

ODESSA NATIONAL MEDICAL UNIVERSITY
Department of General and Clinical Pharmacology and Pharmacognosy

GUIDELINES
on independent work of students / VTS / № 20
on the topic: «Commodity analysis. Quality control methods. »
Course: 3rd Faculty: medico-pharmaceutical

Approved
at the methodical meeting
departments
August 30, 2024
Protocol № 1



Head departments _____
prof. Rozhkovsky Ya.V.

Subject: «Commodity analysis.Quality control methods. " - 4 years

1. Relevance of the topic

The topic is of great importance for students to study the procurement process of LRS. The following stages have the basic value at the commodity analysis: primary processing of raw materials, drying, packing, marking, storage. The main purpose of the topic is to understand the methods of pharmacognostic analysis.

2. Learning objectives:

As a result of independent elaboration of this theme students should:

- *know:*

- Basics of procurement, drying and storage of medicinal raw materials
- Methods of quality control of medicinal raw materials
- The value of LRS analysis
- The value of the analysis of ash and extractives in LRS

- *be able to:*

- to carry out primary processing of medicinal raw materials
- learn the basics of quality control of raw materials
- to determine the benignity of LRS by indicators: purity (contamination by collar pests) and the degree of fragmentation (GOST 24027.1-80, DF XI p.275-277);
- to determine the moisture content in the LRS according to SF XI p. 285-286.
- to determine the content of ash and extractives according to GOST 24027.2-80, DF XI vol.1, p.24, DF XI vol.2, p.295.

3. Materials for pre-classroom training of students.

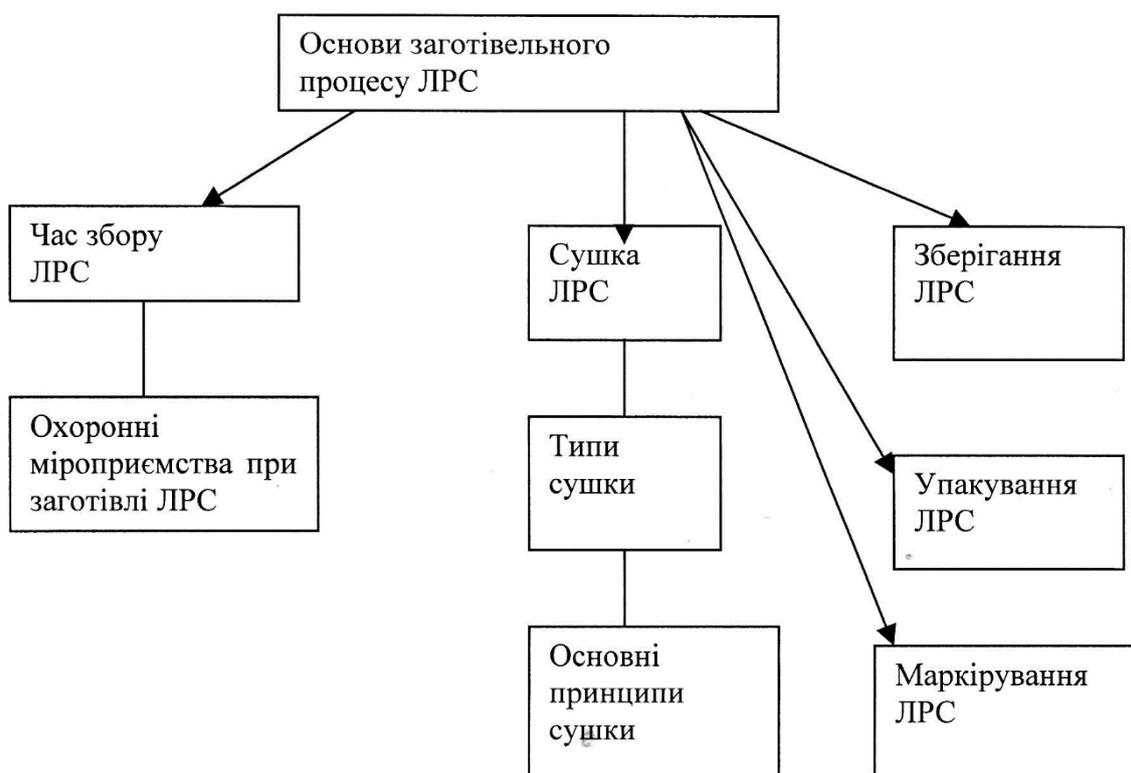
3.1. Basic basic knowledge, skills, abilities that are necessary for independent study and mastering of the topic and which are based on interdisciplinary connections:

№	Discipline	Know	Be able
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№			
1	2	3	4
	1. Botany	Characteristic features of the families of the studied plants. Morphology of stem, bark, leaves, flower, fruit, root and rhizome. Anatomical structure of leaves, bark, fruit, roots, rhizomes.	Use a microscope, prepare surface preparations and cross-sections.
	2. Organic chemistry	Physical and chemical properties of polysaccharides, glycosides, terpenoids, derivatives of aromatic series, heterocycles.	Carry out qualitative reactions; purification of organic compounds.
	3. Analytical chemistry	Methods of acid - base titration (neutralization) and permanganatometry	Work with analytical balances, measuring vessels, photoelectrocalometer, use methods of chromatography on paper and in a thin layer of sorbent.

