your results.


Situation 47
A visitor addressed to your pharmacy with the prescription for «Actrapid» (human insulin):
Rp.: «Actrapid HM» (100 IU/mL) 10 mL No. 1
D. S. 8 units subcutaneously 30 min. before each meal

1. Provide pharmaceutical care to a pharmacy visitor considering that he complained about headache, dizziness and tremor in arms and at the same time asked for a medicine to treat a headache. Provide the substantiated recommendation.

2. Check solution for injection in ampoules “Actrapid HM” - 10 mL for the absence of mechanical matters in the accordance with requirements of the SPhU. Make a conclusion about obtained results. Explain how these requirements are followed at pharmaceutical enterprises.

3. Identify by morphological features medicinal plant raw material that are a component of antidiabetic species “Arfazetin”. Suggest methods of analysis of the main class of biologically active substances in medicinal plant raw material.

4. Make a conclusion about the marketing strategy of the pharmaceutical company that produces insulin medicines. Justify the use of marketing concept.

Situation 48
TERNOPHARM LLC received a batch of medicinal plant raw material for “Valerian tincture” production.

1. Identify medicinal plant raw material by morphological and anatomical features. Suggest a method of obtaining essential oil from this medicinal plant raw material. Perform an organoleptic analysis and determine main physical indicators of the quality of essential oil.

2. Give appropriate calculations, demonstrate technological operations for the preparation of drops, containing Valerian tincture, according to the prescription:
Rp.: Adonisidi 5 mL
    Tincturae Convallariae
    Tincturae Valerianae 10 mL
    Mentholi 0.05
    Kali bromidi 2.0
Use 25 drops 3 times a day (Zelenin’s drops)

Write the front side of the written control passport, perform operations on packaging and labeling.

3. Calculate the balance of goods in a pharmacy at the end of the month and days of supply, given that the level of cost is 65 %.
   • balance of goods on 01.12. – 420 000 UAH
   • retail turnover – 780 000 UAH
   • wholesale turnover – 160 000 UAH
   • received goods from the warehouse on invoices – 610 000 UAH

4. Propose an algorithm of pharmaceutical care for symptomatic treatment of anxiety in the patient with arterial hypertension. Propose a list of effectiveness/safety criteria. Provide an informational and counseling service regarding the use of the medicine “Valerian tincture”.
Situation 49
A visitor addressed to your pharmacy with the prescriptions, «Becloforte Evohaler» (beclomethasone), which he has being taken for the treatment of bronchial asthma during the long period of time.

Rp.: Aeros. «Becloforte Evohaler» 250 mkg/dose – 200 doses
D. S. 2 inhalations 2 times a day

1. Provide pharmaceutical care to a pharmacy visitor considering that at the same time he asked for advice on a medicine to treat sore throat associated with a change in voice. Besides a visitor complains about stomatitis (white spots in the oral cavity). Provide the substantiated recommendation.

2. Assemble the aerosol dosing valve for bronchial asthma medicinal product Becloforte Evohaler. Justify the fundamental difference in the design and principle of operation of dosing and non-dosing aerosol valves. Name indicators by which the operation of valve-spray systems of pharmaceutical aerosols is evaluated.

3. Identify by morphological features medicinal plant raw material, medicines from which are used to treat stomatitis. Suggest a method of obtaining the main class of biologically active substances from medicinal plant raw material and indicators that characterize its quality.

4. Analyze dynamics of the pharmacy No. 34 commodity circulation for 4 years, taking into account inflation (at comparable prices) and make a conclusion.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Unit of measurement</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>I</td>
</tr>
<tr>
<td>Commodity circulation</td>
<td>Thousands, UAH</td>
<td>14800</td>
</tr>
<tr>
<td>Retail price index</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Situation 50
Pharmacist-analyst of the pharmacy carries out quality control of extemporaneous medicine: 5 % glucose solution for injection

1. Carry out the assay of glucose in the medicine by polarimetric method. Make a conclusion about the quality of the product in terms of glucose content in the accordance with requirements of the Order of the Ministry of Health of Ukraine No. 812 dated 17.10.2012.

2. Give appropriate calculations, demonstrate technological operations for the preparation of 50 mL of 5 % Glucose solution for injection, write the front side of the written control passport, perform operations of packaging and labeling.

3. Calculate the amount of temporary disability assistance on 5 days to the pharmacist Ivanova A. A., who works as a pharmacist-analyst of the pharmacy No. 5 and performs the functions of an authorized person. Monthly salary of Ivanova A. A. is 7 800 UAH, the amount of premiums in this year is 9 600 UAH. Work experience is 11 years.

4. Compose a list of main symptoms of hypoglycemia syndrome and early signs of hypoglycemic coma. Explain to patients with diabetes mellitus how to take appropriately hypoglycemic medicines to prevent hypoglycemia.
EXAMINATION PAPER No. 7

Analyze the proposed situation and justify your answer.

