


**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 № 8 «**Triturations are homeopathic. Technology of homeopathic triturations , registration for dispensing and quality control . »**

Methodical recommendations on IWS developed by:

Head of Department

 (Borisjuk I. Yu.)

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:** «Triturations are homeopathic. Technology of homeopathic triturations , registration for vacation and quality control . » - **6 h.**

**Objective:** to acquire theoretical and practical skills in technology complex homeopathic drugs , conducting physico-chemical control .

**Basic concept :** triturations homeopathic.

#### Plan

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

1. Modal factor -
2. Homeopathic triturations are -
3. Basic principles of homeopathy: - similarities; - potentiation principle...
4. Terms and conditions of storage of triturations as in- pharmacy preparations- Triturations homeopathic (powder rubs) - mixtures of dry medicinal substances, essences, tinctures, solutions or their dilutions with milk sugar (lactose) or other excipients permitted for medical use.

Powder rubs are prepared both from dry medicinal substances (mineral or animal origin, chemical compounds ) and liquids of various natures (aqueous and alcoholic solutions, essences or tinctures), in accordance with §§7-9.

In the manufacture of triturations must comply with sanitary requirements in accordance with the current Instruction on sanitary and anti- epidemic regime of pharmacies (order of the Ministry of Health of Ukraine of 14.06.1993 №139).

#### §7.Preparation of triturations from dry matter

To prepare powder rubs from dry drugs, take a certain amount of drug substance and grind with milk sugar only in porcelain mortar, the use of metal mortars is not allowed.

Dry drugs (including metals) and milk sugar must be pre-ground to the finest powder unless otherwise indicated in private articles.

The crushed (dispersion) of the original powders of drugs and milk sugar is estimated by sieve analysis or by the size of their external specific surface area, which is measured by air permeability at atmospheric pressure.

Due to the fact that \_ process friction has very great value to increase forces actions drugs , it is precisely regulated in time . At the same time necessary remember that \_ language it's not easy stirring medicinal substances with dairy sugar , and about the most careful grinding and grinding . According to the guide "Homeopathic medicines" grinding and mixing should be carried out for at least 1 hour. Scraping also trace conduct very carefully to \_ to prevent transfer raw particles in thin rubbing . Hygroscopic substances trace rub only in heated mortars.

Preparation rubbing of dry matter to spend as follows:

- a) *on a decimal scale:* 1 year substances grind with 9 g milk sugar ;
- b) *on the hundredth scale :* 0.1 g substances rub with 9.9 g milk sugar .

At the same time amount of milk sugar divided by 3 approximately levels parts . The first part is placed in a porcelain mortar and stirred several times to rub the pores of the mortar, then add the starting materials and grind thoroughly with effort for 6 minutes, then for 4 minutes scrape and

mix, grind again for 6 minutes and scrape again for 4 minutes. Then add the second third of milk sugar, grind again for 6 minutes, c scrape and 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 - thus cooking 10 parts friction require work for 1 hour .

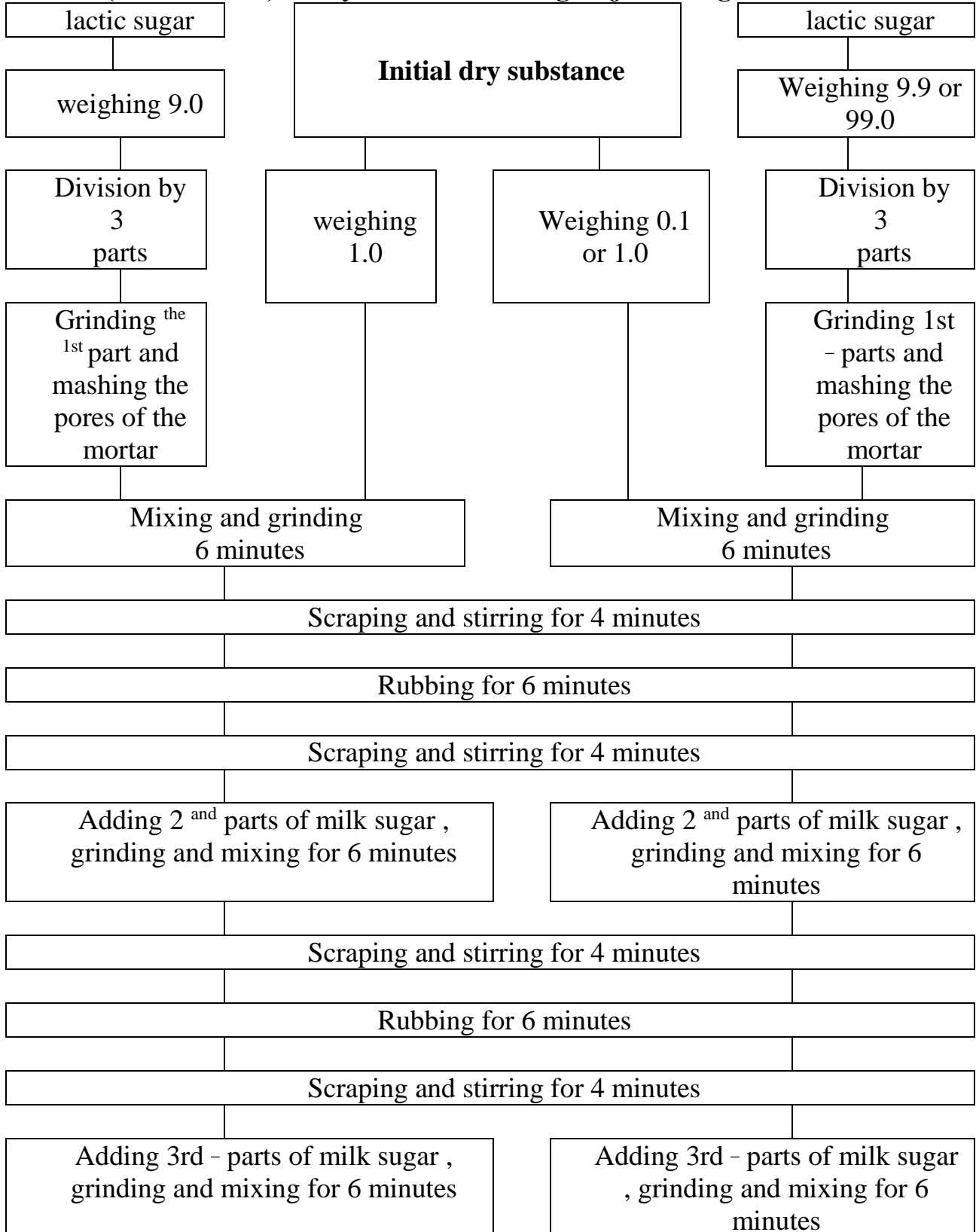
In this case after friction the first Decimal (D1) or first centesimal (C1) potency is obtained (see Scheme 11).

