Federal State Budgetary Educational Institution of Higher Education "Volgograd State Medical University" of the Ministry of Health of the Russian Federation

Department of Management and Economics of Pharmacy, Medical and Pharmaceutical Commodity Science

Use value and quality of pharmaceutical and medical products (Part 1 of Lecture 3)

Lecture № 3

Discipline: medical and pharmaceutical commodity science

3 course, 5 semester

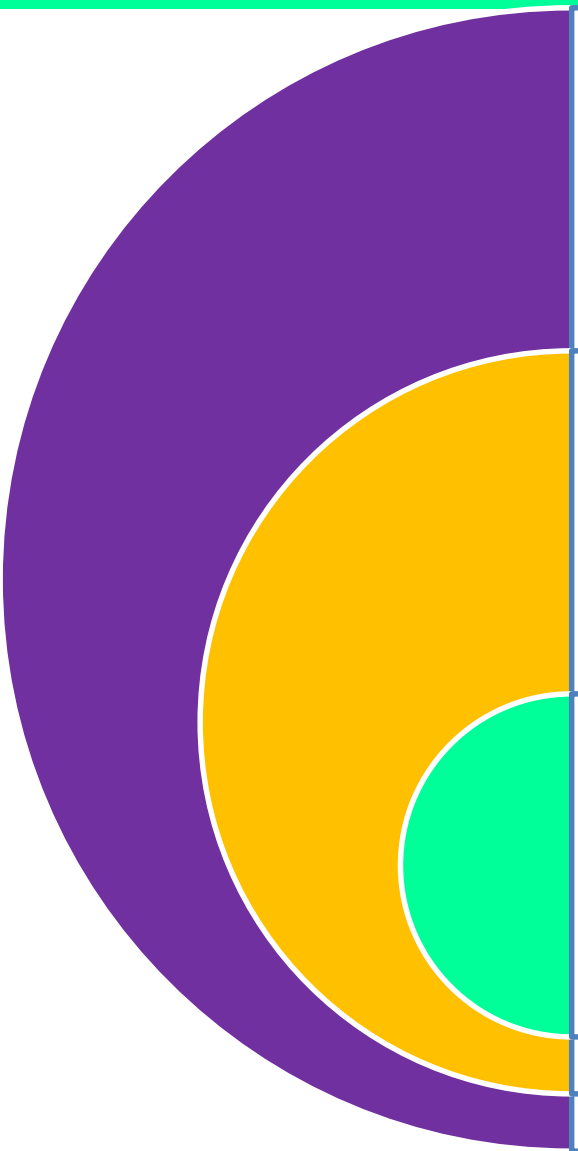
Volgograd -2022

LECTURE PLAN

1. Introduction
2. Relationship between use value and product quality
3. Factors affecting consumer properties and quality of medical and pharmaceutical products
4. Factors that form consumer properties and quality of goods
5. Factors that preserve consumer properties and quality of medical and pharmaceutical products
6. Summary

Factors affecting the consumer properties of medical and pharmaceutical products

Consumer properties and quality of goods depend on many factors:



In merchandising, they are divided into two groups:

- factors that **shape** consumer properties and quality of goods

- factors that **preserve** consumer properties and quality of goods.

Factors affecting the consumer properties of medical and pharmaceutical products

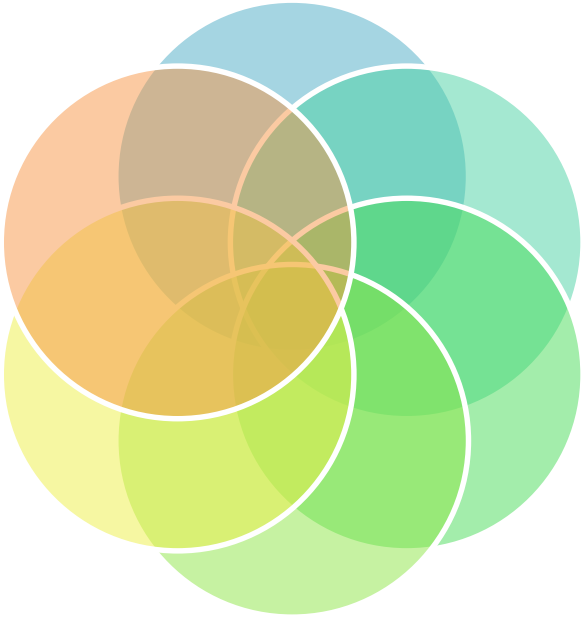
- scale and structure of morbidity;
- the level of technology development in the industry;
- quality of raw materials;
- product manufacturing technologies;
- methods of product quality control;
- means of transportation;
- storage features;
- compliance with the rules for the use of this product.

Factors that form consumer properties and quality of goods

Factors that form the quality and quantity of consumer properties of medical and pharmaceutical products

The factors that form the quality and quantity of consumer properties of the goods include a complex of objects and operations inherent in certain stages of the production cycle:

-production technology.