3.2. Contents of the topic.

- structural and logical scheme



3.3. Recommended Books:

8. Literature

Basic literature

1. Фармакогнозія: підручник (I—III р. а.) / І.А. Бобкова, Л.В. Варлахова. – 3-є видання Всеукраїнське спеціалізоване видавництво «Медицина» 2018, 504с.

2. Фармакогнозія: базовий підручн. для студ. вищ. фармац. навч. закл.(фармац. ф-тів) IV рівня акредитації / В.С. Кисличенко, І.О. Журавель, С.М. Марчишин та ін.; за ред. В.С. Кисличенко. – Харків: НФаУ: Золоті сторінки, 2015. - 736 с.

3. Навчальний посібник з дисципліни «Фармакогнозія» / Я. В. Рожковський, Б. В. Приступа, І. А. Бойко, Н. В. Герасимюк, В. В. Черногорюк -: Методична розробка кафедри фармакогнозії ОНМедУ. – Одеса: ОНМедУ, 2019 – 51 с.

4. Державна Фармакопея України: в 3 т. / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1500 с.

Additional literature:

1 Державна Фармакопея України: в 3 т. / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.

2. Практикум з ідентифікації лікарської рослинної сировини: навч. посіб. / [В. М. Ковальов, С. М. Марчишин, О. П. Хворост та ін.] ; за ред. В. М. Ковальова, С. М. Марчишин. – Тернопіль: ТДМУ, 2014. – 250 с.

3.5. Materials for self-control.

3.5.1. Questions for self-control.

1. Analytical and regulatory documentation for LRS. Categories AND and their requirements and content.

2. Determination of LRS infection by collar pests. What to do with LRS at infection with collar pests of the I, II and III degree?

3. Determining the degree of grinding of LRS. Permissible norms of the degree of grinding for different types of LRS (grass, leaves, roots, bark, flowers, fruits).

4. Methods for determining the humidity of LRS. Permissible norms of moisture content for different types of LRS.

5. LRS ash is common and insoluble in NSI.

6. Determination of the content of total ash.

7. Determination of the content of ash insoluble in NSI.

8. The value of the ash residue in the assessment of the quality of LRS.

9. Extractives. Determination of extractives. The value of the indicator for the quality of LRS.

10. Active, concomitant and ballast substances.

3.5.2. Test tasks for self-control.

1. Underground organs of medicinal plants that accumulate the largest number of active substances, collect:

A after seed maturation and death of the aboveground part

B in the flowering phase

C during green fruiting

D in the budding phase

E in the stalk phase

2. The quality of medicinal plant raw materials depends on the timing of harvesting. Underground organs - roots, rhizomes, tubers should be harvested:

A. In early spring or autumn

- B. During the growing season
- C. Before flowering
- D. During flowering
- E. At the end of flowering

3. The corresponding LRS is collected in the spring during the period of sap flow. Specify this raw material:

- A Bark
- B Flowers
- C Kidneys
- D Roots
- E Fertility

4. During the collection of medicinal raw materials it is necessary to observe precautions: do not taste, do not touch the face, eyes with unwashed hands; After harvesting the plants, wash your hands thoroughly with soap. This is especially true of LRS:

- A LRS, which contain toxic substances
- B LRS, which contain tannins
- C LRS that contain saponins
- D LRS, which contain essential oils
- E LRS that contain steroidal saponins

5. Indicate what is done with LRS after its procurement:

- A Carry out the primary processing of raw materials
- B To dry
- C Packed
- D Bring to a standard state
- E Marked

6. After harvesting, the pharmacist discards foreign plants or unnecessary parts of the same plant (stems in the leaf product, leaves in the flower, woody stems, etc.), as well as raw materials damaged by insects and fungi. This type of analysis refers to:

- A Primary processing of raw materials
- B Preparation of raw materials for sale
- C Conduct research on raw materials
- D Qualitative determination of raw materials
- E Quantitative determination of raw materials

7. LRS in pharmacies are stored in different groups in appropriate conditions. Specify the raw materials belonging to the general storage group of LRS:

- A Oak bark
- B The roots of beauty
- C Mustard grass
- D Strophanthus seeds
- E Rhizome of valerian

8. The pharmacist indicates the name of the raw material, weight, name of the manufacturer, procurement area, date of procurement, batch number, according to regulatory and analytical documentation, using:

- A LRS marking
- B LRS sorting
- C Standardization of LRS
- D Procurement of LRS
- E LRS packaging

9. The pharmacy received a batch of medicinal plant raw materials of rhizomes with valerian roots. Under what conditions raw materials are lacking without further analysis

