

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
Pharmaceutical Faculty

 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 №. 2</i> «Manufacturing of Medicines in the Industrial Conditions»
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

Tasks:

1. To be able to choose a rational dosage form, the method of obtaining and the group of excipients, depending on the initial properties of medicinal substances;
2. To be able to choose the technology for obtaining a specific dosage form with the definition of critical operations and the necessary equipment.

Equipment of the station:

1. Practice-oriented task scenario
2. Results of pharmaco-technological tests.
3. Paper A4.
4. A pen.

In the case of **distance form** (in order to prevent the spread of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2), the procedure of **Objective structured practical exam (OSPE)** is regulated by the Regulations on the introduction of elements of distance learning in VNPMU and will be held **on the Microsoft Teams platform**.

Equipment for remote form of OSPE: practice-oriented situational tasks, data from pharmaco-technological tests.

On the day of the exam, the secretary of the State Examination Commission join a student to the examiner`s meeting accordingly to the schedule of a group that passes the exam. At the station the student must greet and introduce himself, provide a document (passport) proving his identity to the teacher. The student receives a practically-oriented situational task, which has the goal of reproducing the situation that arises in the process of manufacturing officinal medicines that are produced by the pharmaceutical industry, namely: methods of obtaining, features of the influence of excipients on the quality of finished dosage forms, the sequence of stages of the technological process, indicating the critical stages and the equipment used in the manufacture of medicines.

The duration of passing of each station is 8 minutes. When the time is up the examiner will not accept the answer. Note that the teacher is an observer of your actions and does not provide instructions, comment or question.

Requirements for passing the station:

- Use a computer or laptop during the exam.
- The answer will be accepted only when camera and microphone are turned on and the student who passes the exam is clearly visible with a clear sound.
- Video is recorded at station

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

Station №2 «Manufacturing of Medicines in the Industrial Conditions» is one of the two stations of the OSPE in the discipline " Drug thecnology ".

Presented practical situations for the manufacture of dosage forms in the industrial conditions.

An example of evaluating the response of a higher education applicant (HEA) to a practical task.

The tablet shop of the pharmaceutical company is working on the creation of the drug "Valerian extract" in the form of tablets. The carried out pharmacological and technological analysis showed that the dry extract of valerian has the following properties: an amorphous powder with poor flowability and ability to compress, with high adhesion to the press tool of the tablet machine.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

Answer.

Criterion/ Execution	Score	Score received
Dosage form.		
Tablets are the solid dosage form containing one dose of a medicinal substance obtained by pressing.	0/0,3/0,4/0,5	
Advantages and disadvantages		
Advantages: dosing accuracy, ease of use, manufacturability, portability, the ability to mask unpleasant organoleptic properties, the ability to localize the action. Disadvantages: the effect of drugs in tablets develops relatively slowly, the impossibility of administering to a patient who is in an unconscious state, during storage, the disintegration time may increase.	0/0,3/0,4/0,5	
Method of obtaining		
Valerian extract tablets are obtained by pressing with the previous granulation.	0/0,3/0,4/0,5	
Groups of excipients		
Binders, fillers, loosening, glidants, antifriction agents, solvents.	0/0,3/0,4/0,5	
List of stages of the technological process		
Preparation of raw materials, preparation of the humidifier, mixing and moistening of a mixture, wet granulation and drying of granules, dry granulation and calibration, dusting of granules,	0/0,3/0,4/0,5	

tableting and dedusting, standardization, packing tablets in a blister strip, packing in packs, packing packs in boxes, finished product.		
Sequence of stages.		
Stage 1. Preparation of the raw materials Stage 2. Preparation of the humidifier Stage 3. Mixing and wetting the mixture Stage 4. Wet granulation and granulate drying Stage 5. Dry granulation and calibration Stage 6. Dusting of granules Stage 7. Tableting and dedusting Stage 8. Standardization Stage 9. Packing of tablets in a blister strip packaging Stage 10. Packing in packs Stage 11. Packing packs in boxes Stage 12. Finished product.	0/0,3/0,4/0,5	
Critical stages.		
Preparation of the raw materials Preparation of the humidifier Mixing and wetting the mixture Wet granulation and granulate drying Dry granulation and calibration Dusting of granules Tableting and dedusting	0/0,3/0,4/0,5	
Equipment used in the performance of the technological process.		
Vibrating sieve, weights, measuring tank, reactor, mixer, granulator, dryer, calibrator, tablet press, centrifugal deduster, automatic packaging machine.	0/0,3/0,4/0,5	
Indicators that assess the quality of the finished product.		
Description, identification, average tablet weight, uniformity of weight, uniformity of the content of active substances, abrasion, resistance to crushing, disintegration, dissolution, weight loss on drying, associated impurities, microbiological purity, quantitative determination of active substances.	0/0,3/0,4/0,5	
Justification of the selected type of packaging.		
The most often used for tablets is a contour cell packaging made of polymer film and foil, since this type of packaging provides reliable storage of drugs, portability and maximum microbiological purity.	0,3/0,4/0,5	
Minimum / maximum score for the task	3,0/5,0	