- design and development of products;

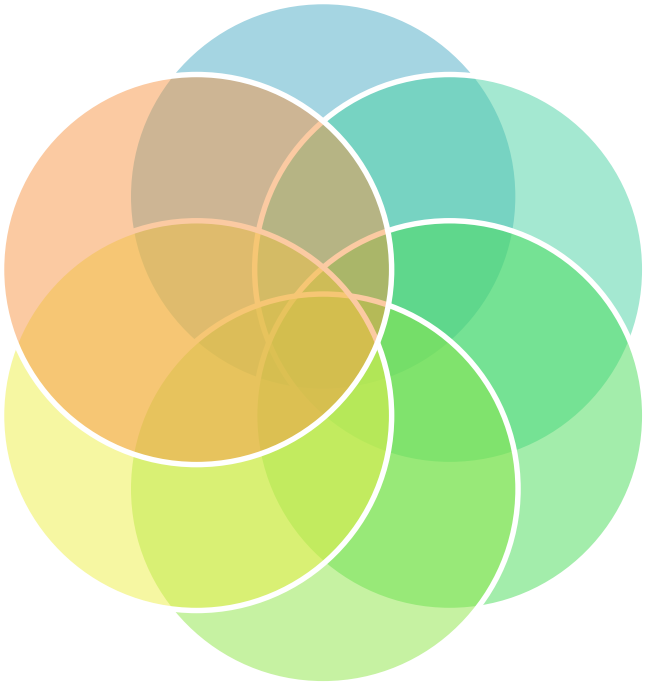
-design;

- raw materials;

Factors that form the consumer properties of medical and pharmaceutical products

1. **Consumer properties and quality of raw materials, materials and components.**

5. **The quality of disinfection and sterilization** (including the quality of regulatory and technical documentation, equipment, the quality of workers' work, quality control, etc.).



2. Composition and ratio of components in the manufacture of the product.

3. Product form (for medical products - product design, for medicines - dosage form).

4. Process quality

1. Consumer properties and quality of raw materials, materials and components

Proper quality of raw materials and materials is ensured by:

- compliance with the rules for the acceptance of these raw materials to the organization;
- mandatory quality control of the raw materials and accompanying documents.

The consumer properties of medicines are influenced by:

- chemical modification of the active substance,
- physical and chemical state of the medicinal substance (crystal shape, particle size, polymorphic modification, etc.),
- nature and amount of excipients.

2 . The composition and ratio of components in the manufacture of the product

Differences in the composition and ratio of components for medicines determine different temperature storage conditions . Such features of storage form differences in the consumer properties of these drugs (safety, reliability).

For medical goods - metal products, the type, grade of metal is decisive:

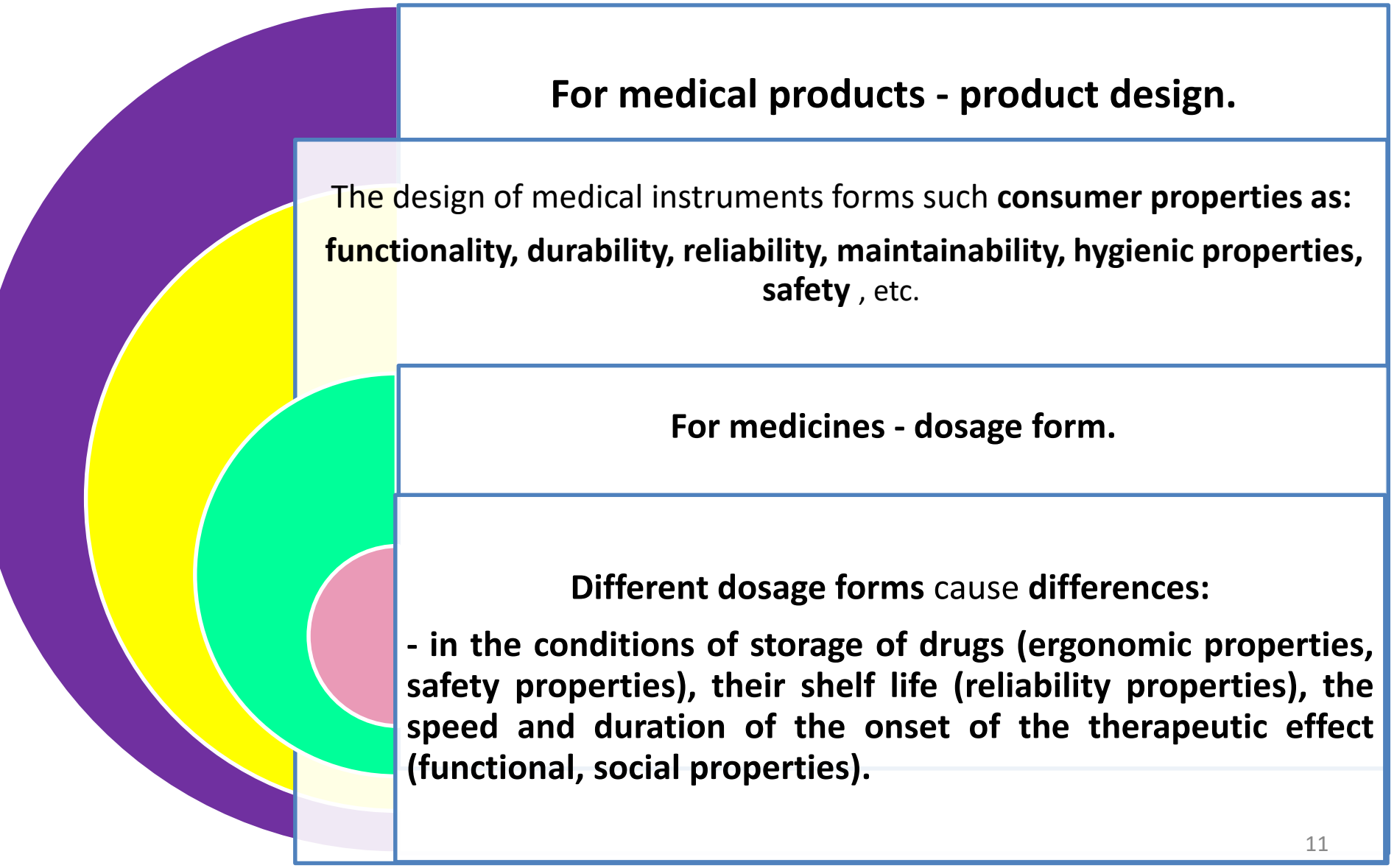
- **cast irons (contain in their composition from 2 to 4% carbon);**
- **steel (carbon content less than 2%).**

With an increase in the carbon content, the hardness increases and the ductility of the metal decreases.

