

**MINISTRY OF DEFENSEHEALTH OF UKRAINE**  
**ODESSA NATIONALMEDICAL UNIVERSITY**  
Department of Pharmacy Organization and Economy  
with post-diploma specialization

**Syllabus of the academic discipline**  
**«Pharmaceutical and medical commodity science»**

<b>Scope of the academic discipline</b>	Total number of hours per discipline: 150 hours, 5 ECTS credits.
<b>Days, time, place of the academic discipline</b>	According to the class schedule. Department of Organization and Economics of Pharmacy with post-diploma specialization Odesa, O. Vadaturskoho St., 37, 2nd floor
<b>Teacher(s)</b>	PhD in Pharmacy, Assoc. Prof. Oksana BIELIAIEVA Senior teacher Oksana STEPANOVA
<b>Contact information</b>	E-mail: oksana.stepanova@onmedu.edu.ua Face-to-face consultations: according to the schedule posted on the department's information stand Online consultations: from 2:30 PM to 5:00 PM every Tuesday. A link to the online consultation is provided to each group separately during class.

**COMMUNICATION**

Communication with higher education applicants will be carried out in-person.

During distance learning, communication is carried out through the Microsoft Teams platform, as well as through email correspondence, Viber messengers (through groups created in Viber for each group, separately through the group leader).

**ABSTRACT OF THE ACADEMIC DISCIPLINE**

*Subject of study of the discipline*– consumer properties of medicines and medical devices, pharmacy assortment, classification and coding, packaging and labeling rules, commodity operations related to the organization, storage and transportation of medicines and medical devices.

*The purpose of studying the discipline*acquisitionhigher education student's acquisition of comprehensive professional competencies in conducting commodity analysis, studying quality requirements and acceptance rules, as well as methods of rational organization of storage of finished medicines and medical devices.

*Discipline objectives:*

1. ensuring understanding of key differences in the product characteristics of various groups of pharmacy assortment based on the systematization of legislative requirements for quality assurance, rules of circulation and state registration of medicines, medical devices, special food products and other pharmacy goods
2. mastering methods for conducting commodity analysis and assessing the quality of finished medicines, medical devices and medical supplies in accordance with current regulations

3. acquiring practical skills in the rational organization of storage of pharmaceutical products, taking into account factors that affect their quality, stability and shelf life
4. development of the ability to monitor product quality, timely identify and withdraw from circulation low-quality, falsified and prohibited for sale by authorized state bodies pharmacy products
5. deepening professional competencies in the field of ensuring the quality of pharmaceutical products and making informed management decisions within the framework of pharmaceutical activities

*Expected results:*

As a result of studying the academic discipline, the applicant must:  
know:

- principles and levels of standardization, types of standards;
- designation of regulatory documentation;
- basic classification approaches to pharmacy products;
- basic concepts and principles of quality management;
- the procedure for state registration in Ukraine of medicines, medical devices, special food products and other pharmaceutical products;
- key differences in the product characteristics of individual groups of pharmaceutical products;
- regulatory documents regulating the circulation of medicines and medical devices in Ukraine;
- rules for rational storage and transportation of medical and pharmaceutical products;
- Pharmaceutical care algorithms when dispensing medical devices and related pharmaceutical products from pharmacies.

*be able to:*

- conduct a commodity analysis of pharmacy products, taking into account current regulatory requirements;
- accept goods and provide a substantiated assessment of their quality in accordance with established standards;
- verify the correctness of labeling of finished medicines and medical devices, including compliance with regulatory documentation;
- distribute received goods to appropriate storage areas and departments in accordance with the requirements of good storage practices;
- conduct incoming quality control of medicines and medical devices in order to identify counterfeit, substandard and prohibited products;
- create and maintain proper storage and transportation conditions for pharmaceutical products in accordance with current standards and GSP (Good Storage Practice) requirements;
- detect violations of storage conditions, prevent the negative impact of external factors on product quality and initiate appropriate corrective actions;
- apply risk management principles in the sphere of circulation of medicines and medical devices to prevent situations that may threaten the quality, safety or effectiveness of pharmacy products;
- apply knowledge of legislation and regulatory documents when making professional decisions in the field of circulation of pharmacy products.

## **DESCRIPTION OF THE ACADEMIC DISCIPLINE**

*Forms and methods of teaching.*

*Forms of study. The discipline will be taught in the form of lectures, practical classes, and the organization of independent work of applicants.*

### ***Teaching methods.***

Lectures: problem lectures, visualization lectures, lectures with analysis of specific situations, discussions.

**Practical classes:** discussion, debate, conversation, discussion of problem situations, role-playing games, solving cases, preparation of necessary documentation and its completion, preparation of reports by applicants.

