THE MINISTRY OF HEALTH
OF THE REPUBLIC OF UZBEKISTAN
TASHKENT PHARMACEUTICAL INSTITUTE

COMMODITY ANALYSIS OF MEDICINAL PLANT PRODUCTS

TASHKENT – 2021

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"I approve»
Vice-Rector of Academic and
Educational Affairs, Prof. Z.
A. Yuldashev
_____
«_____»_____

«COMMODITY ANALYSIS OF MEDICINAL PLANT PRODUCTS»

Methodical guide for laboratory lessons in pharmacognosy for students of the directions: 5510500 - Pharmacy (by type)
5111000 - Professional education (5510500 - Pharmacy)
5510600- Industrial pharmacy (by type)
5310900- Metrology, standardization and product quality management (medicines) for students

TASHKENT – 2021

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COMMODITY ANALYSIS OF MEDICINAL PLANT PRODUCTS

The importance of the topic. Only high-quality medicinal products are used in medicine for the treatment of patients and in the development of medicines. Commodity analysis provides detailed information on what the high quality of medicinal plant products is and what it depends on. Brand analysis is specific to the science of pharmacognosy, which determines the quality and purity of medicinal products.

ND (normative document) is used to evaluate the quality of the product when performing commodity analysis.

ND is divided into the following categories:

- Pharmacopoeia article (PhA);
- Interim Pharmacopoeia Article (IPhA);
- State Standard (SS);
- Specific Industry Standard (SIS).

If the product is used in areas other than medicine (e.g. licorice), if SS is used as ND only for medicine, then SIS can be applied to products as ND.

If the medicinal product is included in the State Pharmacopoeia, the products are accepted and commodity analysis is carried out in accordance with the Pharmacopoeia article (PhA) or (IPhA), otherwise SS or SIS.

This teaching guide provides students with the skills to determine the high quality of medicinal plant products.

Laboratory classes on this topic are designed for 4 hours in the areas of pharmacy, vocational education and industrial pharmacy.

Technological map of laboratory work

Topic	Commodity analysis of medicinal plant products
Goals and tasks	Students are taught to analyze medicinal plant products in pharmaceutical companies on the basis of State Standards and other normative documents. An understanding of ND categories is given.
Subject of study process	Students will be instructed to obtain an average sample for analysis and to know the procedure for conducting a commodity analysis.
Technology of performing study process	The method is "brainstorming", "discussion", "explanation", "working in small groups", "boomerang". Form - laboratory work, in groups and individually.

	Tools - tables, handouts, herbariums and slides of medicinal plants, products. Supervision - written and oral questions, observation, self-monitoring. Evaluation is an incentive based on a 100-point rating system.
Expected results	Teacher: Students will be able to fully master the topic and develop their skills in organizing the commodity analysis of medicinal plant products. Evaluates all students and encourages further study. The student: learns a new topic, becomes more active, becomes more interested, learns a lot in a short time. Gets a guaranteed result, learns to self-monitor and draw conclusions from the results of the work done.
Future plans (analysis, changes)	Teacher: mastering new pedagogical and information technologies and their application in the educational process. Work on yourself, improve your pedagogical skills. Students: Learning to work independently. Being able to defend their point of view. Find out more about the topic, explore it, come up with a solution by analyzing own opinion and the opinion of the group, and build knowledge and skills.

Organizational structure and timing of laboratory classes

- Determining student attendance and level of preparation for class - 30 minutes
- Explain the work done by the teacher on the topic - 10 minutes
- Independent study of students - 100 minutes
- Control over the results of laboratory work and their correctness in the record book - during the lesson
- Final control of students' mastery of this topic - 15 minutes
- Giving homework for the next lab session - 5 minutes

Questions for independent preparation

1. What is the purpose of commodity analysis of medicinal plant products?
2. Where does commodity analysis begin and how is it done?

3. In what cases the product is rejected without analysis?
4. What is a lot?
5. Average sampling procedure?
6. What is ND and its categories?
7. How is the moisture content of a medicinal plant product determined?
8. What is the general ash of a medicinal plant product and how is it determined?
9. How to determine the degree of infestation by warehouse pests?
10. The importance of determining the degree of fragmentation.

Tasks to perform independently

1. Take samples for analysis.
2. ND-based analysis.

• Determining the authenticity of the product.
• Determining the product fragmentation.
• Determination of organic and mineral compounds.

