

**ODESSA NATIONAL MEDICAL UNIVERSITY
DEPARTMENT OF DRUGS TECHNOLOGY**

APPROVE

Head of Department

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«29» august 2022 y.

**METHODICAL DEVELOPMENT
OF INDEPENDENT WORK OF STUDENTS (IWS)**

Course 3 Faculty Pharmaceutical

Course Homeopathic drugs

Topic № 5 "**Technology of basic drugs, liquid homeopathic dosage forms, registration for release and quality control.**"

Methodical recommendations on IWS
developed by:

Head of Department

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The practical lesson was discussed at the
methodical meeting of the department
«29» august 2022 y.
Protocol № 1

Odesa - 2022

Methodical recommendations of IWS

Topic: Technology of basic drugs, liquid homeopathic dosage forms, registration for release and quality control. - 6 h.

Objective: generalization of the received knowledge, abilities and skills concerning the technology of basic homeopathic preparations, liquid homeopathic dosage forms, features of registration before release, physical and chemical methods of their analysis.

Basic concepts: basic homeopathic remedies, dilutions, potencies.

Plan

I. Theoretical questions for the lesson:

1. Complex homeopathic remedy -
2. Calculations for the dilution of ethanol using the dilution formula and alcohol tables
3. Basic drugs are used for -
4. Features of preparation of oil solution containing menthol and camphor -
5. Liquid homeopathic dosage forms include -
6. Homeopathic monopreparation -
7. Modality-
8. Homeopathic constitution -

Answer the test questions:

1. Liquid homeopathic dosage forms do not include:

- A) dilutions
- B) trituration
- C) obodeldoki
- D) homeopathic oils

2. In the preparation of alcoholic solutions, if the strength of ethanol is not specified, then take the alcohol:

- A) 90%
- B) 50%
- C) 75%
- D) 92%
- E) 98%

Preparation of basic (basic) homeopathic remedies

The rules of preparation of GP-drugs are determined primarily by the physical state of the raw material, which allows them to be prepared in different dosage forms . tincture (all liquids) and starting materials (all solids) and denoted by the Greek letter θ (phyta). According to the GP Pharmacopoeia, the original DP drugs include:

Essences (40% of all raw materials) are obtained from fresh juice of plants collected at different times of the year, depending on the part of plants used for this preparation or their parts preserved with 90% alcohol. Prepared in small quantities and not stored for a long time.

Matrix tinctures - tinctures (25% of raw materials) are prepared from dried and ground into powder plants or from fresh animal substances (bees, ants) on the basis of extraction with 70% alcohol by maceration (infusion) or percolation (displacement).

Solutions (10% of raw materials) from soluble salts or acids. Depending on the solubility of the starting materials, the mother liquors are aqueous and alcoholic. For the preparation of the latter use 90% -60% -45% alcohols depending on the solubility of the starting material. Used for lotions, compresses and rinses.

Rubbing (25% of raw materials) is prepared from insoluble minerals and solid parts of plants (roots, seeds). They are mixed with milk sugar and thoroughly ground, not forced into a porcelain (non-metallic) mortar for at least one hour, when a homogeneous mass is obtained, visible not only from the outside but also under a microscope.

Intermediate potencies or to dilute dilutions with the use of the corresponding scale are prepared from initial tinctures and substances. This is achieved by sequential crushing of the drug by dilution in a solvent or grinding with milk sugar. Particles brought to the lowest submolecular state have a large surface area, lose their toxicity and acquire high therapeutic activity, for which after each dilution the solution is shaken vigorously or solids are ground for 10 seconds (10 movements).

The DP uses mainly 2 degrees of dilution: 1) Decimal (Decimal) scale, denoted by the letter D or the Roman numeral X: D1, X1. 2) Hundredth (centesimal), denoted by the letters C, CH, SC or no letters at all, but only the Arabic numeral: C1, CH1, SC1, 1. S. Hahnemann worked first with the hundredth scale, and then moved to 1: 1000 scale M) and 1: 50,000 (scale LM). Modern homeopaths use all scales of dilutions, the Kiev scale of DP immediately begins with breeding on the hundredth scale.

Raw materials for homeopathic medicines

Starting materials (substances, bases) - raw materials of mineral, vegetable and animal origin, used for breeding and dosage forms. Liquid and solid starting materials are used to prepare dilutions (potencies). Liquid substances include:

- solutions (acids, salts, poisons, etc.);
- liquid of various nature;
- matrix tinctures or fits (Q).

