MINISTRY OF HEALTH OF UKRAINE
ODESA NATIONAL MEDICAL UNIVERSITY

International Faculty

Department of Organization and Economics of Pharmacy with post-diploma specialization

GUIDELINES

FOR INDEPENDENT WORK OF STUDENTS IN THE DISCIPLINE

International Faculty, 4th year

The discipline «**PHARMACEUTICAL AND MEDICAL COMMODITY SCIENCE»**

Methodological recommendation from SRS, OPP "Pharmacy, Industrial Pharmacy", 4th year, Faculty of Pharmacy, Discipline: "Pharmaceutical and Medical Commodity science"

Approved: Meeting of the department of pharmacy organization and economics with postgraduate training of the Odesa National Medical University Minutes No. 1 dated September 4, 2023.

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Topic 1. Basics of commodity science. Normative documentation in the pharmaceutical industry.

Goal: Familiarize yourself with the basic concepts of commodity analysis of medical and pharmaceutical products. To study the goals, tasks, features, stages and methods of commodity analysis. To form professional knowledge and skills in conducting commodity analysis of various groups of goods.

Basic concepts:

Input control- control of the quality of medicinal products upon their receipt by the business entity, which is carried out by visual inspection or laboratory research of the quality of medicinal products.

Quality characteristics of goods- a set of intraspecies consumer properties that have the ability to satisfy various needs.

Quality- a set of object characteristics related to its ability to satisfy certain and planned needs.

Quantitative characteristics of goods- a set of certain intraspecific properties, expressed using physical quantities and their measurement units

Normative documentation of AND / MKY- regulatory documents that determine the qualitative and quantitative characteristics of the medicinal product, their permissible limits and testing methods, establish requirements for packaging, labeling, storage and transportation conditions, the shelf life of the medicinal product, approved during the registration of the medicinal product in Ukraine.

Certificate of Compliance- a document that certifies the object's compliance with the requirements of technical regulations, provisions of standards or terms of contracts.

The form of the certificate of conformity is approved by the body of executive power and technical regulation.

Certificate of quality of the medicinal product series- a document issued by the manufacturer (for imported medicinal products - by the importer (manufacturer or a person representing the manufacturer of medicinal products on the territory of Ukraine)) and which certifies the compliance of the series of the medicinal product with the requirements of the AN / MKY established at the time of its registration in Ukraine.

Plan

1. Classification of medical products depending on storage conditions: according to physical and chemical properties, method of application, expiration date, types and methods of packaging.
2. Organoleptic quality indicators, requirements for the quality of medical products.
3. Packaging and its functional purpose. packaging properties
4. Packaging, labeling and transportation of medical products.
5. Definition of the terms "analysis", "commodity analysis", "commodity examination".

Theoretical questions:

Function and principles of commodity analysis.

The main function of the commodity analysis of pharmacy products is to ensure the protection of consumer rights

to receive timely and high-quality products in accordance with their purpose and requirements established by law.

The principles of commodity analysis are safety, efficiency, competence, compatibility, interchangeability and systematization.

Security— absence of unacceptable risk associated

with the possibility of the product, service or process causing damage to the health and property of people, as well as the life of animals and plants.

Efficiency— achieving the most optimal result in production, packaging, storage, rational use of goods, optimization of goods movement, reduction of material resources and losses, sale and consumption, as well as disposal of skins.

Competence is determined by professional training in the field of medical and pharmaceutical commodity science, practical work experience.

To carry out commodity analysis, it is necessary to have detailed knowledge about goods, their consumers, physical, physico-chemical, chemical properties and their changes under the influence of various processes, such as storage, transportation, etc., to be well versed in the technological issues of the production of goods, documentation, organization of accounting and reporting.

Compatibility— suitability of goods, processes and services

to a shared use that does not cause unwanted interactions. This is taken into account when forming the assortment, placing goods for storage, choosing their packaging, as well as the optimal storage mode. The compatibility of goods during their consumption is important for the most complete satisfaction of needs.

Interchangeability— the suitability of one product, process or service for use instead of another in order to fulfill the same requirements, which determines the competition between them and plays an important role in the formation of an assortment of interchangeable products.

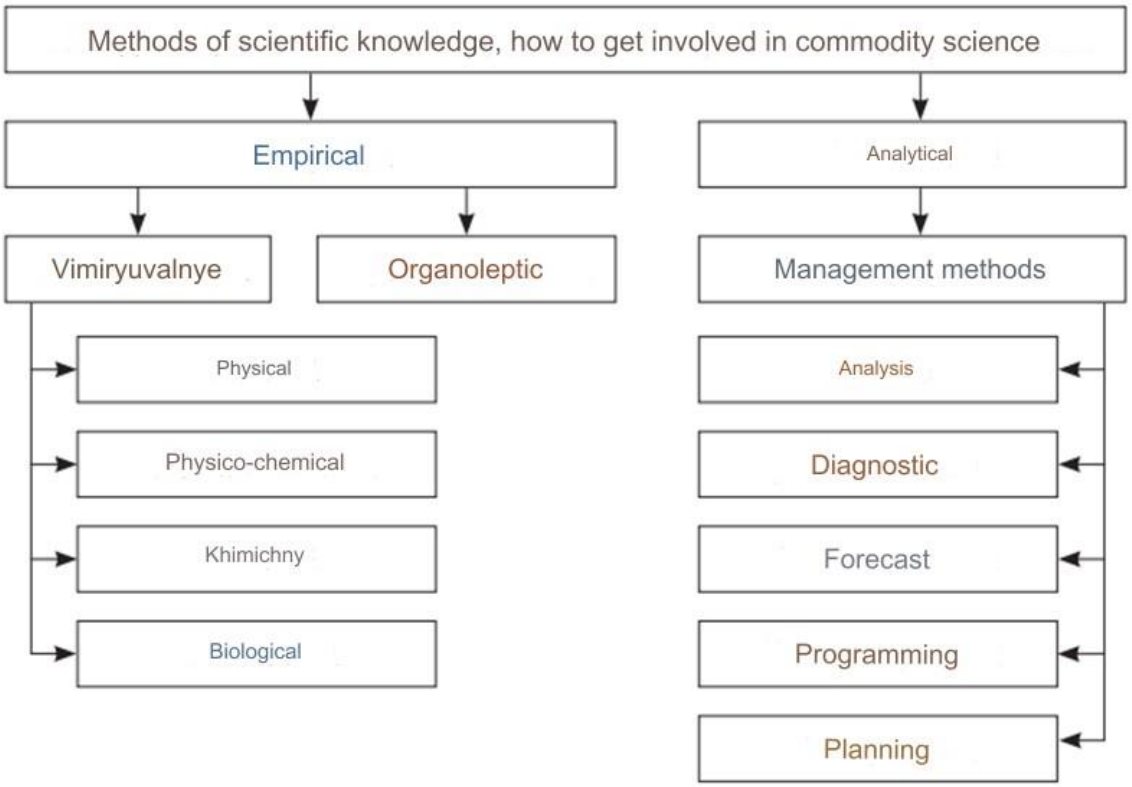
Systematization— establishment of a certain sequence of homogeneous, interconnected goods, processes and services. This is the basis of a group of methods, which include identification, classification, generalization, coding, and is the basis of the product information system.