Cast **iron (having high hardness and low ductility) is used to** make **massive bases for medical equipment** .

From **steel** , which has great ductility - **medical instruments.**

3. Product shape



For medical products - product design.

The design of medical instruments forms such **consumer properties as:**

functionality, durability, reliability, maintainability, hygienic properties, safety , etc.

For medicines - dosage form.

Different dosage forms cause **differences:**

- in the conditions of storage of drugs (ergonomic properties, safety properties), their shelf life (reliability properties), the speed and duration of the onset of the therapeutic effect (functional, social properties).

4. Process quality (1)

The technological process and all stages of manufacturing medical products are regulated **by the State Standard - a regulation that describes in detail all the stages of the technological process for obtaining a particular product.**

Each stage and operation of the technological process has an impact **on the quality of the finished product** .

4. Process quality (2)

Finished products are tested for quality in the technical control department in accordance with regulatory documents.

Sometimes **obvious and / or hidden defects are formed** .

Obvious defects are easily detected by **visual inspection and can be detected upon acceptance of the goods to the pharmacy.**

Hidden defects are revealed **only during operation or application** .

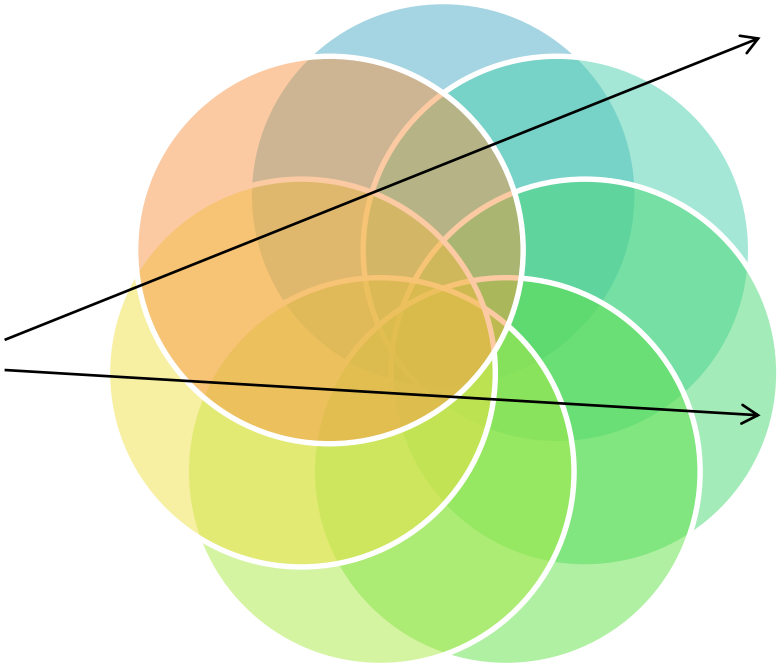
Defects are product defects.

5. Quality disinfection and sterilization (1)

Sterilization is **the process of killing in an object or removing from it microorganisms of all kinds, at all stages of development** .

The following methods are used for sterilization:

- thermal :



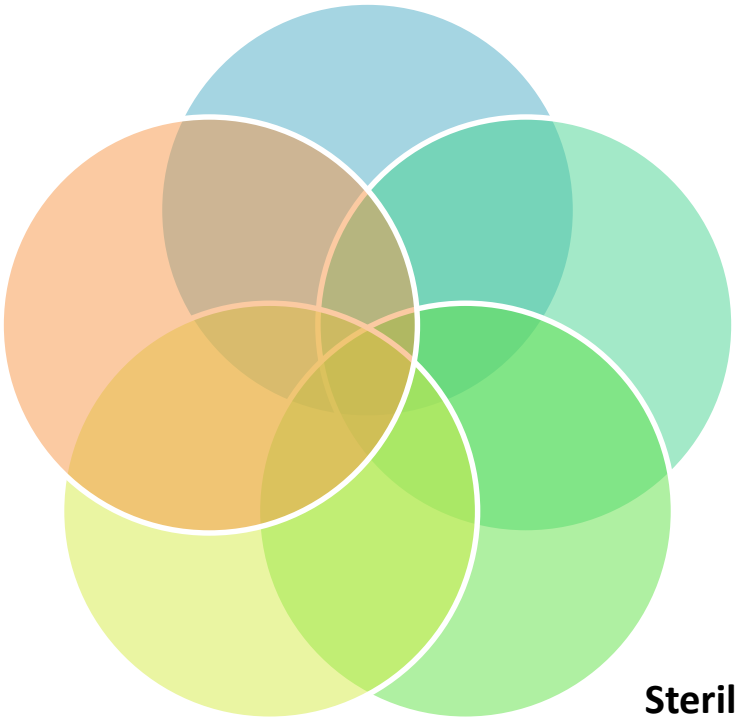
A **) steam** - carried out in steam sterilizers with saturated steam at excess pressure (0.11 and 0.2 MPa) and temperature (120 or 132 degrees Celsius).

B **) air sterilization method** - carried out with dry hot air in air sterilizers at a temperature of 160, 180 or 200 degrees Celsius.

