Seminar no. 7

TOPIC:

1. "The quality of medical and pharmaceutical products and its properties. Quality assurance at the stages of the "life cycle" of medicines and medical products. State system of standardization and certification of medical and pharmaceutical products. Standards. Normative documents. Types of standards and normative documentation.

2. Test No. 1 (on topics 1-14) - 1 hour

The main questions to be discussed at the seminar:

1. Quality, definition of the concept. The quality of medical and pharmaceutical products. Comprehensive quality assessment. Groups of quality indicators.
2. Quality indicators of medicines and medical devices.
3. Standards. Categories and types of standards.
4. Types of regulatory and technical documentation.
5. Types of ND used for medicines and medicinal products.
6. Quality assurance in the field of drug circulation.
7. Standardization. Standardization system for medical and pharmaceutical products.
8. Certification. Certification of medical and pharmaceutical products.

Define the terms:

1. The totality of consumer properties of goods that determine their ability to satisfy certain needs in accordance with their purpose is **the quality of goods.**
2. **The quality of a medicinal** product is a set of properties that give the medicinal product the ability to satisfy consumers in accordance with its intended purpose and meet the requirements established by law and regulatory documents.
3. A scientific discipline within which the methodology and problems of a comprehensive, quantitative assessment of the quality of objects of any nature are studied is **qualimetry.**
4. A quantitative characteristic in relation to specific conditions of production and consumption, regulated by regulatory documentation, is an **indicator of the quality of goods.**
5. Indicators intended to express simple properties of goods (color, shape, acidity, integrity) are called - **single indicators.**
6. The object of research in commodity science is the **technical aspect of quality.**

Give the **signs** by which quality indicators are classified in merchandising:

1. the number of characterized properties (single and complex);
2. purpose (defining and integral);
3. way of expression (in natural units and points);
4. determination method (organoleptic, instrumental, sociological, expert);
5. areas of application (product units, sets of units of homogeneous products, sets of units of heterogeneous products);
6. definition stage (at the design stage, at the production stage, at the consumption stage).

What are the main **criteria for the quality of** medicines

1. authenticity (authenticity),
2. efficiency, safety,
3. bioavailability

The safety of medicines is a characteristic of medicines based on a comparative analysis of their

effectiveness and an assessment of the risk of harm to health.
Bioavailability medicinal substances reflects the content of free substance in the blood plasma after a certain period of time after its administration relative to the initial dose of the drug.
The effectiveness of drugs is a characteristic of the degree of positive effect of drugs on the course of the disease.

Quality can be assessed or quantified.

Qualimetry is a scientific discipline that studies the methodology and problems of a comprehensive, quantitative assessment of the quality of objects of any nature.

In commodity science **, quality indicators** are classified according to the following **criteria** :

1. the number of characterized properties (single and complex);
2. purpose (defining and integral);
3. way of expression (in natural units and points);
4. determination method (organoleptic, instrumental, sociological, expert);
5. areas of application (product units, sets of units of homogeneous products, sets of units of heterogeneous products);
6. definition stage (at the design stage, at the production stage, at the consumption stage).

To characterize the quality of medical equipment and technology, they often use

- basic,
- relative,
- optimal values of the product quality index.

The base values of the quality index are the values taken as a basis for comparing quality.
The base values are:
- values of quality indicators of the best domestic and foreign samples, for which there are reliable data on their quality;
- values of quality indicators achieved in the previous period of time, or planned values of promising samples;
- the values of quality indicators specified in the product requirements.

EXAMPLE: determination of the identity of the active substance by the chromatographic method .

There are groups of forms and methods of quality control (form an effective quality assurance system for medical products):

- **by stages of the product life cycle** : control of the design of new products; control of production and sales of products; control of operation and consumption of products;
- **by stages of the production process:** incoming quality control of materials, semi-finished products, tools and fixtures before the start of production; intermediate control performed during the technological process; final acceptance control carried out over blanks, parts, assembly units, finished products;
- **by the degree of coverage of products:** complete control, performed with full coverage of the presented products; selective control, carried out not over the entire mass of products, but only selectively;
- **at the place of execution:** stationary control performed at stationary control points; sliding control performed directly at the workplace;

The quality of the goods is regulated by the standard.
Standard (from the English standard - norm, sample) - an official state or regulatory document of an

industry, enterprise, firm that establishes the necessary quality characteristics, requirements that a given type of product or product must satisfy.

International Standard: A standard adopted by an international standardization organization and available to a wide range of *users.*

1. International standards include **ISO standards, IEC standards and ISO/IEC standards, which are joint publications of ISO and IEC.**
2. In international standardization, along **with standards , ISO** guides **(ISO Guide), ISO / IEC** guides **(ISO / IEC Guide), ISO** technical reports , denoted by the index **[prefix] ISO / TO (ISO / TR),** international standardized profiles, indicated by the index [prefix] **ISO/IEC ISP (ISO/IEC ISP),** assessments of technology areas indicated by the index [prefix] ISO/OTN (ISO/TTA), ISO recommendations indicated by the index [prefix] ISO/R (ISO/R) , ISO specifications identified by the ISO/TS suffix [prefix] [ISO/TS], ISO public technical specifications identified by the ISO/OTS suffix [prefix] [ISO/PAS], industry technical agreements identified by the ISO/UTS suffix [prefix] [ISO/ITA].

Types of NTDs used for medical products:

- - GOST R
- -OST
- -THAT
- - operational documents.

The regulatory and technical documentation for PRODUCTS includes the following types of documents:

- technical conditions (TU);
- technological instruction (TI);
- technological regulations (TR);
- technological process (TP);
- safety data sheet (PB);
- label;
- formulation;
- quality passport.