Basic methods of analysis

In commodity science, two groups of methods are used: scientific knowledge and practical commodity science activity.

The methods of scientific knowledge are aimed at researching the main object of commodity science — the commodity, its characteristics and changes in the process of

commodity movement. This group includes empirical, or experimental, and analytical methods of scientific knowledge



Questions for self-control:

1. In what cases is a trade analysis conducted?
2. Name and describe the stages of commodity analysis.
3. Tell about the physical, chemical, biological properties of the goods.
4. Name the methods of commodity analysis.
5. What are the requirements for medical devices?
6. Which NDs regulate the requirements for medical devices?

Practical task 1.

Specify the main quality criteria of medicines and medical products. Submit the data in the form of a table.

No	Indicators of the quality of medicinal products
1.	
2.	
3.	
4.	
5.	
6.	

7.	
8.	
9.	
10.	
11.	

Task 2. Task 8. Define the term "shipping documents". Classify the accompanying documentation.

Task 3.List the stages of commodity analysis of medical and pharmaceutical products.

Test tasks for self-control:

1. Methods of scientific knowledge include: **
a) classification methods;
b) experimental methods;
c) analytical methods;
d) commodity methods.
2. What type of commodity analysis is based on an expert's assessment of the product's characteristics, based on information in the shipping and other documents?
a) assortment;
b) quantitative;
c) qualitative;
d) documentary.
3. Objective factors affecting the level of product quality include: **
a) forms of labor organization
b) Characteristics of the product
c) Technologies and methods of control
d) Professional training of specialists
4. The ability of goods to retain their functional purpose during storage/operation is determined by:
a) aesthetics;
b) resource consumption;
c) reliability;
d) functionality.
5. Quality indicators of medicinal products include:**
a) Reception frequency;
b) Stability during storage;
c) maintainability;
d) durability.
6. Name the first stage of commodity analysis of medical and pharmaceutical goods:
a) product marking
b) inspection of goods accompanying documents;

c) barcode verification
d) checking the completeness of the product.

Individual tasks for students of higher education on the topic:

1. Conduct a product analysis of devices for measuring blood pressure.
2. Conduct a trade analysis of temperature measuring devices.

List of recommended literature

The main one

1. Medical and pharmaceutical commodity science: education. manual / O.B. Kalushka, T.A. Groshovyi, A.V. Znaevska, M.B. Demchuk. - Ternopil: TDMU, 2017. p. 149-173.
2. Medical and pharmaceutical commodity science: methodical recommendations for independent work / I. I. Baranova, S. V. Breusova, S. M. Kovalenko and others. - X: National Institute of Scientific Research, 2017. - P. 69-81
3. Pharmaceutical and medical commodity science: texts of lectures for students full-time, part-time and distance education of the Faculty of Pharmacy / L.M. Unguryan, O.A. Stepanova, etc.; under the editorship L. M. Unguryan // – Odesa: ONMeSU, 2020.- 216 p.- Ukrainian language.
4. Pharmaceutical and medical commodity science: educational and methodological manual for students of the pharmaceutical faculty of full-time, correspondence and distance education / L.M. Unguryan, O.A. Stepanova, etc. ; under the editorship L. M. Unguryan // – Odesa: ONMeSU, 2020.- 230 p.- Ukrainian language.

Additional

Pharmaceutical and medical commodity science: an atlas for full-time, correspondence and distance learning students of the Faculty of Pharmacy / L.M. Unguryan, O.A. Stepanova, etc. ; under the editorship L. M. Unguryan // – Odesa: ONMeDU, 2020.- 120 p.- Ukrainian language.

Electronic information resources

1. Order dated 07.12.2012 No. 1008 "On Approval of the Procedure for Certification of the Quality of Medicinal Products for International Trade and Confirmation for Exported Active Pharmaceutical Ingredients" https://zakon.rada.gov.ua/laws/show/z2218-12#Text
2. On approval of the Procedure for quality control of medicinal products during wholesale and retail trade: Order of the Ministry of Healthof UkraineNo. 677 dated 09/29/2014[Electronic resource]. - Access mode:https://www.zakon5.rada.gov.ua/laws/show/z1515-14
3. GOST 5556-81 Medical cotton wool Technical conditions http://helpnik.college.ks.ua/standart/gost/Catalog/Index/13/13732.htm

Topic 2. Packaging, labeling of finished medicines. Clogging agents.

Goal: Familiarize yourself with the basic concepts of commodity analysis of medical and pharmaceutical products. To study the goals, tasks, features, stages and methods of commodity analysis. To form professional knowledge and skills in conducting commodity analysis of various groups of goods.

Basic concepts:

Marking- text, conventional designation (signs) or drawing applied to the packaging and/or product, as well as other auxiliary means intended for identification of the product or its individual properties, providing the consumer with information about the manufacture (performers), quantitative and qualitative characteristics of the product.

Container- a product for placing products for the purpose of their storage or transportation from the supplier to the consumer. A container is a classification unit with a defined geometric shape and structural features. The container performs the functions of packaging independently or together with auxiliary packaging means (capping, sealing and damping elements, labels, etc.)