The source material for the preparation of matrix tinctures can be the juice of fresh plants or their parts (flowers, leaves, etc.), mixed with ethyl alcohol for preservation (essence).

As solids used:

- insoluble minerals;
- Salt;
- dried plants or their parts (roots, seeds, etc.);
- preparations of animal origin (can be used as an animal or insect - bee, spider, red ant, sea sponge, etc., and their release - amber, beaver stream, snake venom, etc.).

From solids in the future prepare triturations (rubbing) or tinctures matrix homeopathic.

In homeopathic practice also introduced the use of sarcoids, a material obtained from healthy animals, from bacterial cultures or various plant secretions and secretions. For example, turpentine belongs to plant sarcoids, and to animals - RNA and DNA, cholesterol, folliculin.

If the material is selected not from healthy but from diseased tissues, the drugs made from it are called nosodes, such as syphilitic ulcer extract, tuberculous tubercle, psoriatic plaques, liver and kidney stones, urine.

As excipients used water, milk sugar, alcohol of various concentrations, glycerin, vaseline, lanolin, cocoa butter.

Fragrant substances are stored in special rooms, as well as in some cases breeding 1X, 2X, 3X.

Basic (basic) homeopathic dosage forms

Essences (primary tinctures) - a mixture of juices of fresh plants or their parts and 90% ethyl alcohol in various proportions.

Tinctures (tinctures) - from dried and crushed herbal medicinal raw materials or from animal tissues, similar to ordinary tinctures.

Solutions (dilutions) are prepared from substances soluble in ethyl alcohol or purified water.

Triturations (powder grinds) are powder mixtures of solids prepared from medicinal substances and milk sugar.

Liquid dilutions from triturations

Method 1. To obtain the fourth hundredth dilution (C4) 1 part of the trituration of the substance of the third hundredth dilution (C3) is dissolved in 79 parts of water, add 20 parts of 86% ethyl alcohol (by weight) and shake. The fifth hundredth (C5) and all subsequent hundredth dilutions are prepared from 1 part of the previous hundredth dilution and 99 parts of 43% ethyl alcohol (by weight) by shaking.

Method 2. To obtain the sixth decimal dilution (D6) 1 part of the trituration of the substance of the fourth decimal dilution (D4) is dissolved in 9 parts of water and shaken. Then 1 part of the obtained dilution is shaken with 9 parts of ethyl alcohol 30% by weight.

Similarly, the seventh decimal dilution (D7) is obtained from the trituration of the fifth decimal dilution (D5), and the eighth decimal dilution (D8) is obtained from the trituration of the sixth decimal dilution (D6).

Homeopathic solutions for injection and eye drops are prepared from freshly prepared dilutions obtained by method 2, using water for injections or isotonic solutions containing sodium chloride, sodium bicarbonate and others.

Homeopathic injectable solutions - a sterile liquid dosage form obtained by potentiation of one or more components in accordance with the methods of homeopathic technology. In the manufacture of dilutions in small quantities (less than 3 g), the initial solutions and liquid drugs are dosed in drops. To do this, use a standard or calibrated (by weight) dropper for a specific solution and drug.

LM dilutions (50,000 potencies) are prepared from triturations of substances in the third hundredth dilution (C3), by sequential potentiation in a ratio of 1: 50,000 and denote LM (L-50, M - 10,000). In the manufacturing process, each dilution is potentiated by shaking 100 times.

For LM-potencies there is a scale from LM I to LM XXX, ie there are 30 degrees of potentiation. In contrast to decimal and hundredth dilutions of LM dilutions are denoted by Roman numerals.

To obtain a dilution of LM I 0.06 g of trituration of the third hundredth dilution of C3 is dissolved in 20 ml of ethyl alcohol 15% by weight and shaken (corresponds to 500 drops). One drop of the resulting solution is transferred into a tightly closed container with a capacity of 5-10 ml, add 2.5 ml of 86% ethyl alcohol (by weight) (corresponds to 100 drops) and shake vigorously 100 times. The resulting dilution is applied per 100 g of original granules № 1 (from 470 to 530 granules per 1 g). Wet granules are dried in air at room temperature to constant weight.