- A Presence of toxic impurities
- B The presence of mineral impurities
- C No marking according to AND
- D Damage to containers and moisture in raw materials
- E Pest infestation of barns I stage

10. When conducting a commodity analysis, the pharmacist must lack medicinal medicinal raw materials, provided that:

- A Presence of poisonous plants
- B Contamination with other parts of vegetable raw materials
- C The presence of mineral impurities in the LRS
- D The presence of organic impurities in the LRS
- E Excess moisture of raw materials

11. What medicinal raw materials can not be tasted during the commodity analysis?

- A Raw materials containing toxic substances
- B Raw materials containing essential oils
- C Raw materials containing polysaccharides
- D Raw materials containing bitter glycosides
- E Raw materials containing vitamins

12. When conducting a commodity analysis, the pharmacist must determine the organoleptic taste of vegetable raw materials:

- A After work
- B At the beginning of the analysis
- C After determining the moisture content of raw materials

D After determination of extractives

E After determining the ash content of raw materials

13. During storage at the pharmacy warehouse of LRS peppermint herb, pest infestation of II degree was detected. What measures should be taken?

A Disinsection factory recycling

B Rejection

C Cleaning and use in a pharmacy

D Prolonged heat treatment

E Use without restriction

14. What should be done with a batch of blueberries, if in the course of commodity analysis established I degree of contamination of raw materials by barn pests?

A Raw materials may be approved for medical use

B Raw materials cannot be approved for medical use

C Raw materials must be dried

D Raw materials must be ventilated

E Sort raw materials

15. When conducting a commodity analysis to determine the degree of infestation of barn pests is carried out in:

A A separate sample of LRS, taken from the combined sample

B The average sample

C The first analytical sample

D Any party unit

E The third analytical sample

16. Determination of the degree of damage to raw materials by barn pests in laboratories necessarily carried out at reception of vegetable raw materials, and

also annually at its storage, for this purpose check:

- A The presence of living and dead pests
- B The presence of acceptable pests
- C The presence of unacceptable pests
- D The presence of sand
- E The presence of glass

17. At establishment of humidity of raw materials at the pharmaceutical enterprises define pharmacopoeial limit figures of admissible humidity., Because:

A High humidity causes mold in the raw material and stimulates enzymatic processes

- B Reducing humidity contributes to better storage of raw materials
- C High humidity is required in the manufacture of extracts
- D High humidity contributes to the quantification of active substances
- E Decreased humidity helps to determine the identity of raw materials

18. After the analysis of rose hips, the increased humidity of raw materials was found. In this case, the pharmacist must:

- A Dry the raw materials
- B Reject raw materials
- C Return to supplier
- D Send to the warehouse
- E Send to the factory

19. The quality of ARS is characterized by the moisture content of raw materials (or weight loss during drying), the determination of which was carried out in:

- A In the analytical sample
- B In a spot sample
- C In the pooled sample

D In the average sample

E In the general sample

20. In chemical laboratories, when determining the ash content in medicinal plant raw materials, the raw materials are burned and calcined. Foreign mineral impurities consist of:

A earth, sand, pebbles

B gums, resins, stems

C wood, bark, roots

D stems, trunks, leaves

E roots, rhizomes, stems

21. Impurities in the LRS get during harvesting, drying and primary processing. Organic impurities include:

A Parts of the same plant that are not raw materials

B Glass particles

C Metal objects

D Other similar plants

E Particles of earth

22. In determining the good quality of vegetable raw materials in laboratories establish mineral impurities, which include:

A earth, sand, pebbles

B Herbs and flowers

C Flowers and roots

D Bark and roots

E Inflorescence and bark

23. Impurities in the LRS get during harvesting, drying and primary processing. Mineral impurities include:

- A Sand, earth, pebbles
- B Metal objects
- C Other similar plants
- D Litter of birds and rodents
- E Other organs of the same plant

24. During packaging and transportation, raw materials are partially crushed, ground. Too much fineness spoils the appearance and reduces the quality of raw materials. Specify by means of which carry out separation of crushed particles:

- A Sita
- B Filters
- C Flask
- D Mortar
- E Scalpel

25. Commodity analysis regulates the content of ash and active substances in LRS determine:

- A In the analytical sample
- B In the sample
- C In the notch
- D In the average sample
- E Immediately after the general analysis of all units of production of the

LRS party

26. Impurities in the LRS get during harvesting, drying and primary processing. Mineral impurities include:

- A Sand, earth, pebbles
- B Metal objects
- C Other Similar Plants
- D droppings of birds and rodents

E Other organs of the same plant

27. After establishing the conformity of the quality of raw materials to the requirements of analytical and regulatory documentation, the quality control department issues a document. Name it:

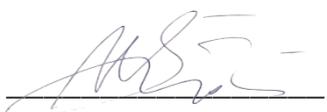
A certificate of analysis

B pharmacopoeial article

C authorization

D requirement

E standard

Methodical recommendations were made by  associate professor Boyko IA