Consumer packaging- packaging that comes to the consumer with products; does not perform the function of a transport container.

Clogging agent- this product is intended for sealing the packaging and preserving its contents.

Ready-made medicinal products (GLZ, medicinal products, drugs, medicines)– dosed medicinal products in the form of a certain dosage form that have passed all technological stages, including packaging and labeling.

Medicines- substances or their mixtures of natural, synthetic, biotechnological origin, intended for diagnosis, prevention and treatment of human or animal diseases.

Plan

1. Classification of pharmaceutical packaging (primary, secondary, group, consumer and transport), packaging properties.
2. Packaging, labeling and transportation of drugs.
3. Concepts of "container", "container for pharmaceutical use" and "packaging".
4. Classification of containers.
5. Assortment of consumer packaging.

Theoretical questions:

Types of packaging and its functional purpose.

Packaging is classified by purpose, composition and application.

According to the purpose, consumer, transport, production and preservation packaging are distinguished.

Consumer packaging is an integral part of the product, it is included in its value, it reaches the consumer together with the product. Transport packaging is used to transport goods in their consumer packaging or without packaging. The production packaging is not intended for the sale of the product in a retail network. It is used as part of the technology in the organization of the production process. Preservation packaging is used for long-term storage of raw materials, products, devices, hazardous substances, etc.

According to the composition, two types of packaging are distinguished - containers and auxiliary packaging materials.

According to the sign of application, primary (individual), secondary (consumer), group and transport are distinguished.

Primary packaging- comes into direct contact with the medicine or medical product (glasses, ampoules, vials, polymer containers, tubes, blisters, etc.).

Requirements for primary packaging: chemical indifference; gas, moisture and vapor impermeability; strength; resistance to temperature fluctuations; barrier resistance to microorganisms, etc.

*Secondary (group) packaging*may combine primary packaging. It includes cardboard boxes, bags, wrappers, packaging made of polymer material and foil, bags, polymer contour packaging for ampoules, etc. In a number of cases, the secondary packaging creates additional sealing and protection of the primary packaging from the influence of external factors.

The main functions of secondary packaging are to preserve the primary packaging; the possibility of providing the consumer with more complete information about the product; possibility of the most simple and convenient control of product accounting.

Group packing(or block) is a group of primary or secondary packaging and is formed in machines or automatic machines during packaging of products in shrink film, paper, paper bags or cardboard boxes

*Transport packaging*intended for delivery of goods to distribution cities. It should protect the product from rain, sunlight, and mechanical damage. These are wooden polymer or cardboard boxes, containers, bags made of fabric, polymer materials, and kraft paper. Transport packaging, as a rule, does not reach the consumer.

The elements of the retail packaging of the medicinal product are the primary packaging, the secondary packaging and the leaflet containing the officially approved instructions for medical use of the medicinal product. The functions of packaging extend to the entire movement of goods from the producer to the consumer. The packaging ceases to perform its functions at the moment when the buyer removes the goods from it and destroys it.

The main functions of packaging: dosing, protective, transport, storage, marketing, regulatory and legislative, ergonomic, operational, ecological and economic.

*Dosing function*requires the packaging to conveniently accommodate a certain dose of products. The geometric shape of the package should facilitate the process of packaging, a strictly specified number of products, as well as further sealing.

*Protective function*requires packaging to take constructive measures to protect products from mechanical, biotic (deterioration of products due to the interaction of living organisms and products) and abiotic (deterioration of products by components and phenomena of non-living, inorganic nature that directly or indirectly affect living organisms, for example, light, temperature, moisture, air, wind, pressure, etc.) deterioration.

*Transport function*provides an optimal combination of the type of transport packaging with the most rational mode of transport, the route of transportation and the properties of the packaging material. The most important factor is the maximum use of the useful area of the cargo vehicle. The existence of compatible and incompatible packaging materials should be taken into account when assembling a batch of cargo. An important requirement for transport containers is to ensure mechanical strength and durability.

*Storage function*require simple and clear labeling from the packaging design, the possibility of stacking on standard pallets and optimal use of warehouse space.

*Marketing function*presents a set of requirements for shape, size, artistic design, print quality, content of information on the package. The use of symbols, trademarks, trade marks and various information helps to establish a connection between the consumer and the producer.

*Normative and legislative function*provides for a set of unified, established by various regulatory and legislative documents (standards, technical specifications, etc.) requirements for packaging in the areas of its production, receipt of packaged products, transportation, storage, distribution through the retail network, sale, consumption and disposal of used packaging.

*Ergonomic function*provides for the convenience of using the packaging and ensuring the dosage of the drug during its consumption, conditions the practical use of the contents. This function is especially characteristic for various types of consumer packaging with measuring cups, dosing devices, atomizers and other closures

*Operational*the function presents requirements for the design of packaging, which provides for the features of all stages of the life cycle of packaging products, as well as convenience for the consumer when using the packaged product. One of the most important is the ease of opening, preferably without special additional costs; the exception of falling packaging with spillage or spillage of contents; unavailability of packaging of dangerous products for opening by children, etc.

*Ecological function*packaging has become increasingly important in recent years. As the pace of production increases, there are problems with the destruction of used packaging, which cause the deterioration of the ecological situation. Environmental problems of used packaging are solved in different ways: collection and processing by traditional methods; the use of polymer materials that can dissolve and be recycled in the solution; incineration using filters and devices that capture harmful volatile products.

*Economic function*packaging is determined by its cost, as well as the price of operation and the price of disposal. The cost of packaging depends on the materials used, as well as on the production technology. For example, paper is cheaper than glass and metal, but the latter are easily melted, shaped or stamped.

Questions for self-control:

1. Tell us about the classification of consumer packaging.
2. Name the main functions of packaging.
3. Describe the range of consumer packaging for medical products.
4. Name the requirements for polymer containers.
5. Name the requirements for paper packaging.
6. Name the requirements for metal containers.

Practical task 1. Classify containers according to various classification features.