**Independent work:** work with methodological developments, recommendations, instructions; solving tests, situational tasks; work with recommended basic and additional literature, with electronic information resources, and regulatory legal acts.

### ***Content of the academic discipline***

*Topic 1. Fundamentals of commodity science. Regulatory documentation in the pharmaceutical industry.*

The concept of a product and its consumer value. Definition of the concepts of "product", "assortment of products". Quality of products as the main category of commodity science. The emergence and development of commodity science. The subject of commodity science. The purpose and tasks of commodity science in the system of training pharmacists at the current stage of pharmacy development. Integration of commodity science with other disciplines. Definition of the concept of "standardization". Principles, levels, subjects and objects of standardization. The main goals and tasks of standardization. Definition of the concept of "standard". Types of standards. Designation of regulatory documentation (ND). Structural elements of a national standard, quality control methods (MCQ). Rules for the construction and presentation of technical specifications (TU). Requirements for the designation of standards and technical specifications. The procedure for approval and validity of regulatory documentation. Certification. Technical regulations and conformity assessment of medical devices. Registration of medicines.

*Topic 2. Classification of goods. Coding of goods.*

The concept of classification of goods and its categories. Purpose, purpose, features and general rules of classification. Types of classification of goods. Coding systems of goods. Coding system in the commodity nomenclature of foreign economic activity (TN FEA). Barcoding.

*Topic 3. Fundamentals of commodity analysis of pharmacy products.*

Definition of the concepts of "analysis", commodity analysis, "expertise", commodity expertise". Functions, goals and objectives of commodity analysis. Features of commodity analysis of medical and pharmaceutical goods. Main stages of commodity analysis. Requirements for medical and pharmaceutical goods. Main properties of materials (physical, chemical, technological, etc.) that ensure the quality of goods. The concept of commodity operations, their classification and characteristics. Acceptance and release of goods, quality assessment, organization of storage and transportation. The process of movement of goods in the pharmacy chain and commodity operations related to it. The procedure for drawing up contracts with suppliers of medical and pharmaceutical goods. Classification of medical goods depending on storage conditions: by physicochemical properties, method of application, shelf life, types and methods of packaging. and organoleptic quality indicators, requirements for the quality of medical goods.

*Topic 4. Packaging and labeling of medical devices.* Packaging and its functional purpose. Packaging properties. Assortment of consumer packaging for medical devices. Labeling of consumer packaging of medical devices. Information signs on the packaging of medical devices. Labeling structure. DSTU EN ISO 15223-1:2022 "Medical devices. Symbols used for marking on medical devices, labels and accompanying documentation". Requirements for marking of medical devices depending on the safety class.

*Topic 5. Packaging, labeling of finished medicines. Closures.*

Classification of drugs depending on storage conditions: by pharmacological action, physicochemical properties, method of application, shelf life, method of production, aggregate state,

types and methods of packaging and organoleptic quality indicators, requirements for the quality of dosage forms. Packaging and its functional purpose. Classification of drug packaging (primary, secondary, group, consumer and transport) properties of packaging. Packaging, labeling and transportation of drugs. The concepts of "tare", "container for pharmaceutical use" and "packaging". Classification of closures by definition, design features, methods of fastening, materials, methods of production. Requirements for closures (general, special and sanitary and hygienic). Storage. Packaging materials and requirements for them. Classification, assortment. Storage of packaging materials.

*Topic 6. Commodity analysis of transport packaging.*

Classification of packaging. Requirements for containers for pharmaceutical use. Assortment of consumer packaging. Glass, metal and polymer containers and technical requirements for them. Cardboard packaging and technical requirements for it. Types of transport packaging and its purpose. Marking of transport packaging. Basic technical requirements for transport packaging. Storage of packaging. Organization of packaging management. Organization of packaging circulation (multi-turnover packaging, certificate for returned packaging, penalties, report on the movement of packaging). Types and sizes of transport packaging. Classification of transport packaging. Unification of packaging. Transport marking. Basic, additional and informational inscriptions. Manipulation signs. Transport equipment. Technical requirements for transport packaging.

*Topic 7. Fundamentals of materials science. Metallic materials.*

Classification of materials, their properties, areas of application in pharmacy. Classification, composition, properties, information on the technology of their manufacture. Quality requirements. Definition of the concept of "metals", their characteristic properties, classification. Basic requirements for metal materials used for the manufacture of medical devices. Classification of metals and alloys. Physico-mechanical indicators of ferrous and non-ferrous metals. Ferrous metals and their alloys (list and definition). Alloyed steels (definition). Quality indicators of metals and alloys. Classification of steels by the degree of alloying. Corrosion-resistant stainless steels. Non-ferrous metals and their alloys (basic list and definition). Physico-chemical properties of copper and its alloys. Main copper alloys and their grades used for the manufacture of medical instruments. Precious metals (list, properties and use in medicine). Concept of the technological process of manufacturing medical devices. Materials for the manufacture of medical instruments. Concept of corrosion of metals and protection against it.

