


ODESSA NATIONAL MEDICAL UNIVERSITY
DEPARTMENT OF DRUGS TECHNOLOGY

APPROVE

Head of Department

 (Borisyuk I. Yu.)

«29» august 2022 y.

METHODICAL DEVELOPMENT
OF INDEPENDENT WORK OF STUDENTS (IWS)


Course 3 Faculty Pharmaceutical

Course Homeopathic drugs

Topic № 2 **«Classification of homeopathic remedies. Preparation of homeopathic mother tinctures according to SPU and quality control.»**

Methodical recommendations on IWS developed by:

Head of Department

 (Borisyuk 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: «Classification of homeopathic remedies. Preparation of homeopathic matrix tinctures according to SPU and quality control.»- 6 h.

Objective: to study the classification of homeopathic medicines, to acquire skills and abilities in the technology of preparation of homeopathic matrix tinctures according to SPU and quality control; to master skills in the technology of preparation of homeopathic matrix tinctures, to acquire knowledge on quality assessment of homeopathic matrix tinctures.

Basic concepts: matrix homeopathic tinctures, dilutions, potencies.

Plan

I. Theoretical questions for the lesson:

1. Repertoire -
2. Vital force -
3. Constitutional type -
4. The principle of similarity -
5. Testing of homeopathic remedies-
6. The source material for the manufacture of matrix tinctures is -
7. A feature of the technology of preparation of homeopathic dosage forms is the process-

8. For preparation of matrix tincture from fresh vegetable raw materials according to SPU the beginning needs to be defined -

9. Give the classification of homeopathic remedies by source of raw materials -

Mother homeopathic tinctures - liquid water-alcohol, alcohol or water extracts from raw materials of plant or animal origin, used for the preparation of drugs or as drugs.

They are made by mixing equal amounts of juice of fresh plants with 86% ethanol or extraction with alcohol of different concentrations of fresh or dry plant or animal raw materials or products of animal life. Tinctures of fresh raw materials are called essences.

Homeopathic tinctures differ from allopathic in the following aspects:

1) sources of production - different parts of plants are used. For example, arnica tincture in allopathy is made from flowers, and in homeopathy - from the top of the plant, if it is used externally, or from the roots, if for internal use;

2) different concentrations of extractant. For example, belladonna tincture in allopathy is prepared on 40% ethanol (from leaves), in homeopathy - on 70% ethanol (whole plant);

3) methods of obtaining tinctures: in allopathy - maceration, bismaceration, percolation, extraction with liquefied gases, etc., in homeopathy - only by maceration;

4) different ratio of raw materials and extractant. In allopathy 1:10, 1:30 for potent raw materials, in homeopathy the ratio depends on the content of active substances.

Differences in technology lead to the fact that allopathic and homeopathic tinctures will contain various biologically active substances. For example, in the tincture of calendula allopathic flavonoids predominate, in homeopathic - carotenoids.

Matrix tinctures denote 0 - phyta.

The method of obtaining a matrix tincture depends on the content of vegetable juice, essential oils, resins and mucus. Obtaining is by weight.

Method 1. From fresh medicinal plant raw materials (without essential oils, resins and mucus), containing at least 70% juice. The scheme of preparation of matrix tinctures by method 1 :

1. Fresh PRM
2. Grinding of raw materials
3. Squeeze the juice
4. Weighing
5. Mixing equal parts of juice and ethyl alcohol 86%, shaking
6. Infusion for 5 days
7. Filtering
8. Installation in the filtrate of the dry residue and BAS
9. Mixing with the calculated amount of ethanol 43%
10. Standing for 5 days and filtering
11. Registration

The first decimal dilution (D1) is prepared from 2 parts of matrix tincture and 8 parts of 43% ethyl alcohol (by weight).

The second decimal dilution (D2) is prepared from 1 part of the first decimal dilution and 9 parts of 43% ethyl alcohol by weight. Subsequent dilutions are prepared similarly.

The first hundredth dilution (C1) is prepared from 2 parts of matrix tincture and 98 parts of 43% ethyl alcohol (by weight). The second hundredth dilution (C2) is prepared from 1 part of the first decimal dilution and 99 parts of 43% ethyl alcohol by weight.