Laboratory work
Commodity analysis of medicinal plant products

Commodity analysis is carried out in 2 stages:
Step 1. Product acceptance and average sampling.
Phase 2. Product analysis.

1.1. Product acceptance

Medicinal plant products are usually accepted in large quantities in batches.

A batch of products weighing at least 50 kg, which is the same in all respects, with a single document confirming its quality.

1. The document attached to the lot contains the following information:
2. Number of the document, month, day and year of its issuance;
3. Name and address of the sending company;
4. Product name;
5. Lot number;
6. Lot weight;
7. Year and month of collection;
8. Place of manufacture;
9. Results of product quality inspection;
10. Establishing a normative document for the product;

11. Name, surname, position and signature of the person responsible for the quality of the product.

For the reception of medicinal plant products in pharmaceutical plants and pharmacies, the following is observed (SS 6077-80):

1. General inspection of the appearance of the accepted lot (usually all items are inspected one by one).
2. Choosing a place to open the packaging of medicinal products.
3. Identify the homogeneity and shortcomings of the received lot.

1.2. Sampling for analysis

The overall appearance of each lot item is checked. Care should be taken to ensure that the container in which the product is placed is not damaged, does not get wet, and is properly packaged and marked in accordance with SS 6077-80. The average sampling depends on the number and size of the batch.

If there are up to 5 lots, they will be all opened.

If there are 10 lots, 5 will be opened.

If there are more than 10, in addition to the first 5 items, 1 will be opened for every 10 more.

When opening the package, attention is paid to the color, fineness, moisture, purity, odor, uniformity, etc. of the medicinal product.

If they are not the same, the product in that container will be analyzed separately. Defective situation must be reported to seller.

1. Has a foul and foreign odor that does not go away when ventilated for a day, or has lost its specific odor;
2. If there is a mixture of poisonous plants;
3. Excessive weed or mineral wastes and bird and animal wastes;
4. If the medicinal product is moldy and rotten;
5. If it is infested by warehouse pests of 2-3 degrees.

If the product is damaged in the first place, it should be used immediately after disinfection.

If the product is damaged in the second or third degree, but if it is easy to prepare, it is discarded, and expensive, difficult-to-prepare medicinal products are used after they are quickly cleaned and sorted.

For analysis, a sample is taken from 3 parts of each product location, ie top, middle and bottom.

This method is called sampling. If the samples are the same, the original sample is added together. Therefore, the sample size may be too large.

The portion taken from the original sample for testing is called the average sample, which varies in size for different products.

To take an average sample, the initial sample is laid flat on a square cardboard and 2 lines are drawn diagonally, and the products of the opposite triangles are obtained. The other opposite is that the product in the opposite triangle is packaged, sealed and stored for arbitration.

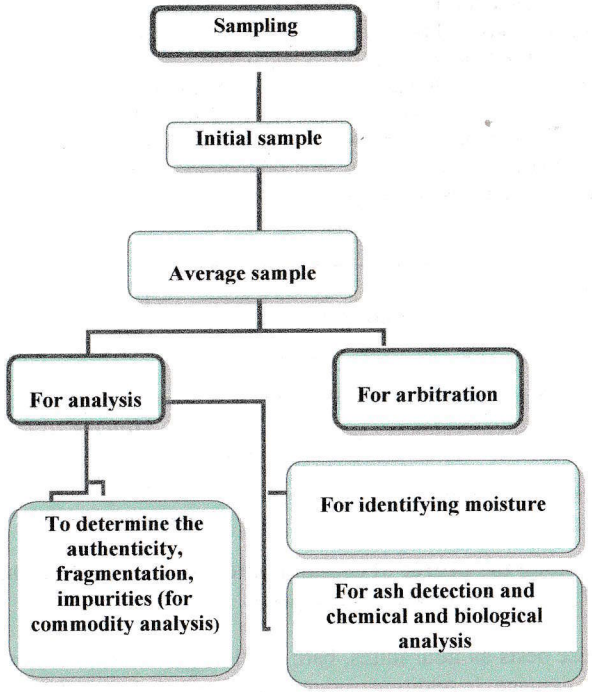
The average sample is divided into 3 unequal parts:

1st part to determine the authenticity, the crushed part, the impurities;

Part 2 - To determine the humidity:

Part 3 - is used to determine the total ash of the product and the amount or potency of the biologically active substance.

