


**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 № 10 "Technology of solid, complex homeopathic dosage forms, registration for release and quality control . »

Methodical recommendations on IWS developed by:

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The practical lesson was discussed at the methodical meeting of the department «29» august 2022 y.

Protocol № 1

Odessa - 2022

## Methodical recommendations of IWS

**Topic: " Technology of solid, complex homeopathic dosage forms, registration for release and quality control " - 6 h.**

**Objective:** to gain skills and abilities in technology production solid homeopathic dosage forms ( practical skills ), registration for vacation and control them quality .

**Basic concept :** matrix homeopathic tinctures, dilutions , potencies, triturations , complex homeopathic medicines; acquire theoretical and practical skills in technology \_\_ complex homeopathic drugs , conducting physico-chemical control .

### Plan

#### I. Theoretical questions for the lesson:

1. Characteristics of solid homeopathic dosage forms.
2. Technology of manufacturing solid homeopathic dosage forms.
3. Quality control of solid homeopathic dosage forms.
4. Registration for the release of solid homeopathic dosage forms.

Triturations (powder rubs) are prepared from a variety of means (essences, tinctures, metals, minerals, substances of animal origin, etc.). As a solvent use lactic sugar because \_ he least hygroscopic . Prepare by one of such methods .

1st method ( used for grinding dry drugs substances different origin ). Certain number medicinal substances rubbed with milk sugar in porcelain mortar ( respectively 1.0 g of substance and 9.0 g of milk sugar per decimal and 0.1 g of substance and 9.9 g of milk sugar on the hundredth scale).

At the same time amount of milk sugar divided by 3 approximately levels parts . The first part placed in a porcelain mortar and mixed sprat times to mash the pores of the mortar, then add weekends substances and grind carefully with effort for 6 minutes after \_ what for 4 minutes scrape and stir again grind for 6 minutes and scrape again for 4 minutes . Then add a second third of milk sugar , again grind for 6 minutes , scrape, stir for 4 minutes and repeat both operations again . Finally add the rest of the milk sugar and again twice repeat both operations as indicated above .

Given that the process of grinding is particularly important (increasing the strength of the drug), according to the guide "Homeopathic Medicines", each Trituration is prepared by carefully grinding and mixing the substance and milk sugar for 1 hour. Hygroscopic substances it is possible rub only in heated mortars.

2nd method ( used for cooking trituration with liquids - solutions water or alcohol ). For this take 2 drops of aqueous solution or 4 drops of an alcoholic solution of the basic substance (0.1 g), grind as described above the rules with 9.9 parts milk sugar and get the first hundredth or the second decimal dilution . From snake venom first receive trituration with dairy sugar to the third dilution , after what diluted with alcohol and released in liquid kind of or granules ( pills ), as indicated below .

3rd method ( used for cooking trituration of essences and tinctures). To do this, 2 weights parts essences prepared by the 1st and 2nd methods are mixed and ground according to the rules with 99 weight parts of milk sugar , while get the first hundred dilution . Others dilution prepare usually .

To receive the first dilution of the essence obtained by the 3rd method, take 3 weight parts essences and grind with 99 weights parts of milk sugar . When mixing 1 weight parts tincture (which is already the first decimal potency ) with 99 weight parts of milk sugar the first hundred turns out dilution . Others dilution prepare usually .

Liquid dilution of powders ( trituration ) is prepared as follows. 1 weight part trituration medicinal substances in the third hundredth dilution dissolved in 79 weight parts of water, add 20 wt parts of 90% ethyl alcohol and shake 10 times in a vessel filled with two thirds . It turns out dilution 4 ( fourth hundreds ). One weight part dilution 4 is mixed with 99 weight parts of 45% ethyl alcohol, shake 10 times - it turns out dilution 5.

The following hundreds dilution prepare mixing 1 weight parts previous dilution and 99 weight parts of 45% ethyl alcohol.

#### Private technology homeopathic dosage forms

All medicines used in homeopathic practice for internal and external use, as a rule, are prepared from the main source drugs (essences, tinctures, triturations , solutions) in strict accordance with the instructions in the manual "Homeopathic medicines" (Homeopathic Pharmacopoeia) .

