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 «23» 12 2024 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 «24» 12 2024 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	***Station №. 2*** «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 2024

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 VNPMMU 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 a solid dosed medicine "Valerian extract". 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, tableting and dedusting, standardization, packing tablets in a blister strip, packing in packs, packing packs in boxes, finished product.	0/0,3/0,4/0,5	
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. Tabletting 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 Tabletting 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 undosed solid medicinal form for external use, which includes zinc oxide, talc, potato starch.

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 pharmaceutical company is working on the creation of a solid dosage form for oral use based on acetylsalicylic acid. 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

The pharmaceutical company is organizing the production of a solid dosage form for internal use, which includes non-tabletting substances. It is planned to use a dragee pan in the production process.

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 a solid dosage medicinal form with a soft shell of a rounded shape, which includes 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 a liquid dosage form for internal use based on licorice root extract and 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 a mixture from the peel of citrus fruits, which contain aromatic substances. The peculiarity of the production is the product's preparing without heating in order not to destroy the volatile compounds.

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 an extractive preparation 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 is working on the introduction into production of an extractive cardiotonic agent based on hawthorn fruits. 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 the drug.

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 phytochemical shop of the pharmaceutical enterprise produces an extractive preparation from the roots and rhizomes of valerian. The finished product is a viscous mass with a moisture content of 25%. Tests have shown that this product can also be used as an intermediate product for obtaining various dosage forms, in particular to produce suppositories, tablets and capsules.

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

The production of an extractive medicine from belladonna leaves is carried out in the photochemical shop of the pharmaceutical enterprise. The finished product is a loose mass with a moisture content of no more than 5%. Tests have shown that this product can also be used as an intermediate product for obtaining various dosage forms, in particular to produce tablets and capsules.

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

The research laboratory of the pharmaceutical company is working on the creation of a solid dosage medicine for rectal use, which contains thermolabile substances. It was decided to use hydrogenated fat as a basis.

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 a heterogeneous dispersion system consisting of small droplets of one liquid evenly distributed in another liquid. 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

The pharmaceutical company is organizing the production of a solution for external use in hermetic bottles. The contents of the bottle are dispensed by mechanical spraying. The composition of the solution includes iodine, potassium iodide, glycerin, eucalyptus tincture 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 14

A pharmaceutical company plans to introduce the production of a medicine in the form of a sterile solution intended for installation in the eye, 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

The pharmaceutical factory is expanding production and working on the introduction of a soft dosage form for external use on a polyethylene oxide base. The product will include 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

The scientific-research laboratory of pharmaceutical enterprise works on introduction into manufacture of medicinal product in the form of solution for parenteral usage including glucose monohydrate, acid hydrochloric acid, sodium chloride, water for injections.

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

The pharmaceutical company is organizing the production of a medicinal product, that is a solid dosage form with a solid cylindrical shell, consisting of two parts: a body and a cap. 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

The pharmaceutical factory is working on the introduction into production of a medicinal product under pressure, 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

The laboratory of the pharmaceutical enterprise is working on the introduction into the production of a solution for long-term parenteral administration into the body with a volume of more than 100 ml, 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 a concentrated extract from medicinal plant raw materials. For obtaining this drug it is planned 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.

PRACTICAL SITUATION 21

The pharmaceutical company is working on setting up the production of a solid dosage form for oral use, in order to mask the unpleasant taste and smell, it was decided to cover the tablet with auxiliary substances, and to improve the flowability and compressibility of the mixture of active and auxiliary substances, granulation of the mass was previously carried out.

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 22

The pharmaceutical company is launching the production of the drug for oral use "Nitroglycerin" in a soft shell, which has a spherical shape, without a characteristic seam.

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 23

At the pharmaceutical factory, preparations have begun to establish the production of a pharmaceutical drug for installation in the nasal cavity. The composition of the drug contains xylometazoline, sodium chloride, 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 24

A pharmaceutical company plans to introduce into production a drug for external use. The peculiarity of this remedy is that it contains camphor and 70% ethyl alcohol.

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 25

The pharmaceutical company produces a solid dosage medicine for rectal use by pouring the molten mass into molds.

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 26

The pharmaceutical company is working on the introduction into production the drug in the form of a solution for parenteral use. The composition of the solution contains active ingredients that are not subject to sterilization in the final package.

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 27

The pharmaceutical factory is working to establish the production of the drug in the form of a free disperse system with a liquid dispersion medium for internal use. It is planned to use a solution of sucrose in water as a dispersion medium

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 28

The experimental laboratory of the pharmaceutical enterprise is working on the introduction of the drug in the form of a solution for parenteral use. The feature of this solution is that it contains active substances that are subject to hydrolysis in the aquatic environment.

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 29

At the pharmaceutical enterprise, it is planned to introduce into production a drug in the form of a 20% camphor solution for parenteral use. As a solvent, it was decided to use olive 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 30

At the pharmaceutical factory, preparations have begun to establish the production of a soft dosage form for external use, which contains more than 25% of powdery substances insoluble in the base. This paste will include acid salicylic zinc oxide, potato starch and white paraffin.

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.