No	A sign of classification	Types of containers
1.	By functional purpose	
2.	By frequency of use	
3.	According to the material of manufacture	
4.	According to the method of receipt	
5.	By form	
6.	By the ability to keep the original shape	
7.	By capacity	
8.	By functional purpose	
9.	By number of uses	

10.	According to the material of manufacture	

Practical task 2. Determine the registration number, number of dosage forms and dosage of the proposed drug

Name GLS	**Registration number**	**The number of dosage forms**	**Amount of dosage**
VIBURKOL suppositories No. 6 (Biologically Heilmittel Heel GmbH, Germany)			
PROTEFLAZID® drops of 10 ml, 30 ml, 50 ml in a glass bottle (NVK Ecopharm LLC)			
FORTRANS® powder for oral solution (BEAUFOUR IPSEN INDUSTRIES, France)			

Test tasks for self-control:

1. The functional purpose of the container can be:
a. Single and reusable;
b. Metal and glass;
c. Full and nominal;
d. Transport and consumer.
2. One of the types of sealing means is a cork:
a. It is screwed onto the tube;
b. It is inserted into the neck of the bottle;
c. It is worn or screwed onto the rim of the container neck;
d. It is fixed around the rim of the container neck.
3. According to the method of production, packaging materials are:
a. Sheet, film, corrugated;
b. Paper, cardboard, polymer, metal, combined;
c. extruded, cast, pressed;
d. For loose, tableted products.
4. The main functions of marking are:

a. protective, airtight;
b. maintaining quality;
c. Ecological and aesthetic;
d. Informative, identifying, motivational and emotional.

5. Consumer labeling is used for:

a. For the transportation of products, methods of handling the goods during transportation;

b. Designation of different types, types, brands of products and their compliance with GOSTs and Technical Specifications.

Individual tasks:

1. Conduct a trade analysis of the modern packaging of the medicinal product ZARSIO® solution for injections or infusions, 48 million units/0.5 ml

2. Analyze the labeling of the medical product packagingTest strip Home Test for determining pregnancy No. 1

List of recommended literature

The main one

1. Medical and pharmaceutical commodity science: education. manual / O.B. Kalushka, T.A. Groshovyi, A.V. Znaevska, M.B. Demchuk. - Ternopil: TDMU, 2017. p. 149-173.

2. Medical and pharmaceutical commodity science: methodical recommendations for independent work / I. I. Baranova, S. V. Breusova, S. M. Kovalenko and others. - X: National Institute of Scientific Research, 2017. - P. 69-81

3. Pharmaceutical and medical commodity science: texts of lectures for students of the pharmaceutical faculty of full-time, part-time and distance learning / L.M. Unguryan, O.A. Stepanova, etc.; under the editorship L. M. Unguryan // – Odesa: ONMeSU, 2020.- 216 p.- Ukrainian language.

4. Pharmaceutical and medical commodity science: educational and methodological manual for students of the pharmaceutical faculty of full-time, correspondence and distance education / L.M. Unguryan, O.A. Stepanova, etc. ; under the editorship L. M. Unguryan // – Odesa: ONMeSU, 2020.- 230 p.- Ukrainian language.

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Electronic information resources:

1. On approval of the Procedure for examination of registration materials for medicinal products submitted for state registration (re-registration), as well as examination of materials on making changes to registration materials during the validity of the registration certificate: Order of the Ministry of Health of Ukraine dated August

26, 2005. No. 426 (with changes) [Electronic resource] – Mode of accesshttps://zakon.rada.gov.ua/laws/show/z1069-05#Text
2. On medicinal products: Law of Ukraine No. 123/96 dated 04.04.1996[Electronic resource]. - Access mode:https://www.zakon3.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80
3. On the approval of the Procedure for labeling medicinal products in Braille: NDecree of the Ministry of Health of Ukraine dated August 25, 2010 No. 722,[Electronic resource]. - Access mode:https://www.zakon.rada.gov.ua/laws/show/z1044-10.

Topic 3. Commodity analysis of transport containers.

Goal:classify the main types of transport containers, analyze materials for the manufacture of transport containers; work out the requirements for polymer, metal and paper containers, graphic symbols in the labeling of transport containers;

Basic concepts:

Transport container— a container that forms an independent transport unit in which products are transported and stored in the process of movement from the producer to the consumer.

Type of container— a classification unit that defines containers by material and construction.

Standard container size— a type of container of the same size.

Disposable container— packaging intended for one-time use.

Collapsible container— a multi-turn container, the design of which allows you to disassemble it into separate parts and reassemble by connecting all the elements.

Collapsible container— a multi-turn container, the design and properties of which allow you to disassemble it into separate parts and fold it without disturbing the articulation of the elements.

Combined packaging— a container consisting of an outer (transport) container and one or more units of an inner container inserted into it.

Plan

1. Theoretical questions:

Depending on the type of packaging materials and physical and chemical properties of the products, the following classification of containers is adopted:

- by functions in the process of commodity turnover;
- by frequency of use;
- by affiliation;
- by appointment;
- by manufacturing method;
- by structural features;
- by degree of strength;

• by resistance to external influences;
• by manufacturing material;
• by production technology.

According to the functions performed in the process of commodity circulation, containers are divided into transport, consumer and equipment containers. Transport containers are used for transporting and storing goods. It is an independent transport unit (box, crate, container, etc.).

Container equipment is a product intended for stacking, transportation, temporary storage and sale of goods (for example, a tray, portioned container, etc.).

Depending on the frequency of use, single-use, rotary and multi-turn containers are distinguished.

The container intended for one-time use is called single-use; this is the case for most types of consumer packaging, as well as transport packaging that is subject to disposal after use. The container is reversible and can be reused.

Reusable packaging is intended for repeated use during the delivery of goods, and therefore, as a rule, is subject to mandatory return to the supplier. According to ownership, a distinction should be made between general-use containers (which are not the inventory of any enterprise) and inventory containers (recyclable containers that belong to a specific enterprise and are subject to return to it).

