ODESSA NATIONAL MEDICAL UNIVERSITY
DEPARTMENT OF DRUGS TECHNOLOGY

APPROVE
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«29» august 2022 y.

METHODICAL DEVELOPMENT OF INDEPENDENT WORK OF STUDENTS (IWS)

Course 3 Faculty Pharmaceutical

Course Homeopathic drugs

Topic № 7 **«Pellets homeopathic . Technology of homeopathic granules , registration before release and their control quality . »**

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

Odesa - 2022

Methodical recommendations of IWS

Topic: " Pellets homeopathic. Technology of homeopathic granules , registration before release and their control quality . » - 6 h.

Objective: generalization of the acquired knowledge, skills and abilities on the technology of solid, complex homeopathic dosage forms, features of registration for leave, physico-chemical methods of their analysis .

Basic concepts: homeopathic matrix tinctures, dilutions , potencies, triturations , complex homeopathic medicines.

Plan

I. Theoretical questions for the lesson:

1. To solid homeopathic dosage forms include
2. Homeopathic medicinal aggravation
3. Repertoire
4. Antodot
5. Nosodes
6. Polychrest
7. Sarcodes - preparations received _
8. Trituration is
9. Specify the ratio in which are preparing trituration :
10. Complex homeopathic medicines -
11. Complex homeopathic remedies are classified-
12. To the positive parties complex homeopathic drugs include : -

Preparation of granules

Homeopathic granules are a solid dosage form for oral administration.

Granules (Table) are made by applying liquid homeopathic dilutions of medicinal substances or mixtures thereof on an auxiliary component - sugar granules obtained from sucrose, lactose and other sugars approved for medical use. To obtain a uniform application of homeopathic dilutions, sugar granules must be of a certain size, which is distinguished by numbers from 1 to 12 or other specified in the private regulations, classified by the number of granules in 1 g or by sieves.

Granules are made in several ways.

Method 1. The original granules are applied water-alcohol homeopathic dilution of liquid preparation, triturations or mixtures thereof prepared on 70% ethyl alcohol (62% by weight), while the alcohol content in the dilution should be at least 68% by volume (60% by weight). If the concentration of alcohol is below the required, the manufacture of decimal or hundredth dilution intended for application (including matrix tinctures) is carried out using ethyl alcohol 70% by volume (62% by weight).

Tables I

Characteristics of homeopathic granules

Number of pellets	The number of granules in 1 g	The weight of the sample to calculate their number, g	The average diameter of the granules, mm
1	470–530	0.1	1.4
2	220–280	0.2	1.7
3	110–130	0.4	2.2
4	70–90	0.6	2.5
5	40–50	1.0	3.0
6	28–32	1.6	3.4
7	22–28	2.0	3.7
8	16–20	2.5	4.1
9	10	5.0	5.0
10	5	10.0	6.3
11	3	15.0	7.4
12	2	25.0	8.5

For uniform distribution of the applied substance sugar granules are pre-moistened with ethyl alcohol 70% (62% by weight), which is added at the rate of 10 g per 100 g of sugar granules. The application of drugs on sugar granules is performed by mixing in mechanical mixers without moving working parts or manually (for weight up to 1 kg) in glass tightly closed vessels. The working volume of the mixer should be 1.5-2 times the loaded mass of sugar granules. Stirring in mechanical mixers is performed for 3-4 minutes, with the manual method - for 10 minutes. Wet granules are dried in air at room temperature to constant weight.

Sugar granules can be homeopathic dilutions below C3 (third hundredth), derived from volatile and odorous substances, as well as from all acids.

Method 2. Homeopathic dilution of the drug substance in 64% sugar syrup with drying between operations is repeatedly evenly layered on the sugar granules. This method is used for the application of aqueous liquid preparations (solutions, extracts, etc.), triturations , mixtures of preparations with low decimal dilutions and in cases where method 1 with the use of alcohol is undesirable.

Layering of liquid drugs. To make 100 g of homeopathic granules 1 g of liquid preparation is shaken from 9 sugar syrup and the obtained 10 g is evenly layered on (100 - X) g of sugar granules, where X is the amount of sugar in sugar syrup (g).

Layering of triturations . To make 100 g of homeopathic granules, 10 g of trituration is shaken from 20 g of sugar syrup, the resulting mixture is evenly layered on (100 X) g of granules.