To obtain a dilution of LM II, one granule in a dilution of LM I is transferred into a tightly closed container with a capacity of 5-10 ml, dissolved in 0.05 ml (one drop) of water, add 2.5 ml of 86% ethyl alcohol (by weight) and shake vigorously 100 times. The resulting dilution is applied to the next 100 g of the original granules № 1.

Preparation of syrups

Syrups homeopathic-liquid dosage form, which is a concentrated solution of sugar, containing homeopathic tinctures, homeopathic dilutions, trituration and is intended for oral administration.

Syrups are prepared by dissolving sugar in purified water by heating at a temperature above 100 ° C with a concentration of not more than 72%. The resulting solution is filtered hot into a sterile container. In the cooled mass of the syrup can be introduced homeopathic tinctures, homeopathic dilutions, triturations or solids.

The concentration of sugar in the dosage form must be at least 64%. Ethyl alcohol can be used as a preservative. The resulting syrup is filtered through a thick cloth or filtered through a paper filter.

Preparation of infusions and decoctions

Infusions and decoctions of homeopathic are aqueous extracts of ARS or aqueous solutions - specially prepared extracts. They are made by infusing crushed dried or freshly harvested APC with purified water at a certain temperature.

Use ARS, approved for use in homeopathy and meets the requirements of ND.

Before infusion, the raw material is ground. In the absence of instructions in the private ND raw materials Freshly harvested grind to obtain a slurry, and dried - to particles passing through a sieve with holes in diameter:

- no more than 4 mm - for leaves, flowers, herbs;
- no more than 3 mm - for shoots, bark, roots, rhizomes, bulbs, tubers;
- no more than 2 mm - for fruits and seeds.

For infusion use tightly closed containers (infundirnye glasses) made of indifferent materials. Prior to the introduction of raw materials porcelain containers must be heated at a temperature above 90 ° C for 15 minutes Preservatives in infusions and decoctions are not added.

Infusions and decoctions of dried raw materials. Produced by weight in the ratio of 1 part APC and 10 parts purified water.

Infusions. The crushed plant material is poured 3-5 times the amount of water at room temperature, mix thoroughly and leave for 15 minutes. Then add to the mixture the remaining water, pre-heated to boiling and insist in a tightly closed container on a boiling water bath (or infusion apparatus) for 5 min, with frequent stirring. The mixture is then left at room temperature until completely cooled.

The infusion is filtered (gently squeezing the APC) through a sterile cloth and weighed.

Decoctions. The crushed plant material is poured boiling water and infused in a boiling water bath (or in the infusion apparatus) for 30 min with frequent stirring. The hot broth is filtered (gently squeezing the raw material) through a sterile cloth and weighed after cooling.

If the mass of the obtained infusion or decoction is less than that offered, the required amount of water at room temperature (for infusions) or boiling water (for decoctions) is added to the remaining plant material, mixed and the raw material is gently squeezed again (filtering through the same filter). In addition, the infusion or broth is brought to the required mass by squeezed extraction.

The infusion or decoction corresponds to the first decimal dilution (D1). Breeding of them is prepared in purified water. The second decimal dilution (D2) is made from 1 part of infusion or decoction and 9 parts of water. Subsequent dilutions are obtained from 1 part of the previous dilution and 9 parts of water.

Infusions and decoctions of freshly harvested ARS. Infusions of freshly harvested ARS and their dilution are used only for the preparation of homeopathic solutions for injection, and decoctions and their dilution - for the preparation of solutions for injection and eye drops.

The technology and composition of extracts from the collected APC depend on the moisture content.

The amount of water X (kg) required for the manufacture of infusions or decoctions is determined by the following formulas:

$$X = M (400 - A) / 100 \text{ (for infusions);}$$

$$X = M (300 - A) / 100 \text{ (for decoctions),}$$

where M is the mass of APC (kg); A - loss in mass during drying (%).

Infusions. The crushed APC is thoroughly mixed with the calculated amount of water, heated to 37 ° C and insisted (at the same temperature) for 1 h with frequent stirring. After this time, the infusion is filtered (gently squeezing the raw material) through a sterile cloth.

Decoctions. The crushed APC is filled with the calculated amount of water, preheated to boiling, and insist in a container equipped with a reflux condenser in a boiling water bath for 30 min or at room temperature for 2 h with frequent stirring. After this time, the broth is filtered through a sterile cloth.