**Example.** It is necessary prepare Triturations *Carbo vegetabilis* C1 10.0.

Giving powders friction it is possible prepare , as indicated in §7, by two methods: immediately dilution of C1 ( weigh 0.1 substance and 9.9 milk sugar ) or by potentiation with X 1. The second method of preparation adds more to the drug strength ( potency ), so better prepare him starting with X1. For this weigh 9.0 milk sugar , divide into 3 parts and 1 part of rub the pores of the mortar. On hand scales weigh 1.0 wood coal , placed in a mortar and grind according to the rules set out in §7. Then again weigh 9.0 milk sugar and 1.0 trituration X1 and prepare powders rubbing according to all the rules for 1 hour , getting dilution X2 (C1). Total cooking time - 2 hours . Ready Triturations check for all necessary indicators quality ( section 7.6.), After what registered in the journal laboratory works and draw up for use label :

<b>Carbo vegetabilis</b>			<b>C1</b>	<b>10.0</b>
			<b>(D2)</b>	<b>trit .</b>
Date	Series _	And	Signature	
		naliz		

**Algorithm of basic powder grinding technology  
 ( triturations ) of dry matter according to §7 of the guide V. Schwabe**



Scraping and stirring for 4 minutes	
Rubbing for 6 minutes	
Scraping and stirring for 4 minutes	
Receiving trituration X1 (D1)	Receiving trituration 1 (C1)
Quality control	
Registration for use	

### **Rules of preparation of homeopathic triturations**

Triturations can be used as a ready-made LF for internal use, as well as for the manufacture of other homeopathic dosage forms for various purposes. As excipients use lactose or other substances approved for medical use, specified in private regulations. The concentration of the drug substance in the trituration is expressed as a ratio of 1: 10 (decimal dilution) or 1: 100 (hundredth dilution). Porcelain mortars are used to make triturations by hand. The use of metal mortars is not allowed. Preparation of triturations in the amount of more than 1 kg is produced mechanically. Powder of medicinal and excipients, pre-ground to a particle size of not more than 65 microns , unless otherwise specified in private regulations.

To obtain triturations from powders to the fourth decimal (D4) or hundredth (C4) dilution, including the weighed excipient (milk sugar) is divided into 3 approximately equal parts. The first part is placed in a mortar and rub the pores. Add the starting materials and grind with effort for 6 minutes, then remove from the walls of the mortar for 4 minutes, repeat the operation. Add the second and third parts of the excipient, repeating with each part of the above operations. The minimum time required for the entire process of making trituration is at least 1 hour

In the mechanical method of making triturations from powders to the fourth decimal (D4) or hundredth (C4) dilution, including drug and excipients, add and grind, following the sequence described above. The whole process of obtaining trituration takes at least 1 hour

Subsequent dilutions of triturations from powders starting from the fifth decimal (D5) or hundredth (C5) are made from 1 g of trituration from the previous decimal or hundredth dilution and from 9 g or 99 g of excipient, pre-divided into 3 equal parts. To the first part of the excipient gradually, in small portions add the entire amount of trituration of the previous dilution and grind thoroughly to obtain a homogeneous powder. Then enter sequentially the second and third parts of the excipient and grind thoroughly until smooth. After long-term storage, the trituration is rubbed again.