Situation
Pharmaceutical company “Merkle GmbH” (Germany) produces medicine in gelatin capsules “Actiferin”.

1. Determine the average weight of capsules and deviation from it according to requirements of the SPhU. Make a conclusion about obtained results.

2. Carry out identification of ferrous sulfate heptahydrate substance by the reaction for iron and sulfates according to the monograph of the EuPh and SPhU.

3. Schematically illustrate possible sales channels of the medicine. Determine the rating of the wholesale pharmaceutical companies and choose the optimal supplier of the medicine.

<table>
<thead>
<tr>
<th>Selection criterion</th>
<th>Weight of the criterion</th>
<th>Evaluation of the supplier of medicines, points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completeness of the range</td>
<td>0.3</td>
<td>Supplier A: 5 Supplier B: 3</td>
</tr>
<tr>
<td>Prices, discounts, payment terms</td>
<td>0.5</td>
<td>Supplier A: 5 Supplier B: 5</td>
</tr>
<tr>
<td>Level of service</td>
<td>0.1</td>
<td>Supplier A: 3 Supplier B: 4</td>
</tr>
<tr>
<td>Reliability</td>
<td>0.1</td>
<td>Supplier A: 3 Supplier B: 4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1.0</strong></td>
<td></td>
</tr>
</tbody>
</table>

4. Explain to a pharmacy visitor clinical and pharmaceutical features of using iron medicines. Propose effectiveness and safety criteria of their use for prophylaxis as well as for therapy of iron-deficiency conditions.

Approved at the meeting of the Central Methodical Council, protocol №_ _ dated __20__

Head of Department                                      Name, surname
## EVALUATION CRITERIA

<table>
<thead>
<tr>
<th>Evaluation criteria</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>The applicant of higher education demonstrates consistent, logical, correct and full implementation of practical skills without mistakes. The answers to the questions are complete, detailed, structured, logical.</td>
<td>Excellent / 90-100</td>
</tr>
<tr>
<td>Practical skills are performed by the applicant correctly, without serious mistakes, but there are 2-3 inaccuracies that are corrected independently. The answers to the questions are complete, but there are inaccuracies that are corrected by the applicant in the process of answering.</td>
<td>Good / 82-89</td>
</tr>
<tr>
<td>Practical skills are performed with minor mistakes or the sequence is broken while performing (which does not significantly affect the final result). The answers to the questions are incomplete, the disclosure of basic concepts is partial or the logic and structure of the presentation is violated.</td>
<td>Good / 74-81</td>
</tr>
<tr>
<td>There are mistakes (more than three) in the implementation of practical skills, but the applicant has the necessary knowledge to eliminate them under the guidance of a teacher. The answers to the content of the theoretical question are not complete and not structured.</td>
<td>Satisfactory / 64-73</td>
</tr>
<tr>
<td>Significant inaccuracies and mistakes in the implementation of practical skills. The applicant of higher education can correct them only under the guidance of a teacher. Answers to theoretical questions are not clear and complete enough, which requires additional and clarifying questions from the teacher.</td>
<td>Satisfactory / 60-63</td>
</tr>
<tr>
<td>Practical skills are not fulfilled or many gross fundamental mistakes are made in the execution, which affect the final result. The main content of theoretical questions is not disclosed, additional and clarifying questions of the teacher have no answers.</td>
<td>Unsatisfactory / 0-59</td>
</tr>
</tbody>
</table>

## RATING SCALE FOR HIGHER EDUCATION APPLICANTS’ KNOWLEDGE EVALUATION

The grade from the integrated practice-oriented qualifying exam in Pharmacy is determined by the examination committee to the rating scale:

<table>
<thead>
<tr>
<th>Rating, points</th>
<th>National scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 – 100</td>
<td>excellent</td>
</tr>
<tr>
<td>82-89</td>
<td>good</td>
</tr>
<tr>
<td>74-81</td>
<td>satisfactory</td>
</tr>
<tr>
<td>64-73</td>
<td>unsatisfactory</td>
</tr>
<tr>
<td>60-63</td>
<td>unsatisfactory</td>
</tr>
<tr>
<td>35-59</td>
<td>unsatisfactory with mandatory re-study of the discipline</td>
</tr>
<tr>
<td>0-34</td>
<td>unsatisfactory with mandatory re-study of the discipline</td>
</tr>
</tbody>
</table>
REFERENCES


METHODODOLOGICAL RECOMMENDATIONS
IN PREPARATION FOR THE COMPREHENSIVE PRACTICE-ORIENTED
QUALIFICATION EXAMINATION IN PHARMACY

Under the editorship of Professor Alla KOTVITSKA