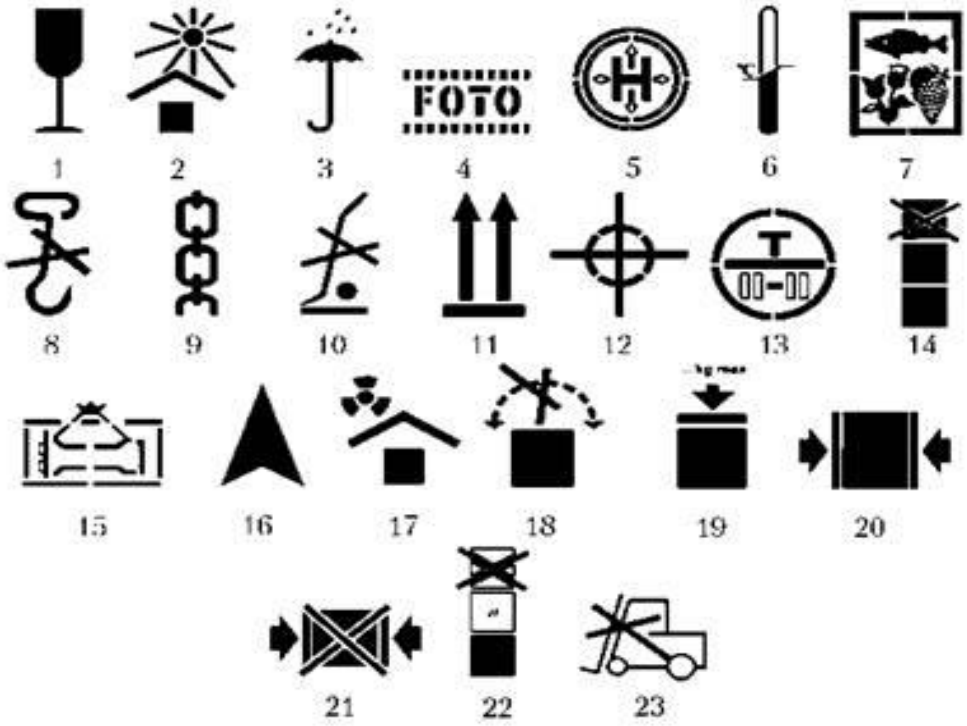
According to the purpose, universal containers are distinguished, which are used for packing various goods, and specialized ones - only for certain goods.

According to the manufacturing methods, there are cooper containers, glued, cast, stamped, welded, etc.

According to the design features, non-collapsible, collapsible, collapsible, collapsible-collapsible, closed, open, and stacked containers are distinguished.

The non-dismantling container consists of non-dismantling, immovably connected parts. The design of the collapsible container allows you to disassemble it into separate parts and reassemble by connecting all the elements.

Practical task 1. Describe the meaning of the proposed transport container markings.



Practical task 2. Specify the main provisions regarding the storage of transport containers.

Test tasks for self-control:

1. What is a container?

a. it is a complex of means that provides protection of goods against damage and loss
b. it is an industrial product intended for packaging, storage, and sale of goods
c. this is a technical tool designed for stacking, transporting and storing goods

2. Rigid packaging is:

a. cardboard container
b. wooden and metal
c. paper

3. According to design features, containers are divided into:

a. non-dismountable, dismountable, continuous
b. disposable, reusable
c. artistic, decorative

4. On the surface and in the thickness of the products, burrs, midges, cracks, chips are not allowed. What type of container does this requirement belong to:

a. polymeric;
b. glass;
c. metal;
d. rubber

5. What does "Möbius strip" mean on the labeling of containers or packaging:

6. a) manufacturer's trademark;

7. b) store away from moisture;
8. c) the possibility of secondary processing of containers;
9. d) do not reuse.

Individual tasks for students of higher education on the topic:

Writing essays

1. Basic technical requirements for transport containers.
2. Describe the storage conditions of transport containers depending on the materials from which they are made.

List of recommended literature

The main one

1. Medical and pharmaceutical commodity science: education. manual / O.B. Kalushka, T.A. Groshovyi, A.V. Znaevska, M.B. Demchuk. - Ternopil: TDMU, 2017. p. 149-173.
2. Medical and pharmaceutical commodity science: methodical recommendations for independent work / I. I. Baranova, S. V. Breusova, S. M. Kovalenko and others. - X: National Institute of Scientific Research, 2017. - P. 69-81
3. Pharmaceutical and medical commodity science: texts of lectures for students full-time, part-time and distance education of the Faculty of Pharmacy / L.M. Unguryan, O.A. Stepanova, etc.; under the editorship L. M. Unguryan // – Odesa: ONMeSU, 2020.- 216 p.- Ukrainian language.
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Electronic information resources:

1. Law of Ukraine "On Protection of Consumer Rights";
2. DSTU EN 980:2007 "Graphic symbols for labeling medical devices";
3. DSTU 3798-98 (IEC 60601-1:1988) Medical electrical products. Part 1. General safety requirements (for active products).

Topic 4."Fundamentals of materials science. Metal materials"

Goal: Work out the classification of the main types of alloys, the properties of metal materials, analyze the areas of application of metal tools according to the material of manufacture; explain the composition of materials and information about the technology

of their production; analyze labeling, packaging, storage conditions and sterilization of materials.

Basic concepts:

Alloy- a combination of two or more metals, in which a substance is formed that has new qualities that are not inherent in any of the components included in the composition.

Alloys of iron with carbon - cast iron and steel - are widely used.

cast iron- alloys of iron with carbon containing more than 2% carbon and other elements (sulfur, phosphorus, silicon, manganese). Obtained by smelting from iron ores in blast furnaces. By purpose, cast iron is classified into:

- Processable (white), intended for processing into steel, have increased hardness and brittleness, are poorly processed and cast, as they are not sufficiently fluid in the liquid state;
- Foundry (grey), endowed with good foundry qualities - fluidity and low shrinkage, easily processed by cutting, well resistant to wear. They make the bases of tables, chairs, crosses, racks, etc.;
- Ultra-strong (modified), for the manufacture of parts subject to significant loads;
- forged (obtained by firing from white cast iron) - endowed with increased plasticity, good mechanical properties and high corrosion resistance;
- Alloyed - contain impurities of non-ferrous metals used for the production of alloyed steels.