Layering of mixtures. Mixtures are made by co- shaking homeopathic dilutions of liquid drugs and (or) triturations in sugar syrup. To obtain 100 g of granules 1 g of the mixture is shaken from 9 g of sugar syrup and 10 g of this dilution are evenly layered on

(100 X-Y) g of sugar granules, where X is the amount of sugar in sugar syrup (g), Y is the amount of excipient, contained in the trituration (d).

Layering of homeopathic dilutions of medicinal substances in sugar syrup on sugar granules is made in Coating boilers with adjustable heating. Sugar granules are placed in a coating pan, preheated to 37-42 ° C, slowly rotated until the whole mass of granules is heated to the same temperature. Homeopathic dilutions of medicinal substances in sugar syrup are poured into the coating pot gradually, in small equal portions, at regular intervals. After the layering is heated , the coating boiler is stopped, and its rotation is continued to dry the granules to a constant weight.

The amount of drugs applied to the original granules by any of these methods does not significantly change their average diameter and other physical and mechanical parameters.

Composition, calculations and manufacturing technology of some homeopathic dosage forms

Triturations (grinding)

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, WPC: The initial substance 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 is rubbed into the 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 grinding and scraping operations twice . 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: _____

Granules

The composition of the drug: Tabacum C12 10.0. Yes . Signa : 8 granules 3 times a day. The main component is the cultivation of C12 tobacco leaf tincture.

Calculation: Sugar granules 10.0. Tabacum C12 mass : 10.0 / 100 = 0.1. Weight of ethyl alcohol 62% (by weight): 10.0 / 100 = 0.1.

Manufacturing technology, WPC: In a jar with a capacity of 30.0 put 10.0 granules of sugar, 4 drops of 62% ethyl alcohol. The jar is closed with a lid wrapped in parchment paper and shaken for 10 minutes. Then the granules are poured on parchment paper and dried at room temperature. The dried granules are poured into a box.

Date _____ WPC № 3

Granulae sacchari 10.0

Spiritus aethylicus 62% 0.1 seu gtt IV Tabacum C12 0.1 seu gttIV

M = 10.0 Signatures: _____

Quality control of various dosage forms

Controlling the quality of homeopathic remedies in any dosage form, determine:

- authenticity and quantitative content of active and excipients;

-deviations allowed in the concentration of active substances for 1X, 2X, 3X. Breeding, trituration 4X, as well as containing toxic or potent substances are tested according to the methods described in private articles;

-Mass or volume of the contents of the package.

All drugs must meet the standards of microbiological purity.

Solid dosage forms

Triturations are homeopathic. 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 MS should not exceed 65 μm .

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 μm or less, there should be no particles larger than 50 μm). Particle size is determined using a microscope with ocular micrometers or on the outer specific surface (according to a private article).

In Trituration 1, 2 and 3 decimal dilutions, the identity and quantitative content of the active substance are controlled according to 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, determine the homogeneity of mixing by examination under a magnifying glass with 7-9 times magnification. No individual particles should be detected during such an inspection. MS should be evenly distributed in trituration . Particle sizes are 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 m2 / g

Triturations are also checked for microbiological purity.

Tablets. Homeopathic pills have the same requirements as allopathic pills (without shells). Indicators such as appearance, abrasion resistance, disintegration , average weight of tablets, microbiological purity, are evaluated in accordance with the articles of the SPh. The authenticity of medicinal and excipients, the quantitative content and homogeneity of the dosage of drugs and other indicators are determined in accordance with the private FS. Deviations in the content of active substances at a dosage of up to 0.001 g should not exceed 15%, at a dosage of 0.001 to 0.01 - 10%, from 0.01 to 0.01 g - 7.5%.

Granules homeopathic . This is the most common homeopathic MF. Some countries use pills that can be of different shapes and sizes. The average weight of the pills is 0.0435,

In the UK, globules weighing 0.0028 g (80-90% composed of lactose) are used. The form (grains) of homeopathic globules is convenient for children and animals.

Quality control of homeopathic granules is carried out in accordance with the General FS "Homeopathic granules", assessing the external signs (uniformity of color) and weight, weight of granules in one package, disintegration , shape and microbiological purity. The identity and quantitative content of BAS are determined in accordance with the requirements of private ND. Granules should be white with a gray or yellowish tinge. Evaluate the type of granules on visual inspection with the naked eye mass of the sample granules, recommended for counting their number, weighed to the nearest 0.01 g

Check for disintegration : 10 g of granules are placed in a conical flask with a capacity of 100 ml, add 50 ml of purified water (37 ° C). The flask is slowly shaken 1-2 times per second. Carry out at least 3 determinations. The granules should disintegrate completely in no more than 5 minutes.