Sampling scheme for analysis



1.3.Commodity analysis of medicinal products

The product is analyzed after receipt. Commodity analysis is performed to determine the quality and purity of the medicinal product.

To determine product quality, commodity analysis is performed on the basis of SS, SST and PhA or IPhA guides.

After the identification of the medicinal product, ie the authenticity, the following is determined using the commodity analysis:

- Darkened, yellowed parts of the product;
- Crushed parts;
- Insect infestation rate;
- Organic compounds;
- The presence of mineral compounds, etc. is identified in quantitative terms.

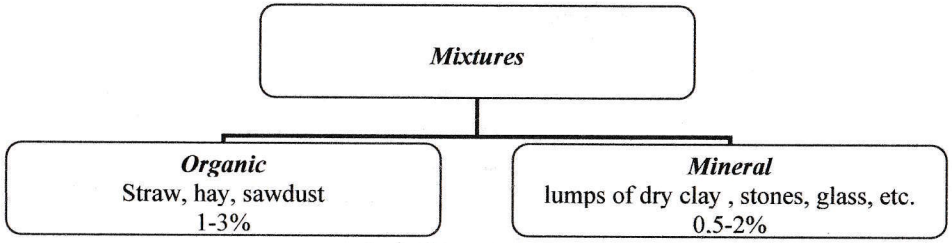
Product preparation, drying, transportation, packaging, etc. If done correctly, the above parameters will change, the amount of active substance will decrease and the quality will deteriorate.

The product is considered clean if it does not contain unauthorized impurities and does not exceed the permissible level.

Organic compounds include parts of other plants, straw, hay, sawdust, etc. Mineral compounds consist of blocks, stones, glass and others.

The average sample is sifted through a special sieve and weighed.

The remaining part of the sieve is spread on cardboard, blackened, yellowed pieces, organic and mineral mixtures are weighed and weighed and identified as a percentage by weight, and according to the results of commodity analysis, the product can be accepted or not. A protocol is drawn up.



1.4. Determining the degree of contamination of medicinal products with warehouse pests

Such warehouse pests as flour mites, barn beetles, grain threshers, and barn mites cause the most damage. In addition, rodents are also dangerous.

Warehouse pests: flour bug - a small white spider-like insect;

Warehouse beetle - a small brown beetle;

Grain mites - brown colored;

Warehouse moth - causes great harm to medicinal products.

To determine the degree of contamination of medicinal products, they are sifted through a sieve with a hole diameter of 0.5 mm (for bugs) or 2.5 mm (for long beetle). Pests in the sifted powder are detected with a magnifying glass.

If there are 20 mites in the sieve, it is 1 degree.

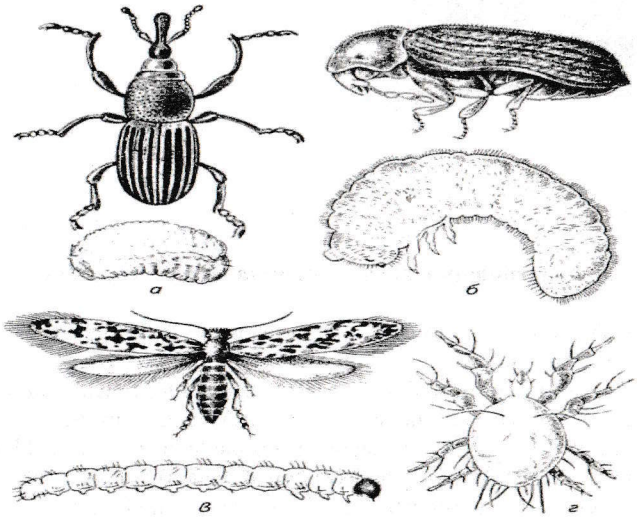
If there are more than 20 in the sieve and the column has not formed, it is considered to be level 2, and if there are too many bugs and no space to walk, it is considered to be level 3.

If there are 1-5 long beetles in the sieve, the product is grade 1.

If it's 6-10, it's level 2.

If there are more than 10 Level 3, the product is considered damaged.

The warehouse is disinfected against pests by wet method or by gas application. Kerosene, lime emulsion, 10-15% solutions of NaOH are used.



