

**Ministry of Health of Ukraine**  
**National Pirogov Memorial Medical University, Vinnytsya**  
**Department of Pharmacy**

«AGREED»

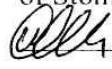
with the Methodical Council  
of Pharmaceutical Faculty  
Minutes № 2  
from « 21 » 12 2023 year  
Head of the Methodical Council of the

 assoc. prof. of HEI Tetyana YUSCHENKO

«APPROVE»

Academic Council of Stomatological  
and Pharmaceutical faculties  
Pirogov Memorial Medical  
University, Vinnytsya

Minutes № 2  
from « 26 » 12 2023 year

Head of the Academic Council  
of Stomatological and Pharmaceutical faculties  
 prof. of HEI Serhiy POLISHCHUK

**Instruction of the station to the objective structured practical  
exam (OSPE)**

|                            |   |
|----------------------------|---|
| Station name               | <i>Station № 1.</i><br>Compounding of extemporaneous dosage forms |
| Subject                    | Drug technology   |
| Speciality                 | 226 « Pharmacy, industrial pharmacy »                             |
| Educational qualification  | Master of pharmacy  |
| Professional qualification | Pharmacist  |
| Course                     | V   |
| Form of study              | Full-time   |

Vinnytsya 2023

**Task:**

- adhere to the norms of sanitary and hygienic regime of pharmacies;
- determine the type of dosage form, provide an expanded description and classification;
- work with regulatory and technical documentation;
- conduct a pharmaceutical expertise of the prescription;
- choose a rational technology in the drugs compounding in various dosage forms;
- identify incompatible combinations of drugs in prescriptions;
- perform basic technological operations during the compounding of dosage forms;
- substantiate the chosen technology of compounding the dosage form;
- apply special technological methods for the compounding of dosage forms according to difficult and incompatible prescriptions;
- to control the quality of the dosage form at all stages of the technological process.

**Station equipment:**

- Assistant table, chair;
- Kit for workplace preparation (bars with sterile cotton balls, sterile gauze napkins, sterile tweezers, hydrogen peroxide solution 3%, chloramine B solution 1%);
- Containers with medicinal matters and excipients;
- Hand scales of different sizes;
- Technical scales VKT-1000;
- Glass measuring devices (cylinders, flasks, burettes, measuring fingers, calibrated droppers, measuring cups);
- Sets of mortars and pestles of different sizes;
- Pill machine;
- Forms for making suppositories by pouring;
- Porcelain infundyr;
- Tare-closing and packaging materials (bottles, stoppers, paper capsules of different types);
- Labels for dosage forms labeling.

In the case of **remote study** (in order to prevent the spread of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2), **the procedure for conducting an objective structured practical examination (OSPI)** is regulated by the Regulations on introducing remote study elements at National Pirogov Memorial Medical University, Vinnytsya and will take place on the **Microsoft Teams platform**.

Equipment for remote form OSP (K) I: practical situations, data sets.

On the day of the exam, the secretary of the State Examination Commission joins the student from the group, which passes the exam according to the schedule, to the meeting of the examiner. At the station, the student must greet and introduce himself, **present a document** (passport) proving his identity to the teacher. The student receives a practical situation, where it is provided to characterize the dosage form, to conduct a pharmaceutical expertise of the prescription; indicate the technology of the dosage form compounding and quality control with theoretical justification.

***The time limit for the station is 8 minutes.*** After exceeding the time limit at the station, the examiner does not accept the answer. Note that the teacher is an observer of your actions and does not provide instructions, comments or question.

**Requirements for the station passing:**

- use a computer or laptop during the response;
- the answer is accepted under the condition of the switched on camera, where the student who passes the exam is clearly visible, and the microphone on with a clear sound;
- video is recorded while working at the station.

**It is forbidden** to use a mobile phone and other electronic gadgets, to transmit, copy and take out any information related to the exam.

Station № 1 «Compounding of extemporaneous dosage forms» is one of the two OSPI stations in the discipline "Drugs Technology".

Practical situations for the compounding of drugs in a pharmacy are presented.