Method 2. From fresh LRS (moisture more than 60%, without essential oils, resins and mucus), containing less than 70% juice. The scheme of preparation of matrix tinctures by method 2:

1. Fresh PRM
2. Determination of humidity
3. Grinding
4. Weighing
5. Making at least 1/2 of the mass of PRM 86% ethanol, mixing
6. Making ethyl alcohol 86% by weight equal to the mass contained in vegetable juice
7. Maceration for 10 days at 10 ° C, periodic shaking
8. Pressing
9. Filtering
10. Registration

Liquid dilutions are prepared in the same way as in method 1.

Method 3. From fresh APC with humidity less than 60%, containing resins, essential oils and mucus, fresh mushrooms. Preparation of matrix tinctures by method 3:

1. Initial PRM

2. Weighing
3. Determination of humidity
4. Grinding
5. Making half the amount of ethyl alcohol 86% by weight of raw materials, mixing
6. Making the calculated amount of ethyl alcohol 86%
7. Maceration for 10 days at 20 ° C, periodic shaking
8. Pressing
9. Filtering
10. Quality control (dry residue, BAS content)
11. Registration

The first decimal dilution (D1) is prepared from 3 parts of matrix tincture and 7 parts of 62% ethyl alcohol (by weight). The second decimal dilution (D2) is prepared from 1 part of the first decimal dilution and 9 parts of 62% ethyl alcohol by weight. Subsequent dilutions were prepared in a similar manner using 62% ethyl alcohol (by weight) and a 43% ethyl alcohol (by weight) from the fourth decimal dilution.

The first hundredth dilution (C1) is prepared from 3 parts of matrix tincture and 97 parts of 62% ethyl alcohol (by weight). The second hundredth dilution (C2) is prepared from 1 part of the first hundredth dilution and 99 parts of 43% ethyl alcohol by weight.

Method 4. From dried ARS, fresh raw materials of animal origin and dried mushrooms. Preparation of matrix tinctures by method 4:

1. Raw materials
2. Weighing
3. Grinding
4. Mixing 1 part of raw material with 10 parts of ethyl alcohol
5. Maceration for at least 8 days in a closed vessel at 20 ° C
6. Drain extraction, extraction of raw materials
7. Filtering
8. Quality control (dry residue, quantitative content of BAS)
9. Registration (D1)

Obtained from 1 part of raw materials and 10 parts of ethyl alcohol in the concentration specified in the private regulations.

Matrix tinctures from dried raw materials of plant and animal origin, dried mushrooms correspond to the first decimal dilution and are denoted by D1.

The second decimal dilution (D2) is prepared from 1 part of matrix tincture (D1) and 9 parts of ethyl alcohol in the concentration used to obtain tincture. The third decimal dilution (D3) is prepared from 1 part of the secondary decimal dilution (D2) and 9 parts of ethyl alcohol in the concentration used to obtain the tincture. Starting with D4, 43% ethyl alcohol is used (by weight), unless otherwise specified in the private regulations, and prepared similarly.

The first hundredth dilution (C1) is prepared from 10 parts of matrix tincture (D1) and 90 parts of ethyl alcohol in the concentration used to obtain tincture. The second hundredth dilution (C2) is prepared from 1 part of the first hundredth dilution (C1) and 99 parts of ethyl alcohol 43% by weight.

Questions for self-control

1. The concept of homeopathy. Basic principles, unlike allopathy.
2. Homeopathy as a science. History of homeopathy. The main periods of development of homeopathy.
3. Basic principles of homeopathy: the principle of similarity, dynamization.
4. Homeopathic doses.
5. Characteristics of homeopathic matrix tinctures.
6. Technology of making homeopathic matrix tinctures according to SPU. Methods of obtaining homeopathic matrix tinctures.

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>		
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:

Formation of professional skills:

- 1.1. content of tasks
 1. Characteristics of homeopathic matrix tinctures.
 2. Technology of production of homeopathic matrix tinctures according to SPU.
To prepare a matrix tincture of fresh vegetable raw materials according to the SPU, you first need to determine?
 3. Quality control of homeopathic matrix tinctures .