Cast iron with a carbon content of 2.6-2.9% is used for medical equipment.

Steel- an alloy of iron with carbon (up to 2% carbon), compared to cast iron, it has great strength, plasticity, and lower hardness.

According to the chemical composition, they are divided into carbon and alloy.

By purpose, there are structural and tool steels.

Copper and its alloys. Copper is resistant to corrosion, does not oxidize easily, can be easily processed by pressure, and is easily stamped.

Brass is an alloy of copper with zinc or zinc with other elements. L62, L63 and LS59-1 brass are used for the manufacture of medical products. The letter "L" is brass, the numbers are the average amount of copper in percent. The zinc content is determined by subtracting 100% - the copper content, for example, in L62 brass, zinc will be 38%.

Brass L62 is used for the manufacture of sterilizers, catheters, probes. L63 - for the manufacture of brackets to be applied to the umbilical cord, mirror frames. LS59-1 - for fittings of syringes, needle cannulas, trocars, etc.

bronze is an alloy of copper with tin and other non-ferrous metals (aluminum, silicon, iron, manganese, etc.). It is divided into tin and non-tin. Fittings for appliances and devices are made of bronze.

nickel silver (НЦС-15-20) - an alloy of copper with zinc and nickel, light, has low thermal conductivity, is used for the manufacture of tracheotomy tubes, cannulas, eye spoons, Voyachek probes, Michel brackets.

*Aluminum and its alloys.*Aluminum alloys with copper, manganese, nickel (duralumin), silicon (silumin), aluminum scrap (secondary foundry alloy) are used.

*Titanium and its alloys.*In terms of strength, titanium corresponds to structural steels, and in terms of corrosion resistance, it is superior to highly alloyed stainless steels.

Strong alloy VT5-1 (5% aluminum, 2.5% tin) - used for tools that are intended for connecting bones.

*Alloy VT-14 (*5% aluminum, 3% molybdenum, 1% vanadium) - used for making clamping tools for microsurgery.

In medical practice, tantalum is used as a suture material (brackets for staplers). Nails for stitching bones are made from vitalium.

Corrosion- this is the destruction of metal as a result of the influence of the external environment on it

1. Theoretical questions:

1. Classification of materials, their properties, scope of application in pharmacy.
2. Metal materials.
3. Ferrous metals and their alloys.
4. Non-ferrous metals and their alloys.
5. Noble and precious metals.

Steel is an alloy of iron with carbon (up to 2% carbon), endowed in comparison with cast iron with great strength, plasticity, and lower hardness.

According to the chemical composition, they are divided into carbon and alloy.

Carbon steels are named after the main element - carbon, which in these steels is no more than 1.35%. With an increase in its content, strength, hardness, elasticity increases and its plasticity, relative elongation and impact strength decrease.

By purpose, there are structural and tool steels.

Structural steels contain carbon in a small amount - 0.06-0.5%, as a result of which they are endowed with plasticity, are well processed by casting, pressure, cutting; suitable for the manufacture of products of complex shape.

Structural steel grades 15, 30, 45, containing 0.15; 0.30 and 0.45% carbon is used for the manufacture of tool handles, parts of devices and apparatus. Some dental instruments are made from steel 45.

Tool carbon steels, due to a higher carbon content (0.65-1.35%) and reduced sulfur and phosphorus content, have significant hardness, wear resistance, as well as strength and plasticity. Therefore, tools made of tool steel are not brittle and do not deform during operation.

According to DSTU 1435-74, these steels are made of quality (grades U7, U8...U13) and high-quality (grades U7A, U8A...U13A), the latter contain less sulfur and phosphorus.

Marks are deciphered as follows:

U - carbon, A - high-quality steel, the numbers indicate the average carbon content in tenths of a percent.

Carbon tool steels U10A, U12A are used for the manufacture of cutting tools (scalpels, knives), U7A - for spring tools.

Alloy steels– in addition to carbon, contain 1 or more specially added alloying elements (chromium, nickel, tungsten, vanadium, titanium, molybdenum, manganese, etc.)

Tool alloyed steels are used for the manufacture of drilling, cutting, measuring and other tools, which are characterized by increased hardness, resistance to wear (tooth burs, milling cutters, etc.).

The following instrument alloy steels are used for the manufacture of medical instruments:

steel 9x18 (0.9% carbon and 18% chromium) - for the manufacture of cutting tools in neurosurgery and ophthalmology,

EI-515 steel (1% carbon, 13% chromium, 1.6% molybdenum);

XV4 steel (4% tungsten), etc.

Corrosion-resistant (stainless) alloyed steels are resistant to acids, salts, sterilizing substances and have a beautiful appearance.

According to GOST 5632-72, chrome stainless steel grades 12x13, 20x13, 30x13, 40x13 are used for medical instruments. The first number indicates the average carbon content in hundredths of a percent, X-chromium, 13 percent chromium content.

Steel grade 20x13 is used for the manufacture of tweezers, hooks, elevators, the axis of pins, lock joints of scissors, nippers.

30x13 grade steel has elastic properties, it is used to make spring tools (clamps, tweezers, needle holders, etc.)

40x13 grade steel has increased hardness, scissors, chisels, reamers, nippers, etc. are made.

Chromium steels are inferior in terms of mechanical and corrosion properties to chrome-nickel steels of the 08X18H9, 12X18H10T brands.

The first number indicates the carbon content in hundredths of a percent, the second - the chromium content in percent, the third - nickel in percent, the letter T indicates the titanium content (1%).

Sterilizers are made from chrome-nickel steels, displacing tools, dental crowns.

*Marking of alloy steels.*An alphanumeric system is adopted for the marking of alloy steels. According to this system, alloyed elements that are in steel are indicated by the initial letters of the Russian alphabet. For example, X is chromium, H is nickel, T is

titanium, K is cobalt, with the exception of some conventionally accepted abbreviations: H is manganese, C is silicon, F is vanadium, and Y is aluminum.

Quantitative content of alloyed elements and carbon are indicated by numbers. The first two numbers in the marking of alloy steel indicate the amount of carbon contained in the steel to the nearest hundredth of a percent.