**An example of assessing the response of a higher education applicant (HEA)  
to a practical situation**

**Practical situation.** A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Rp.: Analgini 3,0

Solutionis Natrii hydrocarbonatis 2% – 300 ml

Natrii benzoatis 4,0

Liquoris Ammonii-anisati 10ml

Misce. Da. Signa. 1 table spoon 3 times a day

**Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

| №<br>n/o | Criterion   |  |
|----------|---|--|
| 1.       | <b>Characteristics of the dosage form</b>               | This MF is a turbid mixture-suspension, which includes a substance of list B - analgin, substances of the common list - sodium bicarbonate, sodium benzoate and ammonia-anise drops (fragrant substance containing essential oils). Solvent - purified water.  |
| 2.       | <b>Pharmaceutical expertise of the prescription</b>     | Form of prescription blanc (order of the Ministry of Health №360) - №1, requisites: a corner stamp of the hospital, signature and stamp of the doctor who wrote the prescription. Valid for one month, the prescription is not stored.<br>Medicinal substances are compatible.<br>Check the doses of the potent analgin. |
| 3.       | <b>Work with regulatory and technical documentation</b> | Order of the Ministry of Health of Ukraine №275 <i>Requirements for personal hygiene</i> <ul style="list-style-type: none"> <li>• Before the start of the shift is provided with clean towels for personal use;</li> <li>• It is forbidden to store personal belongings</li> </ul>                                       |

|    |  |  |
|----|--|--|
|    |  | <p>other than a clean handkerchief in the workplace and in the pockets of bathrobes;</p> <ul style="list-style-type: none"> <li>• Short trimmed nails, not varnished;</li> <li>• No rings on the fingers;</li> <li>• No makeup.</li> </ul> <p><i>Sanitary and hygienic requirements for the manufacture of non-sterile MF</i></p> <ul style="list-style-type: none"> <li>• Medicines used for the manufacture of non-sterile dosage forms should be stored in tightly closed barriers in conditions that exclude their contamination.</li> <li>• Auxiliary material required for the manufacture and packaging of drugs is prepared and sterilized.</li> <li>• The pharmacy is cleaned regularly.</li> </ul> <p>The manufacture of liquid dosage forms is regulated by orders of the Ministry of Health of Ukraine № 197 and № 398.</p> <p>Quality control and requisites of dosage forms compounding in pharmacies are regulated by orders of the Ministry of Health of Ukraine № 812 and № 398.</p>  |
| 4. | <b>Description of dosage form technology</b> | <p>1. Liquid dosage forms are made by mass-volume method, which provides the required mass of drug substance in a given volume of solution (soluble substance is taken by weight, and the solvent is added to obtain the required volume of solution).</p> <p>2. The solvent is not specified in the prescription, so make an aqueous solution. The word "water" means purified water.</p> <p>3. Since the concentration of the aqueous solution is given as a percentage, the mass-volume percentage should be understood.</p> <p>4. Concentrated solutions are used to accelerate the manufacture of drugs.</p> <p>5. The total volume of the drug consists of the volumes of all liquids that are part of the prescription.</p> <p><b>MF technology consists of the following technological stages:</b></p> <ul style="list-style-type: none"> <li>•weighing and measuring;</li> <li>•dissolving and mixing the components of the drug;</li> <li>•percolation;</li> <li>•packaging and labeling;</li> <li>•quality control.</li> </ul> <p>According to the requirements of the order of the Ministry of Health of Ukraine № 197 it is recommended to make liquid dosage forms using concentrated solutions if possible.</p> |