*Topic 8. Rubber, methods of production. Production of rubber products.*

The concept of rubber. Classification of rubber. Production of rubber. The concept of the technological process of manufacturing rubber products. Aging of rubber. Storage and restoration of rubber products. Requirements for rubber quality, labeling, packaging, storage, sterilization and disinfection.

*Topic 9. Glass, ceramic materials and products made from them.*

Definition of the concept of "glass". Composition and properties of glass. Classification of glass for medical devices by purpose. Ceramic materials (definition, composition and properties). Wood, cardboard, paper, leather and its substitutes. Requirements for the quality of materials, labeling, packaging, storage, sterilization and disinfection.

*Topic 10. Polymeric materials and plastic masses used in pharmacy*

General characteristics of natural and synthetic polymers and plastics based on them (definition, composition). Classification of plastics by purpose and composition. Information on the technology of their manufacture. Composition of plastics and requirements for their functional properties. Application of polymers in pharmacy and medicine. Requirements for the quality of plastic products. Labeling, packaging, storage conditions and sterilization of plastic products.

*Topic 11. Product analysis of medical general surgical instruments.*

Medical classification instruments. Classification of general surgical instruments. Cutting instruments (knives and scalpels, medical chisels, surgical hammers, rasps, medical scissors and saws, bone nippers). Clamping instruments (hemostatic clamps, clamps for temporary vascular crossing, gastric and intestinal clamps, needle holders, forceps, forceps, forceps). Main structural elements. Material used for the manufacture of medical instruments. Testing for corrosion

resistance. Classification. Assortment. Technical requirements. Functional tests. Packaging, labeling, transportation, storage. Methods of determining quality. Sterilization. Rules for acceptance and accounting. Impression instruments (hooks, wound retractors, Buyalsky's spatula, spatulas, etc.). Probing and bouging instruments. Main structural elements. Classification. Assortment. Technical requirements. Functional tests. Packaging, labeling, transportation, storage. Methods of determining quality. Sterilization. Rules for acceptance and accounting.

*Topic 12. Product analysis of special instruments: neurosurgical, ophthalmological and otorhinolaryngological.*

Classification of special instruments by purpose. Neurosurgical instruments. Instruments for opening bone tissues (rotary drill with a set of drills and cutters, wire saw, nippers, bone forceps). Cutting instruments (scissors, hemostats, wound dilators, spatulas, cannulas, bone spoons). Ophthalmic instruments (scalpels and knives, scissors, eye spoons, loops, spatulas, tweezers, impression instruments, probes, Filatov-Martinskovsky set). Otorhinolaryngological instruments. Diagnostic devices, cutting instruments, tracheotomy instruments, ear instruments, auxiliary instruments. Purpose of each group of special instruments. Main elements and design features. Materials used to manufacture special instruments. Classification by purpose. Assortment. Technical requirements. Packaging, labeling, transportation and storage. Methods of determining quality. Sterilization.

*Topic 13. Product analysis of special instruments: urological, obstetric and gynecological.*

Classification of special instruments by purpose. Urological instruments. Catheters, bougies, probes, devices for crushing stones in the bladder and their removal. Obstetric and gynecological instruments. Obstetric instruments, instruments for embryotomy, gynecological instruments, vacuum devices, a set of instruments for abortion. Purpose of each group of special instruments. Main elements and design features. Materials used for the manufacture of special instruments. Assortment. Technical requirements. Packaging, labeling, transportation and storage. Methods of determining quality. Sterilization.

*Topic 14. Product analysis of dental instruments.*

Dental equipment: dental chairs, drills, dental units, flexible sleeves, handpieces. Products for therapeutic dentistry: dental burs, root canal instruments, instruments for filling teeth and removing dental plaque. Filling material. Instruments for surgical dentistry: dental forceps, dental elevators. Auxiliary instruments. Products for orthopedic dentistry and prosthetics: artificial teeth, abrasive instruments, devices for prosthetics.

*Topic 15. Product analysis of technical equipment for traumatology.*

Product types, assortment of tools and equipment used when working with plaster. Instruments for skeletal traction. Instruments used in osteosynthesis. Assortment of medical splints. Classification by purpose of equipment used in traumatology, and technical requirements for it. Product analysis of instruments and equipment for traumatology upon their acceptance. Storage of technical equipment for traumatology.