The amount of carbon less than 0.15% is not indicated in the labeling. The numbers located after the letter that designates the alloying element indicate the quantitative content of this element in percent. The figure is not put in those cases when the quantitative content of the element is less than 1.5%. For example, 2X18N9 steel contains 0.20% carbon, 18% chromium, and 9% nickel.

The marking of high-quality steels ends with the letter "A", for example, 35X1H3MA - a high-quality alloy steel that contains 0.35% carbon, 1% chromium, 3% nickel, up to 1% molybdenum.

Questions for self-control:

1. What is materials science?
2. Specify the classification of materials and describe their properties.
3. Specify the field of application of materials in pharmacy.
4. What are the requirements for quality, marking, packaging, storage conditions, materials?
5. Define "metallic materials" and indicate their classification.
6. Specify the most efficient and rational use of materials, their manufacturing technology.
7. What brands of steel do you know? Determine the iron content in them.

Practical task 1.

Schematically depict the classification of the main types of raw materials for the manufacture of medical and pharmaceutical products.

Practical task2. Decipher the steel markings:

1. 35X1NZMA
2. 9x18
3. 20X13
4. 08X18H9

Practical task 3. Specify the main requirements for materials for the manufacture of medical and pharmaceutical products.

Test tasks for self-control:

1. In medical practice, an alloy of iron and carbon is used, specify the carbon content in steel.

a) more than 2%;

b) up to 2%

c) 1.5%

d) 2.5%.
2. Processing (white) cast irons have:
a) increased plasticity;
b) contain impurities of non-ferrous metals;
c) increased hardness and brittleness;
d) good casting qualities.
3. Alloy steels contain:
) bronze and copper
b) chrome, nickel, tungsten, titanium;
c) cast iron, aluminum;
d) tin
4. Bronze is an alloy:
a) copper and zinc;
b) nickel and copper;
c) copper with tin, etc. non-ferrous metals
d) aluminum and silicon
5. By chemical composition, steels are divided into:
a) structural and alloyed;
b) stainless and instrumental;
c) carbon and alloyed;
d) foundry and chrome.

Individual tasks for students of higher education on the topic:

1. Prepare presentations on the following topics:
2D codes on surgical instruments and devices
Marking of medical products made of thin polymers

List of recommended literature

The main one

1. Medical and pharmaceutical commodity science: education. manual / O.B. Kalushka, T.A. Groshovyi, A.V. Znaevska, M.B. Demchuk. - Ternopil: TDMU, 2017. p. 149-173.
2. Medical and pharmaceutical commodity science: methodical recommendations for independent work / I. I. Baranova, S. V. Breusova, S. M. Kovalenko and others. - X: National Institute of Scientific Research, 2017. - P. 69-81
3. Pharmaceutical and medical commodity science: texts of lectures for students full-time, part-time and distance education of the Faculty of Pharmacy / L.M. Unguryan, O.A. Stepanova, etc.; under the editorship L. M. Unguryan // – Odesa: ONMeSU, 2020.- 216 p.- Ukrainian language.
4. Pharmaceutical and medical commodity science: educational and methodological manual for students of the pharmaceutical faculty of full-time, correspondence and

distance education / L.M. Unguryan, O.A. Stepanova, etc. ; under the editorship L. M. Unguryan // – Odesa: ONMeSU, 2020.- 230 p.- Ukrainian language.

Additional

Pharmaceutical and medical commodity science: an atlas for full-time, correspondence and distance learning students of the Faculty of Pharmacy / L.M. Unguryan, O.A. Stepanova, etc. ; under the editorship L. M. Unguryan // – Odesa: ONMeDU, 2020.- 120 p.- Ukrainian language.

Electronic information resources:

"Technical regulation on medical devices" was approved by the Resolution of the CMU dated October 2, 2013. No. 753.

"Technical regulation on medical devices for in vitro diagnostics" was approved by the Resolution of the CMU dated October 2, 2013. No. 754.

"Technical regulations on active implantable medical devices" approved by the Resolution of the CMU dated October 2, 2013. No. 755.

Also, the labeling of medical products must meet the requirements of the Laws of Ukraine:

Law of Ukraine "On Protection of Consumer Rights";

DSTU EN 980:2007 "Graphic symbols for labeling medical devices";

DSTU 3798-98 (IEC 60601-1:1988) Medical electrical products. Part 1. General safety requirements (for active products).

Topic 5. Rubber, production methods. Production of rubber products.

Goal: work out the classification of rubber, the technological process of manufacturing rubber products, aging of rubber; to be able to use NTD and reference literature on issues of acceptance, quality, storage and release of rubber products.

Basic concepts:

Rubber (lat. Resina-resin) is a product of vulcanization of rubber, which is a composite material - a rubber mixture, containing up to 15-20 ingredients that perform various functions.

Natural rubber is a polymer of plant origin, by vulcanization of which rubber is obtained. Commodity rubber is obtained from the milky juice - latex of Brazilian Hevea, which grows on plantations in Indonesia, Indochina, Ceylon and some African countries. In the Crimea and Central Asia, kok-sagiz is cultivated, which can also be a source of industrial rubber production.

Latex is a milky-white liquid that is a polydisperse colloidal system containing 34-37% rubber, 52-60% water, 2-2.7% proteins, 1.65-3.4% resins, 1.5- 4.2% sugar and 0.2-0.7% mineral salts. The composition of the latex depends on the age of the tree, climatic conditions, and the time of extraction.

Rubber vulcanization is the process of turning rubber into rubber by heating it with ash.

Plan

Theoretical questions:

1. Concept of rubber, its classification.
2. Obtaining rubber and the concept of the technological process of manufacturing rubber products.
3. Aging of rubber and features of storage and restoration of rubber products. Marking, sterilization, disinfection. Rubber testing.
4. Assortment of rubber products.
5. Subjects of patient care.

A large range of medical products is made from rubber: sanitary and hygiene items, patient care, sealing products, X-ray protection products, etc.