5. Quality disinfection and sterilization (2)

Sterilization methods (continued):

- **gas (ethylene oxide or its mixture with methyl bromide, freons, carbon dioxide, etc.)** - carried out in gas sterilizers for 4-16 hours.

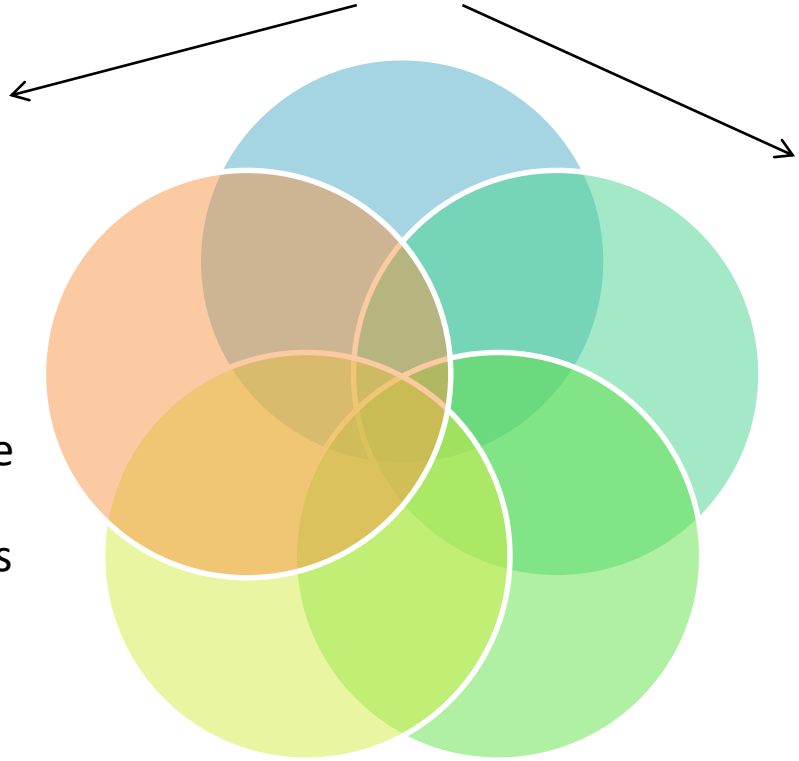


- **solutions (hydrogen peroxide and peracids)** - carried out in closed containers made of glass, plastic or enameled containers, after which the products (made of polymeric materials, rubber, glass, corrosion-resistant materials) are washed with sterile water under aseptic conditions.

Sterilization time depends on the concentration and temperature of the sterilizing solution.

5. Quality disinfection and sterilization (3)

Sterilization methods (continued):



- radiation

sterilization method - carried out for plastic products, disposable products, dressings, some medicines and other types of medical products in the final package on sources of ionizing radiation.

- sterilization by filtration (through membrane and depth filters) - used for solutions of thermolabile substances.

Sterilization and bottling of the solution is carried out under aseptic conditions.

5. Quality disinfection and sterilization ((4)

Control of parameters and efficiency of sterilization methods is carried out using:

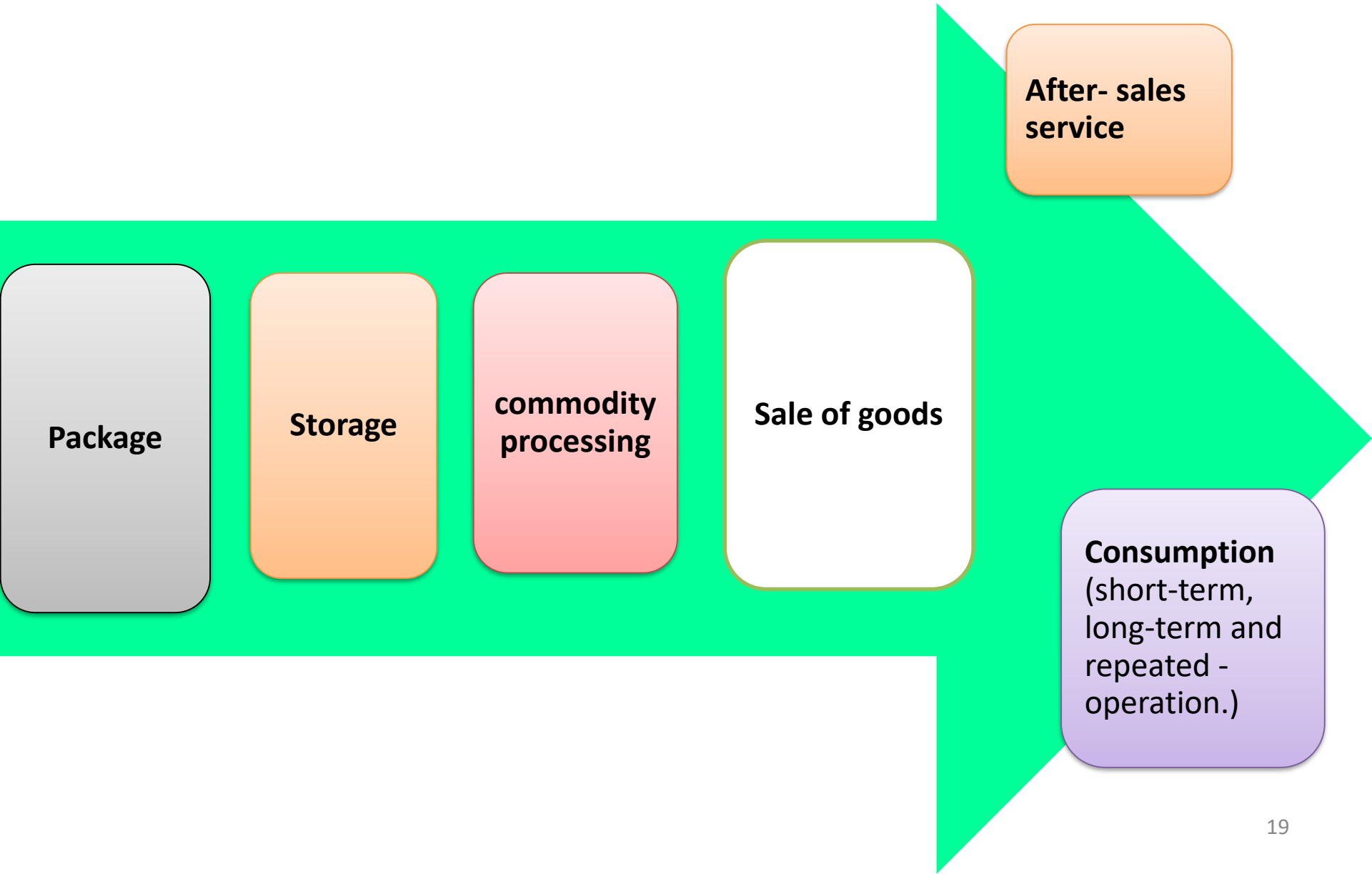
- instrumentation, chemical tests

- biological tests.

The effectiveness of filtration sterilization is checked by direct inoculation of a sample of the filtrate into the culture medium.

Factors that preserve consumer properties and quality medical and pharmaceutical products

The factors that preserve the consumer properties of the product include:



In the process of circulation and operation of goods, their consumer properties change under the influence of factors:

physical and chemical (humidity, temperature, light, oxygen, various gases and other air components)

mechanical (compression, stretching, bending, impacts, shocks, shaking, etc.),

biological (impact of microorganisms, insects and rodents).

The types, nature and size of the damage they cause **are determined by the intensity of the impact and the properties of the material of the product.**

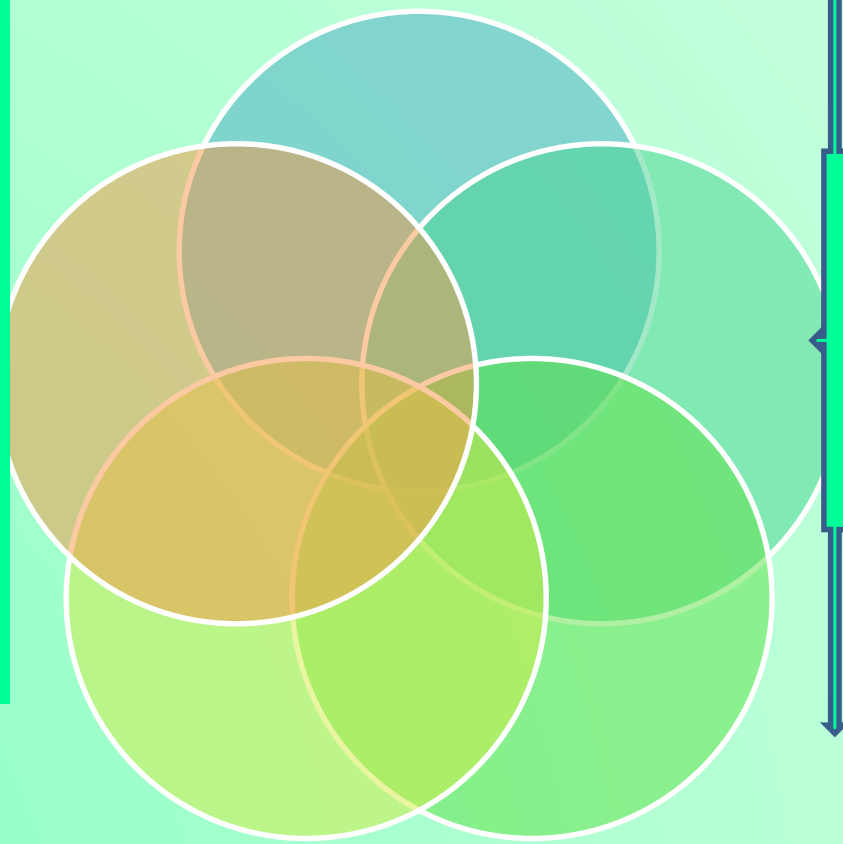
preservation of consumer properties of goods

- **Preservation of consumer properties of goods depends on:**

- packaging quality;
- quality labeling for goods and packaging;
- packing goods into packages;
- transportation conditions;
- storage conditions;
- disinfection method;
- sterilization method;
- conservation method;
- depreservation method .

When accepting goods in terms of quantity and quality, it is necessary to pay attention to:

necessary to organize the **proper storage of goods,** if **necessary** - **sterilization, conservation and re-preservation of medical instruments** , instruments and equipment .



- conditions for the transportation of goods,

- safety of packaging and labeling,

- their compliance with the standards for accepted goods.

Methods of protection from environmental factors to preserve consumer properties and quality of medical and pharmaceutical products

No.	Environmental factors	Protection methods
one	Physico-chemical	1. Use of packaging that protects against the penetration of moisture, gases and light. 2. Creating the optimal storage temperature. 3. Rational preservation of products. 4. Rational sterilization of products.
2	Mechanical	1.Using rational packaging with high mechanical strength. 2. Proper packing of goods during transportation. 3. The use of closures.
3	Biological	one . aseptic production conditions. 2. rational sterilization. 3. Creation of rational storage conditions. 4. Systematic treatment of premises with disinfectants.