The amount of MS applied to the granules does not change their diameter and physicochemical parameters, so to characterize homeopathic granules use indicators of the original granules.

Caramel is homeopathic. Used in homeopathy, as it provides a prolonged effect. It is made by introducing into the molten caramel mass of active ingredients in the form of liquid homeopathic dilutions, mixtures or triturations . Caramel mass consists of sugar and starch molasses and is made by evaporating sugar syrup.

The quality of homeopathic caramel is controlled by such indicators as authenticity, quantitative content of active substances, weight of caramel, weight loss during drying, microbiological purity.

When describing caramel characterize its shape, size, color, smell and taste. In the absence of other instructions, the surface of the caramel should be uniform in color, smooth, without cracks and stains.

The mass of caramels is determined by weighing 20 caramels separately with an accuracy of 0.01 g. The deviation in the mass of individual caramels should not exceed 10%, only two caramels can have a deviation of 15%.

To determine the loss of mass during drying, weigh 5 g of ground caramel, dried for 2 h at 105 ° C, cooled in a desiccator for 30 min, weighed. Weight loss should not exceed 4%.

The decomposition of caramel is determined by the norms of SPh (30 min). Authenticity is assessed by BAS in accordance with private ND (up to the 3rd decimal dilution), in other cases - determine the excipients.

At marking specify structure, degree of cultivation and quantity of homeopathic caramel. The dilutions indicated in the label correspond to those made in the caramel mass.

Question for self-control

1. The concept of homeopathy and it basic principles .
2. State normalization production homeopathic drugs
3. Features prescribing homeopathic recipes .
4. Nomenclature of homeopathic medicinal funds .

5. Goering's law of healing . Treatment acute and chronic diseases. Homeopathic groups drugs .

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**
Explore:		
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) Follow individual task set _ teacher : Describe optimal version technology complex homeopathic medicinal funds . Fill in facial side of the written control passport and indicate design drug before release .
2) Currently, more than 100 complex homeopathic remedies of well-known Ukrainian and foreign companies (National Homeopathic Union, Arnica, Deutsche) are registered on the pharmaceutical market of Ukraine. Homeopathy Union, «Dr Wilmar Schwabe »,« Neei »,« Materia Medica »,« Russian Homeopathic Association », etc.). Give examples of complex homeopathic remedies presented on the Ukrainian market.

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

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

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

Specify the potency weekend breeding, which saturate granules:	A – dilution, which equal to what is being prepared; B – dilution, which an order of magnitude lower for being preparing; C – dilution, which twice lower than that is being prepared.	Specify the correct one sequence technology homeopathic granules:	A – shipment of unsaturated sugar granules, measurement of initial dilution, measurement of ethyl alcohol 70%; B – shipment of unsaturated sugar granules, measurement of ethyl alcohol 70%, measurement of initial dilution; C– measurement ethyl alcohol70%, shipment unsaturated sugar granules, measurement weekend dilution.
Specify the number ingredient for production plantain granules X3-10.0:	A – 10.0g unsaturated granules, 0.1 g ethyl alcohol 70%, 0.1 years tinctures plantago X1; B – 10.0g unsaturated granules, 0.1 g ethyl alcohol 90%, 0.1g tinctures plantago X2; C – 10.0g unsaturated granules, 0.1 g of ethyl alcohol 60%, 0.1 years tincture of plantago X1.	Specify what should be the auxiliary vial during saturation granules:	A – 10 times more compared with quantity loaded granules; B – in 1.5-2 times more compared with quantity downloaded granules. C – 20 times more compared with quantity downloaded granules.
Specify necessary number weekend	A – 10.0 g; B – 1.0 g;	Specify concentration	A – 45%; B – 60%;

dilution tanacetum 3 for making 1 kg tanacetum granules 4:	C – 20.0 g	ethanol that used for wetting granud and their technology saturation according to with V. Schwabe .	C – 70%; D – 90%.
Specify from which dilution saturate granules according to W. Schwabe :	A – X1; B – C3; C – C1; D – C6.	Enter the number granules, which used most often;	A – №2; B – №4; C – №7; D – №10.

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.

- Granules homeopathic .
- Technology of homeopathic granules , registration before release and their control quality

Recommended literature

Main:

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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.
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