In the manufacture of manual or mechanical trituration with tinctures, solutions or liquid dilutions to the required amount of excipient gradually, in small portions add the

entire amount of tincture or homeopathic dilution and grind thoroughly to obtain a homogeneous mass. The ratio of the mass of tincture or homeopathic dilution and excipient should correspond to a decimal dilution of 1: 10 (total weight of trituration 10 g), for the hundredth - 1: 100 (total weight of 100 g). Subsequent dilutions of triturations from tinctures, solutions or liquid dilutions are made from 1 g of trituration of the previous dilution and 9 g or 99 g (divided into three equal parts) of the excipient, thoroughly grinding until smooth. If a wet mass is formed during the production of triturations with tinctures, solutions or liquid dilutions , it is dried at the temperature specified in the technological documentation and, if necessary, ground and sieved before the next grinding.

Trituration (grinding) is an example of cooking

The composition of the drug: Trit . Borax C3 400.0 (VAZ). The main component is sodium tetraborate .

Calculation: 0.1 part of the substance and 9.9 parts of milk sugar - C1. Mass Borax C2:  $400.0 / 100.0 = 4.0$ . Weight of milk sugar:  $400.0 - 4.0 = 396.0$ .

Manufacturing technology, PPK:

The starting material is ground with milk sugar in a porcelain mortar very carefully and for at least 1 hour. Scraping from the walls of the mortar should also be done very carefully. A portion of milk sugar is divided into three parts. The first part of the rubbed pores of the mortar, add the substance, grind for 6 minutes, scrape for 4 minutes, grind again for 6 minutes and scrape for 4 minutes. Add the second part of milk sugar and repeat the operation of grinding and scraping . Add a third of milk sugar and perform the same operations. Total: 1 hour of work. Subsequent dilutions from the previous one are made in the same way.

Date \_\_\_\_\_ WPC № 2

Borax C2 4.0 Saccharum lacticum 396.0 M = 400.0

Signatures: \_\_\_\_\_

### **Quality control of homeopathic triturations .**

For the manufacture of triturations use lactose or other substances approved for medical use and listed in the relevant parts of the regulations for each drug. The particle size for LV and BB should not exceed 65  $\mu\text{m}$  .

The quality of triturations is assessed by such indicators as appearance, color, homogeneity, particle size (the bulk of the finished trituration should consist of particles of 25  $\mu\text{m}$  or less, there should be no particles larger than 50  $\mu\text{m}$  ). Particle size is determined using a microscope with ocular micrometers or on the outer specific surface (according to a private article).

In the trituration of the 1st, 2nd and 3rd decimal dilutions, the identity and quantitative content of the active substance control compliance with the requirements of private PhA. Triturations containing toxic or potent substances in the 4th decimal dilution are analyzed according to the methods described in the Sun. Deviations in the content of MS should not be more than 5% in the Trituration of the 1st and 2nd decimal dilution, as well as more than 10% in the Trituration of the 3rd decimal dilution.

In trituration containing metals and dyes, the homogeneity of mixing is determined by examination under a magnifying glass with 7-9-fold magnification. No individual particles should be detected during such an inspection. LV should be evenly distributed in trituration . Particle size is determined using a microscope or the size of the specific surface area. The value of the outer specific surface of the trituration made with lactose must be at least 0.65 m<sup>2</sup> / g

Triturations are also checked for microbiological purity.

**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):*

<b>Basic and tasks and</b>	<b>In the fairy tale</b>	<b>Answers</b>
<b>1</b>	<b>2</b>	<b>3</b>
<i>Explore:</i>		
Potency	Define the term.	
Dynamization	Define the term.	
Homeopathic medicine	Define the term. Drug cycles.	

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

1. recommendations ( instructions ) on implementation tasks ( professional orienting algorithms \_ cards for formation practical skills and abilities etc. );

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

requirements for results works , including \_ before registration ;

According to the course of practical training to carry out registration individual tasks at work notebooks .

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

According to the course of practical training to carry out registration individual tasks at work notebooks .

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

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

1. The dose per powder is approximately:

- A - 0,2 г
- B - 1,0 г
- B - 0,5 г
- G -5,0 г
- D -10,0 г

2. Determination of the validity and quantitative content of medicinal substances is carried out in triturations before dilution:

- A - X3
- B - X1
- B - X2
- D - X6
- D - X12

3. For the preparation of triturations of dry medicinal substances, essences, tinctures, solutions or their dilutions as an excipient is most often used:

- A - lactose
- B - ethanol
- B - talc
- G - starch
- D - glucose

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 presentations.**



Triturations are homeopathic. Technology of homeopathic triturations , registration for vacation 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.
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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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