When describing each drug included in the pharmacopoeia, the relevant section is indicated, according to which the drug is prepared from this drug and the degree of its dilution.

Dosage forms of solid consistency. This group of dosage forms includes powders, granules (pills, granules) and tablets that are used for internal use. Specified medicinal forms are not swallowed , but absorbed in the mouth . In homeopathic practice most often granules and powders are used .

The powder ( Triturationes ), as mentioned above, is prepared and released in the form of appropriate dilutions of solid and various liquid media. For dosing their apply special glass or bone scapulae or just recommend take on tip coffee spoon. Dose for one reception it turns out about 0.2 m

Calcarea iodate 3 trit .

At the tip teaspoon 3-4 times a day

Prepare according to this recipe Trituration by the 1st method and accordingly draw up before the holiday as an undivided powder. Because \_ the amount of powder is not specified , release 10.0 g

Granules ( Granulae ) are prepared from cane sugar higher quality . If necessary, in homeopathic pharmacies granules are saturated certain quantity liquid drugs ( essences , tinctures , solutions , etc.). After this grain is dried , each has a weight of 0.032-0.033 g

If in the recipe the number of grains is not specified, then them release 10.0 g. Saturation of the granules is as follows. In a vessel download granules per 1 kg of granules take 10.0 g of the corresponding dilution medicinal substance , add 10.0 g of 60% ethyl alcohol, tightly clog and shake for 10 minutes manually or 3-4 minutes when using mechanization .

Granules air dried , after \_ what their pour into a suitable container. It is impossible saturate granules drugs prepared from volatile , odorous substances , as well as from all acids in concentration lower third hundredth dilution .

Aurum muriaticum 6 gran .

For 8 granules 3-4 times a day

Tablets ( Tabulettae ) are the same triturations , because they are compressed without the addition of any excipients, and each tablet corresponds to a single dose of trituration , ie about 0.2 g. Take tablets in the same way as triturations and granules. Abroad , tablets are currently being prepared using sucrose and magnesium as fillers stearate , wheat starch , talc.

Rating quality , storage and release homeopathic drugs

The quality of liquid preparations is determined by the following indicators: liquid density, content of ethyl alcohol, extractives, fatty oils, alkaloids, reducing agents; coloring of essences, tinctures and liquid dilutions; capillary and capillary-luminescent analysis of liquid dilutions, triturations , and others.

uniformity of the distribution of the drug in the Trituration is determined using a magnifying glass or microscope. In the low dilution it is possible to determine color , smell, taste appropriate medicinal substances . In some cases for verification trituration use phenomenon recrystallization medicinal substances from supersaturated solutions . The size of the particles of metals and coal in Trituration measured under microscope .

In the ointment determine homogeneity , in suppositories - full time deformation . Authenticity drugs determined by \_ general , specific colored reactions as well methods thin layer chromatography . This method is used as a guide for installation benign matrix tinctures . In the analysis chromatograms are usually not specified current substances , and given only her description from indication sequence location of zones.

Quantitative content of BAS is indicated only in rare cases, in particular, in the analysis of tinctures containing toxic substances, as well as preparations of arsenic, mercury, cadmium. The quality of tinctures is guaranteed by the parameters of chromatographic analysis of a given number of samples, as well as the test of the fourth decimal dilution, which is subjected to tinctures containing toxic and potent substances (aconite, strophanth, nux vomica , Ignatius , belladonna).

In the homeopathic pharmacopoeias of some countries (USA, Belgium ) medicinal means are given in homeopathic dilution which \_ also are being tested . Yes, French Boaron firm in certificates \_ quality leads tests of the fourth decimal , second and fourth hundredth dilution with reference to the pharmacopoeia article , and sometimes - to the standard of the firm .

In homeopathic pharmacies, various complex remedies with appropriate names are available without a prescription: anti- influenza , anticlimacterin , antinervin , anti- asthmatic drops , gold, pertussis, and Dr. Fleming's ointment.