|                            |                                   |   |      |                   |                   |        |          |     |                            |                   |                       |                   |                          |       |
|----------------------------|-----------------------------------|---|------|-------------------|-------------------|--------|----------|-----|----------------------------|-------------------|-----------------------|-------------------|--------------------------|-------|
|                            |                                   | <p>According to the order of the Ministry of Health №197 (annex 1) there are the following concentrated solutions of substances that are part of the prescription:</p> <p>Sol. Natrii benzoatis 10% (1:10) = 4,0* 10 = 40 ml<br/> Sol Natrii hydrocarbonatis 5% (1:20)=6,0* 20=120 ml<br/> V (purified water) = 310-10-40-120 = 140 ml</p>  |      |                   |                   |        |          |     |                            |                   |                       |                   |                          |       |
| 5.                         | <b>Compounding of dosage form</b> | <p>140 ml of purified water (order of the Ministry of Health № 197) is measured in the working glass by the burette system behind the lower meniscus, in which 3.0 analgin, weighed on BP-5 hand scales, is dissolved; strain into a vial for handled.</p> <p>120 ml of 5% (1:20) sodium bicarbonate solution and 40 ml of 10% (1:10) sodium benzoate solution, measured by a burette system, are added to the vial. Aromatic-anise drops are added last, pre-mixed in a working glass with an equal amount (10 ml) of the finished solution (order of the Ministry of Health № 197).</p> <p style="text-align: center;">Front side WCP</p> <table data-bbox="549 976 1305 1227"> <tr> <td>Date</td> <td>№ of prescription</td> </tr> <tr> <td>Aquae purificatae</td> <td>140 ml</td> </tr> <tr> <td>Analgini</td> <td>3,0</td> </tr> <tr> <td>Sol Natrii hydrocarbonatis</td> <td>5 % (1:20) 120 ml</td> </tr> <tr> <td>Sol. Natrii benzoatis</td> <td>10 % (1:10) 40 ml</td> </tr> <tr> <td>Liquoris Ammonii-anisati</td> <td>10 ml</td> </tr> </table> <hr/> <p style="text-align: right;"><math>V_{total} = 310 \text{ ml}</math></p> <p>Has made:<br/> Has checked:<br/> Has handled:</p> <p><b>Packing and capping.</b> Orange glass bottle, capped with plastic stopper and screw cap.</p> <p><b>Dosage form must be subject to in-pharmacy control:</b></p> <ul style="list-style-type: none"> <li>- written control (filled in the back and front of the PPK);</li> <li>- organoleptic control (checked the purity of the solution by light shaking and inspection of the capped solution in direct and reflected light - no suspended particles are determined; the solution is transparent, colorless, without visible mechanical inclusions);</li> <li>- questions control;</li> <li>- control during handled (№ dosage form, prescription, and WCP, affixed label "Internal" with the inscription "Potion".</li> </ul> <p>The label states: № pharmacy, № prescription, full</p> | Date | № of prescription | Aquae purificatae | 140 ml | Analgini | 3,0 | Sol Natrii hydrocarbonatis | 5 % (1:20) 120 ml | Sol. Natrii benzoatis | 10 % (1:10) 40 ml | Liquoris Ammonii-anisati | 10 ml |
| Date                       | № of prescription                 |   |      |                   |                   |        |          |     |                            |                   |                       |                   |                          |       |
| Aquae purificatae          | 140 ml                            |   |      |                   |                   |        |          |     |                            |                   |                       |                   |                          |       |
| Analgini                   | 3,0                               |   |      |                   |                   |        |          |     |                            |                   |                       |                   |                          |       |
| Sol Natrii hydrocarbonatis | 5 % (1:20) 120 ml                 |   |      |                   |                   |        |          |     |                            |                   |                       |                   |                          |       |
| Sol. Natrii benzoatis      | 10 % (1:10) 40 ml                 |   |      |                   |                   |        |          |     |                            |                   |                       |                   |                          |       |
| Liquoris Ammonii-anisati   | 10 ml                             |   |      |                   |                   |        |          |     |                            |                   |                       |                   |                          |       |

|  |  |   |
|--|--|---|
|  |  | <p>name, patient, method of application, date (date, month, year), price. There is a separate prescription number, warning labels "Keep out of reach of children", "Keep in a cool, dark place" and "Shake before use", the package is airtight: the mixture is packaged in a bottle of orange glass, when turned over.</p> <p>Also (selectively) for the dosage form can be carried out the following types of control:<br/>- physical and chemical.</p> <p>The bottle is decorated with general labels "Potion", "Internal".</p> <p>The label should say "Shake before use", "Store in a cool and dark place", "Keep out of reach of children".</p> <p>The label must contain the following markings:</p> <ul style="list-style-type: none"> <li>• emblem of medicine or emblem (logo) of the business entity;</li> <li>• pharmacy number or name, address;</li> <li>• prescription number;</li> <li>• surname, initials of the patient;</li> <li>• composition of the drug;</li> <li>• detailed method of application;</li> <li>• series (for serial production);</li> <li>• date of manufacture;</li> <li>• expiration date.</li> </ul> |
|--|--|---|