Types of ND used for drugs and MPC

❖ *General pharmacopoeial monograph (GPM)* - general pharmacopoeial monograph - a document approved by the authorized federal executive body and containing a list of quality indicators and (or) quality control methods for a specific dosage form, medicinal plant materials, descriptions of biological, biochemical, microbiological, physicochemical, physical, chemical and other methods analysis of the medicinal product, as well as the requirements for the reagents used for this analysis, titrated solutions, indicators. *(Federal Law No. 61 "On the Circulation of Medicines" (current edition)*

❖ Its designation:

OFS-42-0007-19,

where: OFS - index,

42 - symbol of the ministry or department,

0007 - registration number,

19 is the year of approval.

Pharmacopoeia article of the enterprise (FSP) - a quality standard for drugs under a trade name, containing a list of indicators and methods for quality control of drugs produced by a particular enterprise, taking into account the specific technology of this enterprise and passed the examination and registration in the prescribed manner.

Its designation:

FSP-42-0208-00046-12,

- ❖ FSP - index,
- ❖ 42 - symbol of the ministry or department,
- ❖ 0208 - company code,
- ❖ 00046 – registration number of the standard,
- ❖ 12 - year of approval.

For foreign drugs, RD includes:

- GF
- foreign pharmacopoeias
- specifications (articles, norms, quality certificates) developed by foreign firms.
- The term "Pharmacopoeia" comes from the Greek words pharmakon - medicine and poieo - I do, and is translated into Russian as a guide to the preparation of medicines.

The State Pharmacopoeia (SP) is a collection of state drug quality standards that has a legislative character.

Currently, the GF XIU edition is in force.

Certification is a form of implementation by the certification body of confirmation of compliance of objects with the requirements of technical regulations, the provisions of standards or the terms of contracts.

The certificate of conformity (quality certificate, safety certificate, customs certificate) is a document confirming that the product meets the quality and safety requirements established for this product by the current standards and regulations.

The main **goal of certification** is to protect the rights and interests of consumers, to pursue a unified state policy in the field of providing the population with high-quality drugs.

The system of certification of medical devices is aimed at achieving the following goals:

- assistance to consumers in the competent choice of products;
- promoting exports and increasing the competitiveness of products;
- consumer protection from an unscrupulous manufacturer;
- safety control for the environment, life, health;
- confirmation of product quality indicators.

Product certification is carried out **in the following order** :

- filing an application for certification;
- consideration and adoption of a decision on the application;
- selection, identification of samples and their testing;
- verification of production (if provided by the certification scheme);
- analysis of the obtained results, decision making;
- the possibility of issuing a certificate;
- issuance of a certificate of conformity;
- inspection control over certified products in accordance with the certification scheme.

The methods of proof are:

- trial;
- verification of production (used when an analysis of the technological process is necessary to assess the quality);
- inspection control (provided for in most schemes, it is carried out after the issuance of a certificate);
- consideration of the application-declaration (with attached documents).

Final examination No. 1: "Fundamentals of medical and pharmaceutical commodity science" - 1 hour

Questions for the final test No. 1

1. Commodity science as a scientific discipline. Subject, purpose, tasks. Historical stages in the development of commodity science.
2. Concepts: product, consumer value, medical merchandising.
3. What are the properties of goods?
4. What is the purpose of medical and pharmaceutical merchandising?
5. What is the role of a pharmacist in organizing the supply of health services and the population with the necessary medical equipment.
6. Definition of the concepts "medical products", "medical equipment products", "medical devices", "medical equipment", medical complexes, "patient care items".
7. Definition of the concepts "drugs", "drugs", "pharmacy products", " parapharmaceutical products", "materials", "products".
8. Use value and usefulness of the product. Individual and social use value.
9. Definition of the term "consumer". Consumer properties, characteristic.
10. Characteristics of groups of consumer properties - social, functional, reliability, safety, ergonomic, aesthetic, environmental.
11. Consumer properties that determine the quality of medical products. Indicators for assessing the consumer properties of medical and pharmaceutical products.
12. Factors that preserve consumer properties and quality of medical products from metals and alloys, polymeric materials.
13. Methods of protection against environmental factors to preserve consumer properties and quality of medical and pharmaceutical products.
14. Classification of goods. Basic definitions, concepts. The purpose of the classification.
15. Trade classification of goods. Characteristic. Place of medical and pharmaceutical products in the trade classification.
16. Classification systems for medical goods. Signs by which medical and pharmaceutical products can be classified.
17. Goods coding: concept, structure, coding methods. The structure of the code, its main elements.
18. Characteristics of sequential, ordinal, serial-ordinal and parallel encoding methods (methods). Anatomical-therapeutic-chemical classification. Application in the commodity analysis of medicines.
19. Bar coding of goods. Characteristics of bar coding systems for goods. Bar code structure in EAN/UCC systems.
20. The concept of classification. Classification methods. Classification of medical and pharmaceutical goods.
21. Classification coding methods. Commodity classification of medical goods.
22. Classifiers of products and goods.
23. Characteristics of consumer properties that determine the quality of medical products.
24. Quality, definition of the concept. The quality of medical and pharmaceutical products. Comprehensive quality assessment. Groups of quality indicators. Quality indicators of medicines and medical devices.
25. The role of standards in preserving the use value and quality of goods. Types of regulatory and technical documentation.
26. Types of standards and normative documentation.
27. Types of ND used for medicines and medicinal products.
28. Quality assurance in the field of drug circulation.
29. Standardization. General provisions. Standardization system for medical and pharmaceutical products.
30. Certification. General provisions. Certification of medical and pharmaceutical products.