Factors that preserve consumer properties and quality of medical products from metals and alloys

Corrosion is a physical and chemical interaction of a metallic material and an environment, leading to a deterioration in the consumer properties of the metal.

According to the flow conditions, the types of corrosion are distinguished:

atmospheric corrosion - in the atmosphere of air;

contact corrosion - in the electrolyte environment when metals come into contact with different electrode potentials;

biocorrosion (microbiological) - under the influence of vital activity of microorganisms;

corrosion with full or partial immersion - corrosion of metal, completely or not completely immersed in a liquid corrosive medium;

crevice corrosion - increased corrosion in cracks and gaps between metals .

Corrosion. Corrosion protection methods:

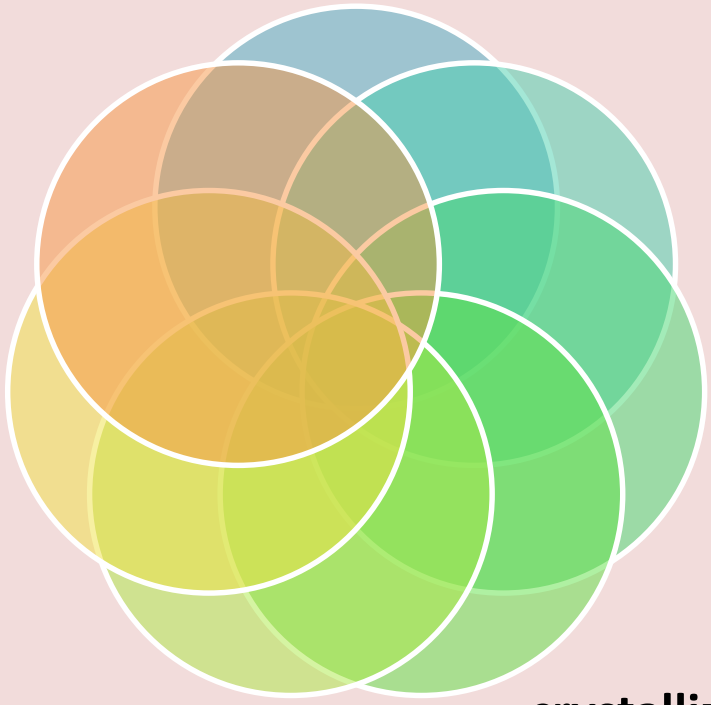
In order to improve consumer properties metal products Various **corrosion protection methods are used** :

- **Exposure to metals or alloy during fabrication** (plating).
- **Impact on a corrosive environment - heat treatment, surface finishing, grinding, application of a protective layer** (observance of storage conditions for metal products).
- **Temporary protection of the tool from contact with aggressive media - lubricating the tool with preservative oils or introducing corrosion inhibitors into the packaging** (sodium nitrite, ammonium benzoate , etc.), as well as by wrapping the products with anti-corrosion packaging paper).

Factors Preserving Consumer Properties and Quality of Medical Goods Made of Polymeric Materials

During the aging of polymers, the following **physicochemical processes occur:**

Change in mechanical (strength) and **aesthetic** (change in color, gloss, etc.) **properties of the product** .



destruction - rupture of chemical bonds in the main chain of macromolecules;

structuring - the formation of new bonds between macromolecules, i.e. the formation of new chemical compounds;

amorphization - formation of an amorphous structure.

crystallization - the formation of highly ordered crystalline regions (crystallites);

Signs of aging of polymeric materials

The main **external signs of aging of polymeric materialsvisible** during external examination:

increase in hardness;

increased fragility;

the appearance of stickiness (for rubber products);

loss of elasticity;

color change;

the appearance of wrinkles and cracks on the surface .

Methods for protecting polymeric materials from environmental factors

Methods of protection against the action of environmental factors:

Active protection methods - due to rational packaging.

Passive protection methods - by **adding various stabilizers** to the polymer composition (thermal stabilizers , light stabilizers , antioxidants, non- chain inhibitors).

Combined methods.

Factors that preserve consumer properties and quality of medicines

Changes in consumer properties and quality of drugs occur mainly as **a result of chemical transformations of active substances.**

Knowledge **of the mechanism and rate of chemical processes** that occur during storage, transportation and operation of drugs allows you to eliminate or slow down the course of chemical reactions, as a result - to increase the shelf life, increasing the stability of medicinal substances (for most drugs, the shelf life is from 2 to 5 years).

Factors that preserve consumer properties and quality of medicines (2)

The stability of drugs largely depends not only on their chemical composition, but also on the properties of the packaging material, in particular, permeability and light transmission.

Examples:

The orange glass container does not transmit light with a wavelength of less than 470 nm and reliably protects compounds that are sensitive to ultraviolet radiation.

A polymer film containing UV absorbents protects the tablets from light, and those containing inhibitors protect them from oxygen.