PRODUCTS' WAREHOUSE PESTS :
***а* — warehouse long beetle;**
***б* — grain mite;**
***в* — warehouse moth;**
***г* — flour bug**

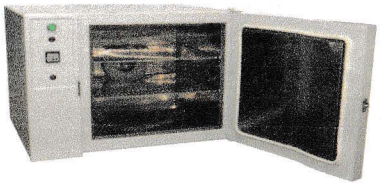
1.5. Determination of moisture content of medicinal products

About 3-5 g of the product, which is clearly weighed on the analytical scales, is dried and weighed to a constant weight. It is then dried at a constant weight of 100-1050. It is then cooled in a desiccator for 30-50 minutes and weighed.

The product is considered to be completely dry if the difference in weight of the next two beads does not exceed 0.01 g. Humidity percentage is determined by the following formula:

$$x = \frac{(a-b)\cdot 100}{a},$$

x – humidity,%;
a – product's weight before drying;
b – product's weight after drying.



1-picture. Drying oven

2- picture. Product's weighing bottle

1.5. Determination of ash content in medicinal products

When the product is heated to a high temperature, it turns to ash, which is called 'total ash'.

When total ash is treated with a 10% hydrochloric acid solution, water-soluble salts are formed, and the silica in the ash remains in the sediment. This precipitate is called "dead ash" or "ash that is insoluble in 10% hydrochloric acid."

The total ash often depends on where the product is collected.

Poorly cleaned, high-mineral products have a high ash content that is insoluble in 10% NCl.

To determine, take 3-5 g of product, place it in a muffle furnace heated to high temperature in a dried crucible, heat slowly until the smoke is gone, and dry the muffle in the oven at 500 C to constant weight. Ammonium nitrate can be added to speed up the burning process. The total amount of ash is found by the following formula:

$$x = \frac{B\cdot 100}{a},$$

x – percentage of total ash;
a – product weight,g;

B – ash quantity remained after burning, g.

3-picture. Tigel

4-picture. Muffle oven

1.6. Determination of ash insoluble in hydrochloric acid

Adding 2-3 ml of 10% HCl to the total ash and heated in a water bath for 10 minutes. It is then diluted with 5 ml of hot water, filtered through an ashless filter paper, and the filter paper, along with the residue, is burned in a crucible and the muffle is heated to a high temperature in the oven.

The amount of ash insoluble in hydrochloric acid is given by the following formula:

$$x = \frac{C\cdot 100}{B},$$

x - percentage of ash insoluble in hydrochloric acid;
C – ash weight;
B – total ash weight.

1.7. Determination of the amount of extracts in the medicinal product

The sum of substances extracted from a product by a solvent is called an extract.

Water and various alcohols (40%, 50%, 60%, 70%) are used as solvents.

Method of determination: 1 g of the weighed product is placed in a conical container with 50 ml of solvent, weighed (to the nearest 0,01 t), the flask is left to stand for 1 hour, then the refrigerator is connected and slowly boiled (2 hours). Cool the flask and add the same solvent to the previous weight on the scales. It is filtered into another vessel through a dry filter. It is evaporated in a 25 ml porcelain dish in a water bath and dried at 100-1050 for 3 hours. It is cooled in a desiccator and weighed.

The amount of extract is found by the following formula.

$$x = \frac{(a-b)\cdot 200}{C},$$

x – percentage of extracts;
a - the total weight of the container dried with the extract substance;
b - empty cup weight;
C – product weight

ACT ABOUT ACCEPTING MEDICINAL PLANT PRODUCTS

_____ CITY "____" _____20___

The signatories below are the manager of the medicinal plant products warehouse _____,
chemist-analyst _____and the company representative who sent the product _____ drew the current document on the date _____ _____ in quantity (units of commodity) about the acceptance of medicinal product _____
(uzbek, russian, latin name of the product)
as per the lot_____ shipped to the warehouse under railway bill of lading No_____. Weight of the lot: including container (packing) _____, without container _____.
When inspecting the general appearance of the product batch, it is noted that its condition is satisfactory, packaging (placement in the container) is arranged in accordance with GOST 6077-80 it is determined that it is performed correctly, that the marking (marking) meets the requirements of GOST 6077-80 and is accurate, that the container is not damaged (opened), not wet and no other defects.
Sampling volume _____ product part (unit).
Determining the uniformity of the product indicates the uniformity of the batch and the absence of unacceptable defects.
The average sample is divided by _____ weight in accordance with GOST 24027-1-80.
From average sample: 1) separated by _____ weights to determine authenticity, crushed parts, and impurities. 2) _____ weight to determine moisture; 3) _____ is allocated for the determination of ash and active substances.
Determination of the authenticity, crushed part and impurities of the analyzed sample is carried out in accordance with GOST 24027-80 _____. (MTX name and number)
The appearance of the product _____
_____
_____
Microscopy _____
_____
_____
Quality reactions _____
_____