4. Participating homeopathic medicines remedies are represented by both new substances and new homeopathic remedies. Make a scheme " Homeopathic medicines".

1.2. 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 homeopathic matrix tincture written control passport.

1) Characteristics of raw materials-

2) Technology-

3) Registration of matrix tincture -

1.3. 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 of matrix tincture -

III. Test tasks for self-control

1. Calculate the amount of juice and ethanol to obtain 10.0 g of matrix tincture according to method 1SPhU:

A) 0.5 + 9.5

B) 0.1 + 9.9

C) 1.0 + 9.0

D) 5.0 + 5.0

2. Indicate whether any dilution corresponds to the matrix tincture prepared according to method 1 SPhU:

A) the first decimal

B) the second decimal

C) the first hundred

D) another hundredth

3. For the preparation of matrix tincture raw materials are:

A) insoluble minerals

B) soluble salts

C) soluble acids

D) fresh juice of plants

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

1. Classification of homeopathic remedies.

2. Preparation of homeopathic matrix tinctures according to SPU and quality control .

Recommended literature

Main:

1. Гомеопатична фармація і медицина. Глосарій термінів та визначень: навч. посібник для студ. вищ. Навч. Закладів / Л.І. Вишневська, О.Ю. Сергеева, С.В. Олійник ; за ред. Л.І. Вишневської. – Х. : Оригінал, 2017. – 340 с.
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.
4. Аптечна технологія ліків: підручник для студ. фарм. ф-тів ВМНЗ України III-IV рівнів акредитації / Тихонов О.І., Ярних Т.Г. ; за ред. О. І. Тихонова. – Вид. 4-те, випр. та допов. – Вінниця : Нова Книга, 2016. – 536 с.
5. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів». - 2-е вид. - Доповнення 1. - Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2016. - 360 с.
6. Допоміжні речовини у виробництві ліків : навч. посібн. для студ. вищ. фармацев. навч. закл. / О.А. Рубан, І.М. Перцев, С.А. Куценко, Ю.С. Маслій; за ред. І.М. Перцева. – Х.: Золоті сторінки, 2016. – 720 с.
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.
10. Організація самостійної роботи студентів з дисципліни «Технологія гомеопатичних лікарських засобів» : методичні рекомендації / Л. І. Вишневська, Н. П. Половко, С. В. Олійник, І. С. Коноваленко. – Харків: НФаУ, 2018. – 39 с.

Additional literature:

1. Гуцол Л. П., Гуцол К. М., Цимбал І. П. Доказова база класичної гомеопатії: джерела, сьогодення, перспективи. *Фітотерапія*. Часопис. 2019. 1. С. 31-34.
2. Чекман І. С., Мощич О. П. Гомеопатія, як піонер наномедицини. *Український гомеопатичний щорічник*. 2017. Т.14. С.169-175.
3. Гомеопатичні препарати промислового виробництва як питання для самостійного розгляду у післядипломній підготовці спеціалістів фармації / Л. І. Шульга, Т. С. Безценна, Т. Д. Губченко, О. В. Лукієнко // *Фармацевтична наука та практика: проблеми, досягнення, перспективи розвитку*. Pharmaceutical science and practice:

problems, achievements, prospects : матер. II наук.-практ. інтернет-конф. з міжнар. участю, м. Харків, 27 квітня 2018 р. – X. : НФаУ, 2018. С. 451-453.

4. Mathie R.T., Fok Y., Viksveen P., To A., Davidson J.T. Systematic review and meta-analysis of randomised, other-than-placebo controlled, trials of non-individualised homeopathic treatment. *Homeopathy*. 2019. 108(2). P. 88–101.

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.

6. Surender S. Prerna K., Ritu K. Safety studies of homeopathic drugs in acute, sub-acute and chronic toxicity in rats. *Indian Journal of Research in. Homeopathy*. 2017. Vol. 11, N 1. P. 48 – 57.