Conditions for storage and transportation of medicines

When choosing **storage and transportation conditions, it is necessary to take into account** :

product properties (PM);

the need for protection against mechanical influences;

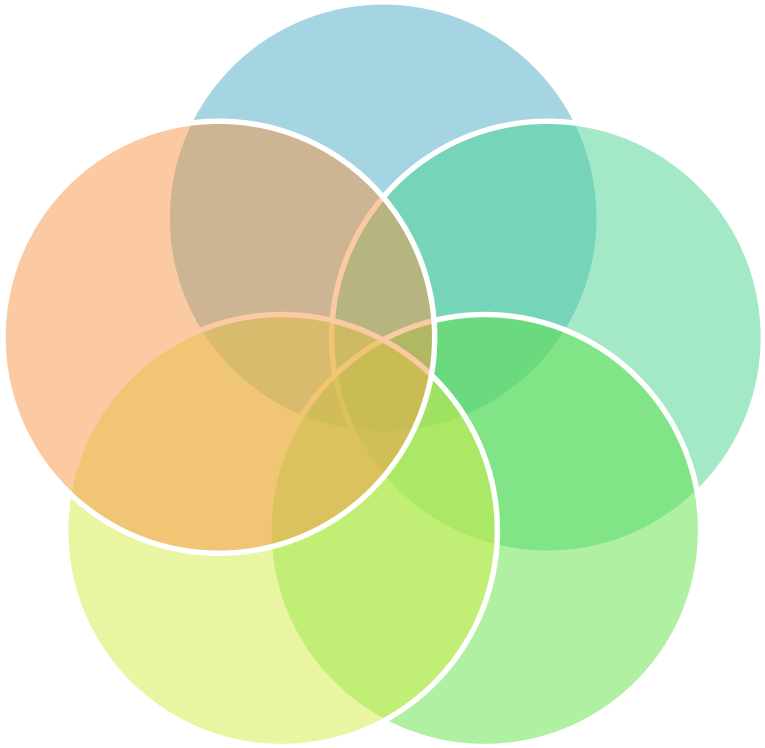
the need for weather protection.

The storage conditions of goods are specified in the storage orders .

Conditions for transporting medicines

The preservation of the quality of goods (PM) **during transportation largely *depends on* :**

on the degree of protection of the goods from mechanical and atmospheric influences.



rationality of the choice of packaging and its quality;

on the density of packing of goods in containers, and containers with goods - in containers and vehicles;

TRANSPORTATION

Goods, depending on their type and properties, as well as the type of transport , are **transported in various types of packaging** .

Products must be: **packed tightly, empty spaces filled with appropriate packing materials with shock-absorbing ability.**

When loading and unloading it is necessary to pay attention to: **warning signs and inscriptions on containers, cleanliness of vehicles.**

Falling loads and excessive shocks must not be allowed.

Basic principles of storage of medicines (1)

Classification features of the organization of storage of medicines , taking into account:

Toxicological group (list A, list B, general list)

Pharmacological group

By type of application (for external and internal use)

Medicinal substances **" angro ", taking into account the state of aggregation** : liquid bulk, gaseous, etc.

Basic principles of storage of medicines (2)

In accordance **with the physico-chemical properties and the influence of various environmental factors , drug groups**

- From exposure to gases contained in the environment

- Requiring protection from light

- From exposure to low temperatures

- From exposure to moisture

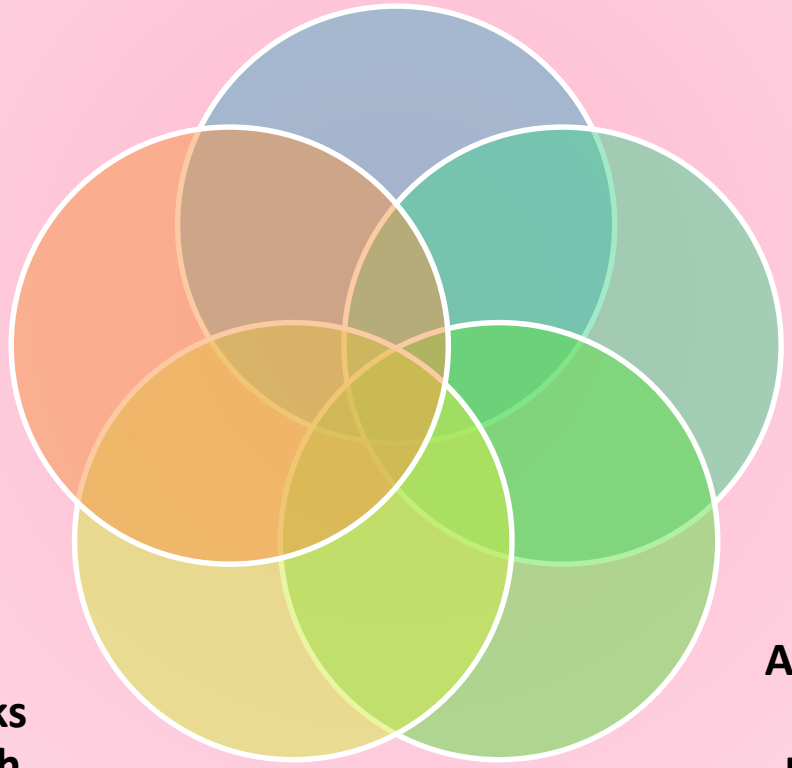
- From exposure to elevated temperatures

- From volatilization and drying

Features of storage of finished dosage forms

Storage of GLF should meet the requirements of the Global Fund and all general requirements for drugs, taking into account the properties of the ingredients that **make up their composition.**

In the stock department of the pharmacy, a card index is maintained by expiration dates.



The storage temperature is indicated on the package .

A shelf card is attached to the racks and shelves for each series of the drug.

All GLFs are stored in their original packaging with the label facing out.

Temperature regime for storage of medicines (OFS.1.1.0010.18)

The cold place means storage of medicines in the refrigerator at a temperature **from 2 to 8 °C** , without allowing freezing.