Dilution of the obtained infusions and decoctions is prepared in purified water. The first decimal dilution (D1) of infusions is made of 4 parts of infusion and 6 parts of water; the first decimal dilution (D1) of broths - from 3 parts of broth and 7 parts of water. The second decimal dilution (D2) is obtained from 1 part of the first decimal dilution of the

infusion or decoction and 9 parts of water; subsequent dilutions - from 1 part of the previous dilution and 9 parts of water.

Questions for self-control

1. Characteristics of basic homeopathic remedies, matrix tinctures.
2. Technology of making homeopathic matrix tinctures.
3. Features of potentiation of homeopathic matrix tinctures.
4. Quality control of homeopathic matrix tinctures.
5. Characteristics of liquid homeopathic dosage forms.
6. Technology of production of liquid homeopathic dosage forms.
7. Quality control of liquid homeopathic dosage forms.
8. Registration in liquid homeopathic dosage forms.

Approximate tasks for the study of theoretical material

1. *Make a dictionary of basic concepts on the topic*
2. *Fill in the orientation card for independent preparation of the student with the use of literature on the topic (the need to include in the guidelines of the orientation card is decided by the staff of the department):*

Basic and tasks and	In the fairy tale	Answers
1	2	3
<i>Explore:</i>		
Basic homeopathic remedy	Define the term.	
Matrix tincture	Define the term.	
Potentiation	Define the term. Drug cycles.	

II. Practical work (tasks) that will be performed in class:

Complete an individual task set by the teacher: Describe the best option for technology. Fill in the front of the written control passport and indicate the registration of the drug before the holiday.

- 1.1. recommendations (instructions) for performing tasks (professional algorithms, orientation maps for the formation of practical skills, etc.);

Complete an individual task set by the teacher:

Describe the best technology.

Fill in the front of the written control passport.

- 1) Characteristics of medicinal products-
- 2) Technology-
- 3) Registration for vacation -

1.2. requirements for the results of work, including before registration;

According to the course of the practical lesson to design an individual task in a workbook.

- 1) Characteristics of raw materials-
- 2) Technology
- 3) Registration for leave (packing, marking)

III. Test tasks for self-control

1) Indicate the potency of the drug prepared by mixing 5.0 g of hawthorn juice and 5.0 g of 90% ethyl alcohol:

A – C1;

C – C2;

B – X1;

D – X2.

2) In the manufacture of alcohol solutions, if the strength of ethanol is not specified, use alcohol

A – 90%;

B – 50%;

C – 75%;

D – 92%;

E – 98%.

3) Dilutions - dosage forms:

A – liquid;

B – solid;

C – soft;

D – gaseous

4) The pharmacist prepared a glyceric solution of boric acid. Specify the correct method of administration of boric acid:

A – dissolve in a volumetric flask

B is dissolved in a mortar by grinding

C – dissolve in the stand at room temperature

D is dissolved with ethanol in a mortar and mixed with glycerol

E-dissolve in the vial when heated

IV. Individual tasks for students on the topic of the lesson - to present in the form of presentations or IWS.

1. Technology of basic drugs, liquid homeopathic dosage forms, registration for release and control of their quality

Recommended literature

Main:

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2. Modern aspects of extemporaneous allopathic, homeopathic and cosmetic medicines creation: collection of scientific works. Issue 6. – Kharkiv: NUPh publishing house, 2021. – 109 p.
3. Гомеопатичні препарати: навчальний посібник / упоряд.: Борисюк І.Ю., Фізор Н.С., Валіводзь І.П. Одеса, ОНМедУ, 2020.-168 с.
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7. Технологія гомеопатичних лікарських засобів : навчально-методичний посібник для викладачів / Л. І. Вишневська, Н. П. Половко, С. В. Олійник, І. С. Коноваленко. – Х.: Вид-во НФаУ, 2018. – 86 с.
8. Методичні рекомендації з підготовки до підсумкового модульного контролю з технології гомеопатичних лікарських засобів для здобувачів вищої освіти / Л. І. Вишневська, Н. П. Половко, С. В. Олійник, І. С. Коноваленко. – Х.: Вид-во НФаУ, 2018. – 27 с.
9. Технологія гомеопатичних лікарських засобів : метод. рек. до практичних і семінарських занять / Л. І. Вишневська, Н. П. Половко, С. В. Олійник, І. С. Коноваленко. – Х.: Вид-во НФаУ, 2018. – 56 с.
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