Homeopathic poisons and potent drugs are stored according to the general rules of pharmacy and are issued with appropriate labels. Strong medicinal substances and poisons it is possible let go , starting only from the fourth decimal dilution .

Homeopathic medicinal drugs depending \_ from the type of drug forms let go in bottles , boxes, packages. On the labels indicate the pharmacy number, prescription number and serial number of the drug in the prescription , weight dispensed drug, date and signature of the pharmacist. Order and priority reception prescription drugs are listed separately the schedule written out doctor .

#### Improvements homeopathic medicinal drugs

In order to improve homeopathic remedies, with positive results of clinicians' testing of homeopathic remedies, it is necessary to resolve contradictions in their nomenclature, technology, regulation and quality control. Research should be conducted to review the arsenal of homeopathic remedies, enrich it with modern effective means, search for domestic counterparts of imported products. The range of drugs and forms regulated in homeopathy should be expanded by injectable solutions, ophthalmic dosage forms, aerosols, pills, therapeutic systems, etc. The effectiveness of homeopathic remedies can be increased by using modern excipients - macromolecular compounds , surfactants solvents, stabilizers, emulsion and hydrophilic bases for ointments, etc. Need to to improve technological processes homeopathic essences , tinctures , granules, drops and other forms.

Modern sensitive methods of physicochemical analysis can be used to study and control the quality of homeopathic medicines in different concentrations (dilutions).

The urgent task is to study the quality of medicinal and animal raw materials, as well as the stability of various homeopathic remedies during storage, including those used in submicroconcentrations .

#### Question for self-control

1. Characteristics of triturations homeopathic as medicinal forms .
2. Technology production triturations homeopathic according to the SPhU.
3. Auxiliary substances for manufacture homeopathic triturations .
4. Features potentiation \_ triturations homeopathic .
5. Quality control triturations homeopathic .
6. Registration for vacation triturations homeopathic .

#### *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>		
Complex homeopathic remedy	Define the term.	

Homocords	Define the term.	
Iniel drugs	Define the term.	

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

1) Follow individual task set \_ teacher : Describe optimal version technology . Fill in facial side of the written control passport and indicate design homeopathic dilution drug before release .

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

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

1.2. requirements for results works , including \_ before registration ;

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

- 1) Characteristics of the drug-
- 2) Technology
- 3) Registration for vacation -

## **III. Test tasks for self-control**

1. Indicate how long it takes to grind and mix when preparing triturations according to Schwabe's guide:

A - 60 minutes

B - 180 minutes

B - 90 minutes

D - 30 minutes

D - 120 minutes

2. From the following substances indicate insoluble in water:

A - Carbo vegetabilis

B - Borax

B - Potassium bichromicum

G - Cuprum sulfuricum

D - Sodium nitricum

3. Note the potency of the trituration produced by mixing 0.1 g of Acidum sulfuricum and 9.9 g of milk sugar:

A - C1

B - C2

B - C6

D - X1

D - X6

4. Dynamization comes from the word " Dynamis ", which means:

A - strength (potency)

B - dilution

B - multiplication

G - shaking

D - improvement

5. Dynamization is:

A - increase the strength of the drug

B - homeopathic exacerbation

B - life force

G - shaking

D - medicine

6. Designation of the word " proving " in homeopathy:

A - test

B - infection

B - diagnosis

G is a symptom

D - distribution

Answer the theoretical ones questions .

1. Principles integrated homeopathy .

2. Characteristics of complex homeopathic dosage forms.

3. Technology production solid complex homeopathic drugs .

4. Technology production liquid complex homeopathic drugs .

5. Features of potentiation of complex

**IV. Individual tasks for students on the topic of the lesson - to present in the form of presentation.**

Technology of solid, complex homeopathic dosage forms, registration for release and quality control

### **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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5. Relton C, Cooper K, Viksveen P, Fibert P, Thomas K. Prevalence of homeopathy use by the general population worldwide: a systematic review. *Homeopathy*. 2017. 106 (2). P. 69–78.



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