Do not freeze. Not lower than +2 °C, unless otherwise specified in the monograph or normative documentation

Cool storage refers to storing medicines at temperatures **between 8 and 15°C** . In this case, it is allowed to store medicines in a refrigerator, with the exception of medicines that, when stored in a refrigerator at a temperature below 8 ° C, can change their physical and chemical characteristics, for example, tinctures, liquid extracts, etc.

Storage under deep freezing conditions provides for a temperature regime below -18 **°C.**

Freezer storage provides the temperature regime of medicines **from -5 to -18 ° C.**

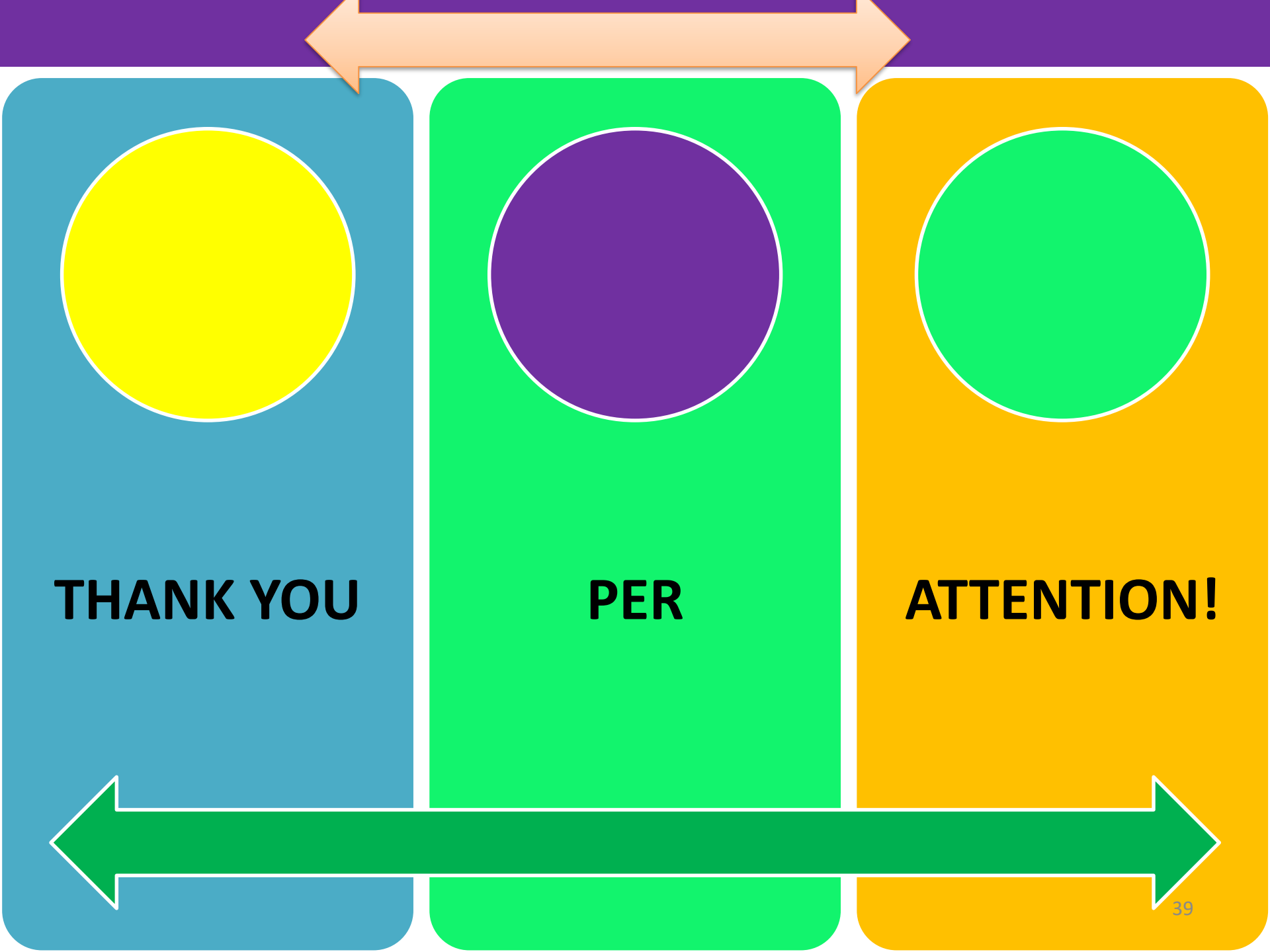
Storage at room temperature implies a temperature regime from **15 to 25 ° C** or, depending on climatic conditions, up to 30 ° C.

Storage of medicinal plant raw materials and medicinal plant preparations OFS.1.1.0011.15

The storage conditions of MPC and herbal medicinal products in warehouses should **ensure the safety of raw materials and drugs in terms of quality indicators that may change during storage within the periods established in pharmacopoeial articles or regulatory documentation** ..

Medicinal herbal products that require protection from light must be stored in a place protected from light and / or in light-protective packaging in accordance with the requirements of the General Pharmacopoeia Monograph “Packaging, labeling and transportation of medicinal herbal raw materials and herbal medicinal products ”.

Medicinal herbal raw materials and medicinal herbal preparations should be **stored at a relative air humidity of not more than 60 ± 5%, depending on the respective climatic zone** (I, II, III and IV A) and the physicochemical properties of the medicinal herbal raw materials/preparation and biologically active substances, included in its composition, in a packaged form in accordance with the **General Pharmacopoeia Monograph "Packaging, labeling and transportation of medicinal herbal raw materials and medicinal herbal preparations".**


THANK YOU
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