List of practical situations

PRACTICAL SITUATION 1

The pharmaceutical company produces baby powder. When determining the technological properties of the components, it became known that the mixture of substances has good flowability, uniform distribution of active and auxiliary substances in the entire mass, homogeneity of mixing.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 2

The tablet shop of a pharmaceutical company is working on the development of the drug acetylsalicylic acid in the form of tablets. The carried out pharmacological and technological analysis showed that the drug substance has the following characteristics: isodiametric crystal shape, good cohesion and weak adhesion ability to the pressing tool tablet machine.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 3

A pharmaceutical company is organizing the production of the drug "Diazolin", in the form of dragee. Which contains mebhydrolin, sucrose, starch syrup, talc, wax, sunflower oil.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 4

A pharmaceutical company is organizing the production of the drug in the form of soft gelatin capsules, which contains fat-soluble vitamins A, E.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 5

A pharmaceutical company plans to introduce into production a drug in the form of licorice syrup. During the pharmacological and technological analysis, it became known that the dosage form has the following characteristics: the dark heavy bodied liquid with a characteristic odor, the active substance is dissolved in a concentrated sucrose solution.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 6

At the pharmaceutical factory, preparations began to establish the production of essential oils from the peel of citrus fruits, without heating the product. A feature of this type of raw material is that essential oils are localized most in the peel of the fruit.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 7

The galenic shop of the pharmaceutical enterprise is organizing the production of tincture from the roots and rhizomes of valerian. It is planned to use 70% ethanol as an extractant, and the amount of raw materials should be taken so as to obtain five volume parts of the finished product from one weight part.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 8

At the pharmaceutical enterprise, they are working on the introduction into production of a cardiogenic agent based on a liquid hawthorn extract. To ensure the same ratio of active ingredients in the raw material and the finished product, 1 kg of raw material was used to obtain 1 kg of liquid extract.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 9

The photochemical workshop plans to introduce into production a preparation from belladonna leaves in the form of a soft extract. Tests have shown that this extract can also be used as an intermediate product for obtaining various dosage forms.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 10

In the photochemical workshop of a pharmaceutical enterprise, dry extract of belladonna is produced. Due to the increased content of biologically active substances in the finished extract, it was decided to add fillers to the dried product.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 11

In the research laboratory of a pharmaceutical company, they are working on the development of a medicinal product in the form of suppositories, which contains thermolabile substances. Tests have shown that with the introduction of medicinal substances into the base, there is an incompatibility of the medicinal substances with the molten suppository base.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 12

A pharmaceutical company plans to introduce the drug in the form of an emulsion into production. A feature of this product is that it contains beeswax as a component that requires preliminary melting.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 13

A pharmaceutical company is expanding and organizing the production of a solution for external use in the form of a spray, which contains iodine, potassium iodide, glycerin, eucalyptus tincture, purified water.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 14

A pharmaceutical company plans to introduce the production of a medicine in the form of Levomycetin eye drops, which will include chloramphenicol, boric acid, and purified water.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 15

A pharmaceutical factory is expanding production and is working on the introduction of an ointment type "Levomikol" on a polyethylene oxide base. The ointment contains chloramphenicol, methyluracil, polyethylene glycol 1500 and 400.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.

2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 16

In the research laboratory of a pharmaceutical enterprise, they are working on the introduction into production of a 40% glucose solution for injection, which includes glucose monohydrate, hydrochloric acid, sodium chloride, and water for injection.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.
2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 17

A pharmaceutical company is organizing the production of a medicinal product in the form of hard gelatin capsules. The composition of the mixture for encapsulation includes the following substances: ascorbic acid, microcrystalline cellulose, magnesium stearate.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.
2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 18

At the pharmaceutical factory is working on the introduction into production of a medicinal product in the form of an aerosol, which includes: soluble streptocide, eucalyptus oil, ethyl alcohol, glycerin, tween-80, purified water, nitrogen.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.
2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 19

In the laboratory of the pharmaceutical enterprise are working on the introduction into the production of an infusion solution under the trade name "Rheosorbilact", which includes sorbitol, sodium lactate, sodium chloride, calcium chloride, potassium chloride, magnesium chloride.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.
2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

PRACTICAL SITUATION 20

A pharmaceutical company expands its production and launches the production of a drug for the treatment of trophic ulcers in the form of an oil extract. To obtain this extract, they plan to use the hypericum herbs and sunflower oil.

1. Give the definition and characteristics of the dosage form, propose a method of obtaining it and groups of excipients for the production of this dosage form.
2. Name the stages of the technological process for obtaining this dosage form, determine the critical operations and the necessary equipment, suggest the optimal packaging.