Name of numerical indicators and active substance	Permitted according to the NTD (in%)	Found as a result of inspection (in%)
Humidity		
Total ash volume		
The amount of ash insoluble in a 10% solution of hydrochloric acid		
Crushed parts		
Mixtures		
a) organic б) mineral		
The amount of extractives		
The amount of active substances		

Conclusion:
Signatures:
Annex
_____

EVALUATION OF STUDENTS' KNOWLEDGE

* "I KNOW * I WANT TO KNOW * I GOT THE KNOWLEDGE" helps to assess the level of knowledge acquired in the training on specific topics. The use of the method is carried out in the following stages: the level of understanding of the acquired knowledge is determined; the need to enrich knowledge on the topic is studied; expresses his / her opinion on the acquired knowledge and draws his / her own conclusions.

I KNOW	I WANT TO KNOW	I GOT THE KNOWLEDGE

«Boomerang» training

Students are divided into small groups and the task material is distributed. Each group expresses their ideas and questions are answered between the groups. With the help of the teacher, the correct answer is determined by summarizing the ideas.

Ist group task

1. What documents determine the medicinal product to be accepted?
2. How is the moisture content of a medicinal product determined?
3. Organic compounds found in medicinal products.

II-group's task

1. What is a normative document?
2. In what order the average sample is taken?
3. What is the aim for performing commodity analysis?

III-group's task

1. How to determine the degree of contamination of a medicinal product with warehouse pests?
2. How are compounds detected in a medicinal product?
3. How is the number of places to be opened in a given lot determined?

IV-group's task

1. In what cases is a drug product rejected without analysis?
2. How can one determine if the product is crushed?
3. What is the total ash of the product and how is it determined?

Situational issues

The medicine arrived in a railroad car. What to do in the following cases:

- Railway car door seal is broken;
- Part of the product is damaged when the water is leaking the roof corner of the car;
- There is a pharmacopoeia article and SS for the product. Which ND can be used for commodity analysis?

Tests

1. What happens if the product has a high degree of fragmention?
A. leads to oxidation and degradation of biologically active substances;
B. becomes moldy;
C. decays;

D. the quality improves due to the fact that it turns into ash.
2. What determines the high ash content of a product?
A. depends on whether the product is made of dust and the crystals it contains
B.the abundance of mineral compounds in the product
C. to the chemical composition of the product
D. depending on the crystals present in the product
3. Initial sampling rules for product analysis.
A. from three places, the upper, middle, and lower
B. taken only from the top
C. taken only from the middle
D. taken from all parts
4. The rule of averaging in product analysis.
A. the opposite side is obtained by the diagonal method in the form of a rectangle;
B. The opposite side of the triangle is obtained.
C. the opposite side is taken from the top;
D. taken from the lower part.
5. In what cases is an arbitration analysis conducted?
A. at the request of the buyer;
B. such analysis is not performed;
C. it must always be done;
D. at the request of the supplier.
6. What are allowed mixtures?
A. organic and mineral compounds;
B.mineral compounds;
C.organic compounds;
D. crushed parts of the plant.
7. In what cases is the product not accepted?
A. if there is a bad smell, if it is rotten and moldy, if there are a lot of poisonous plant parts and warehouse pests;
B. a mixture of foul-smelling and poisonous plants;
C. foreign plant and bird wastes;
D. if the product is rotten and contaminated.
8. In what cases is the amount of extractives of the product determined?
A. if it is not possible to determine the amount of biologically active substances;
B. always detected;
C. only for poisonous plant products;
D. Not detected.
9. If there are 1-5 flawless places in a lot, how many places will be opened?
A. everything will be opened;
B. 4 will be opened;
C. half will be opened;
D. 20% will be opened.

10. Is it allowed to receive the product in case of warehouse pest infestation?

A. acceptance depends on the degree of damage;
V. discarded;
S. accepted after disinfection;
D. will not be accepted if the product is level 1 damaged.

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