**List of situations:** complex powders with hard-grinded substances; complex powders with volatile, odoriferous and dyeing matters; solutions for internal use (mixtures) using dry substances and concentrated solutions; solutions of slightly soluble medicinal matters; suspensions; emulsions; infusions and decoctions from medicinal plant material and extracts-concentrates, mucouses; homogeneous, heterogeneous and combined liniments; homogeneous, heterogeneous and combined ointments; suppositories; injection solutions without stabilizers; injection solutions with stabilizers; isotonic solutions; infusion solutions; eye drops; dosage forms with antibiotics; dosage forms for newborns and children under 1 year

## List of practical situations

### Practical situation № 1

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Unguenti Benzylpenicillini 20,0

Da. Signa: Apply for an eyelid in 3-4 hours

#### Task:

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

### Practical situation № 2

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Solutionis acidi hydrochlorici 1 ml

Pepsini 2,0

Aquae purificatae ad 100 ml

Da. Signa: 1 teaspoon 3 times a day for a child 10 months

#### Task:

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

### Practical situation № 3

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Dicaini 0,2

Zinci sulfatis 0,03

Solutionis Acidi borici 2% 10 ml

Misce. Da. Signa: 2 drops into each eye

#### Task:

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.



#### **Practical situation № 4**

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Solutionis Ringer-Lokk                      400 ml  
Da. Signa: For intravenous infusion

##### **Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

#### **Practical situation № 5**

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Solutionis Novocaini isotonicae 100 ml  
Sterilisa!  
Da. Signa: 2 ml for intravenous injection

##### **Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

#### **Practical situation № 6**

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Solutionis Glucosi      5 % – 100 ml  
Sterilisa!  
Da. Signa: For injections. 1 ml 2 times a day

##### **Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

#### **Practical situation № 7**

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Solutionis Natrii hydrocarbonatis 5 % – 100 ml  
Sterilisa!  
Da. Signa: For intravenous infusion

##### **Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

### **Practical situation № 8**

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Xeroformii                    3,0  
          Picis liquidae                3,0  
          Olei Jecoris aselli        ad 100,0  
          Misce. Da. Signa: For bandages

**Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

### **Practical situation № 9**

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Unguenti Dermatholi 10 % – 20,0  
          Da. Signa: Lubricate the affected areas of skin with the ointment

**Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

### **Practical situation № 10**

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Dicaini                            0,05  
          Vaselini  
          Lanolini                            ana 10,0  
          Misce, ut fiat unguentum.  
          Da. Signa: Lubricate the nasal cavity 2-3 times a day

**Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

### Practical situation № 11

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Papaverini hydrochloridi                    0,03  
          Extracti Belladonnae                         0,015  
          Olei Cacao                                        quantum satis,  
          ut fiat suppositorium  
          Da tales doses № 10  
          Signa: 1 suppository rectally at night

**Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

### Practical situation № 12

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Infusi radices Altheae                    120 ml  
          Natrii hydrocarbonatis                    3,0  
          Liquoris ammonii-anisati                6 ml  
          Misce. Da.  
          Signa: 1 table spoon 3 times a day

**Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

### Practical situation № 13

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Emulsi oleosi                                100,0  
          Mentholi                                         2,0  
          Misce. Da.  
          Signa: 1 table spoon 3 times per day

**Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

### **Practical situation № 14**

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Camphorae 0,2  
Natrii hydrocarbonatis  
Natrii chloridi ana 0,5  
Aquae purificatae 100 ml  
Misce. Da.  
Signa: Rinsing

#### **Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.

### **Practical situation № 15**

A patient applied to the pharmacy with a prescription for the compounding of a dosage form:

Recipe: Solutionis Prothargoli 1 % 100 ml  
Da. Signa: For sprinkling

#### **Task:**

1. Describe the dosage form. Provide a pharmaceutical expertise of the prescription.
2. Describe the technology of the dosage form compounding and quality control with theoretical grounding.