The main technical characteristics of any types of natural and synthetic rubber include their operational properties, which are manifested in the process of manufacturing rubber products. The operational properties of rubber include:

1) mechanical properties - tensile strength, wear resistance, tear resistance;
2) set of plasticity characteristics;
3) physical and chemical properties: heat and frost resistance, light,ozone, oil and gasoline resistance, gas impermeability, resistance to the action of aggressive environments, to aging, dielectric properties, specific gravity, etc.

Rubber is obtained from natural or synthetic rubber.

Depending on the various operating conditions in which the rubber retains high elastic properties, the following groups of rubber are distinguished:

1. general purpose, operated at temperatures from 50 to 1500C;
2. heat-resistant, intended for long-term operation at 150-2000C;
3. frost-resistant, suitable for long-term operation at temperatures below -500C;
4. oil and gasoline resistant;
5. resistant to aggressive environments; - radiation-resistant (x-ray protective).

The technological process of manufacturing medical rubber products consists of the following stages:

1. Obtaining a rubber mixture;

2. Production of semi-finished products - this operation is carried out for rubber warmers, ice packs, lining vessels, catheters, tubes;

3. Molding or production of rubber products is carried out by one of the following methods:

The extrusion method (punching, squeezing) is the pushing of a heated rubber mixture through a profiling hole. It is used for the production of medical tubes, harnesses, probes, etc.

Dipping method - a form imitating a product made of wood, porcelain, glass and other materials is immersed in latex. Gloves, pacifiers, thimbles, and condoms are produced by this method.
Form method. This method is used to obtain rubber products that have an internal cavity (warmers, syringes, ice packs, balloons, catheters, etc.) or a complex configuration of different thicknesses.
4. Vulcanization of rubber is the final stage of manufacturing rubber products. All rubber blanks undergo vulcanization for a specified time at a given external pressure. There are two types of vulcanization: hot and cold;
Hot vulcanization of the rubber mixture by heating to a temperature of 130-180 0C is the most acceptable. This process gives rubber a number of valuable properties, for example, increased mechanical strength, elasticity, elasticity, resistance to temperatures, chemical reagents, etc.
5. Post-mould processing, assembly, rejection.
6. Quality control, packaging, labeling

Questions for self-control:

1. Designation of rubber products and patient care items.
2. Empty rubber products obtained by the molding method.
3. Tubular elastic products
4. Elastic products for anesthesia and artificial respiration Products made of latex.
5. Subjects of patient care.
6. Packaging, labeling, storage, transportation.
7. Disinfection and sterilization.

Practical task 1. Classify medical gloves according to classification features and the proposed list of products.

Disposable, anatomical, reusable, surgical, smooth, diagnostic, latex, dental, roller, nitrile, powdered, universal, vinyl, sterile, rollerless, textured, powder-free, polychloroprene, polyisoprene, micro-rough, lubricated with special lubricants, vinyl

Classification sign	Product types
1. According to the material of manufacture	

2. By form	
3. By surface treatment	
4. According to the presence or absence of substances that facilitate putting on gloves	
5. For multiplicity of application	
6. On the presence or absence of a roller	
7. In the presence of prior sterilization	
8. By purpose and areas of application	

Practical task 2. Specify the proposed rubber medical products. Give a description.

Test tasks for self-control:

1Natural latex contains:

a. 42-50% water
b. 42-52% water
c. 42-58% water
d. 52-60% water
e. E. 56-60% water

2. Natural latex contains:

a. 14-24% rubber
b. 15-25% rubber
c. 34-37% rubber
d. 32-42% rubber
e. 44-47% rubber

3. On the warmer with an imprint of engraving on a press form or with marking paint, whether on a shortcut or by a combination of the specified methods, everything must be indicated, for
with the exception of:

a. Trademark
b. Name of the product
c. A type of heating pad
d. Capacities
e. Distributor logo

4. Deviation from the norm for the body of the type B heater and the tube is considered to be:

a. Blurring of individual elements of the picture
b. Deformation of reefs due to the presence of a summer
c. Multicolored in the form of separate points or streaks of a different color, and
d. due to the fading of the ingredients
e. Traces of glue on the sleeve and the inner surface of the neck of the heater
f. Cracks on the surface

5. Heaters in the packaging of the manufacturer must withstand climatic influences during transportation:

a. 0° - +25° C
b. 0° - +50° C
c. -20° - +20° C
d. -30° - +30° C
e. - 50° - +50° C

Individual tasks:

1. Prepare a presentation on the types of surgical gloves
2. Prepare a presentation on the types of baby pacifiers and pacifiers

List of recommended literature

The main one

1. Medical and pharmaceutical commodity science: education. manual / O.B. Kalushka, T.A. Groshovyi, A.V. Znaevska, M.B. Demchuk. - Ternopil: TDMU, 2017. p. 149-173.
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3. Pharmaceutical and medical commodity science: texts of lectures for students full-time, part-time and distance education of the Faculty of Pharmacy / L.M. Unguryan, O.A. Stepanova, etc.; under the editorship L. M. Unguryan // – Odesa: ONMeSU, 2020.- 216 p.- Ukrainian language.
4. Pharmaceutical and medical commodity science: educational and methodological manual for students of the pharmaceutical faculty of full-time, correspondence and distance education / L.M. Unguryan, O.A. Stepanova, etc. ; under the editorship L. M. Unguryan // – Odesa: ONMeSU, 2020.- 230 p.- Ukrainian language.

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Pharmaceutical and medical commodity science: an atlas for full-time, correspondence and distance learning students of the Faculty of Pharmacy / L.M. Unguryan, O.A. Stepanova, etc. ; under the editorship L. M. Unguryan // – Odesa: ONMeDU, 2020.- 120 p.- Ukrainian language.

Electronic information resources:

1.Law of Ukraine 124-VIII,"On technical regulations and conformity assessment"https://zakon.rada.gov.ua/laws/show/124-19#Text

2.On the approval of the Technical Regulation on medical devices: Decree of the Cabinet of Ministers of Ukraine dated02.10.2013 No. 753::http://zakon2.rada.gov.ua/laws/show/753-2013-p

3. DSTU 2909-94 (GOST 3302-95) "Rubber bubbles for ice. Specifications".)http://ksv.do.am/publ/dstu/dstu_2909_94/3-1-0-1112