*Topic 16. Product analysis of suture materials and piercing needles.*

Sutures and their purpose. Classification of sutures. Absorbable sutures: catgut, oxcelon, vicryl, etc. Non-absorbable sutures, linen threads, lavsan threads, horsehair, metal wire, Michel staples. Conditionally absorbable sutures. Product types. Technical requirements for sutures. Sterilization of sutures. Packaging, labeling, transportation and storage of sutures in accordance with standards. Surgical needles. Classification of needles by purpose: surgical, cutaneous, general purpose (thick and thin), ophthalmic, piercing, intestinal (bent, straight, with a flat-oval part), vascular (bent and straight), renal. Product types. Classification of needles depending on their design: by shape, by degree of bend, cross-section and tip, shape of the eye, size. Atraumatic needles. Ligature needles and forks. Symbols of needles. Technical requirements for needles. Packaging, labeling, transportation and storage. Methods of sterilization of surgical needles, forks and ligature needles. Methods of determining quality. Suturing surgical devices.

*Topic 17. Product analysis of instruments and devices for punctures, injections, transfusions and suction*

Assortment of disposable and reusable syringes. Classification of syringes by design and purpose. Injection and puncture-biopsy needles. Infusion and transfusion devices. Technical requirements. Packaging, labeling, transportation and storage. Methods of determining quality. Sterilization. Trocars. Equipment for transfusions, injection and suction

*Topic 18. Product analysis of disinfection and sterilization equipment.*

Concept of disinfection, sterilization and pre-sterilization treatment. Disinfection and sterilization methods used in pharmacy and medicine. Physical methods of disinfection and sterilization (thermal sterilization, sterilization by infrared, ultra-high frequency, ultraviolet radiation, radiation and plasma sterilization) of medical and pharmaceutical products. Chemical methods of disinfection and sterilization of medical products. Agents used for chemical disinfection and sterilization. Sterilization equipment (steam sterilizer, air sterilizer, gas sterilizer, sterilization boxes, etc.). Classification of steam sterilizers: by design, heating method, control. Stationary, portable, double-sided steam sterilizers, etc. Installations for radiation sterilization of medical instruments, suture material and pharmaceuticals with an electron accelerator and gamma rays. Plasma sterilizers. Disinfection equipment (portable boilers, stationary boilers, disinfection chambers, disinfection shower installations, hydraulic controls, "Disinfal" type sprayer, manual sprayers, etc.).

*Topic 19. Product analysis of rubber products and patient care items.*

Purpose of rubber products and patient care items. Hollow rubber products obtained by molding (rubber hot water bottles, rubber ice packs, rubber liners, rubber liners, syringes, rubber irrigation cups, uterine rings, rubber balloons and bellows). Tubular elastic products: gas discharge tubes, catheters and probes. Elastic products for anesthesia and artificial respiration: airways, intubation tubes, oronasal anesthesia masks. Latex products: surgical and anatomical gloves, fingertip gloves, caps for medical pipettes, baby nipples. Patient care items. Packaging, labeling, storage, transportation. Disinfection and sterilization.

*Topic 20. Product analysis of dressing materials and ready-made dressings.*

Bandages and their purpose. Types dressing material: hygroscopic medical cotton wool (ophthalmic, hygienic, surgical), compress, gauze, alignin. Main types of raw materials for obtaining dressing material and requirements for it. Ready-made dressings: non-woven medical bandages, non-sterile and sterile. Modern dressing materials in the treatment of infectious and inflammatory diseases of the skin and soft tissues. Types of adhesive plasters. Conducting commodity analysis (definition of the product type, quality assessment). Laboratory determination of the functional properties of the dressing material (absorbent properties, capillarity, wettability). Packaging, labeling, transportation and storage.

*Topic 21. Ocular optics. Product analysis of devices and tools for the study, correction and protection of the organs of vision.*

Devices and tables for testing visual acuity. Devices for determining eye refraction. Devices and apparatus for testing visual functions. Devices for examining and testing the eye. Ocular lenses: purpose, classification (by nature of optical action, by number of optical zones for correcting ametropia of vision, by purpose). Lenses for correcting eye refraction anomalies (myopia, hyperopia, astigmatism). Lenses for presbyopia and convergence anomalies (strabismus). Technical requirements for ocular lenses, marking, packaging, transportation, storage. Methods for determining the type, sign and optical power of a lens. Eyeglass frames: purpose, classification (by rim shape, by materials, by earpiece type), technical requirements. Protective glasses: purpose, classification, technical requirements for glass and frames. Devices for controlling vision correction devices (dioptrimeter, centriscope). Technical requirements for ophthalmic devices, packaging, transportation. Prescriptions for glasses. Selection of glasses. Latin terms used when writing a prescription for glasses. Contact lenses: classification, marking, packaging, storage.

*Topic 22. Product analysis of related products in the pharmacy assortment.*

Mineral waters. Classification. Requirements for mineral waters. Packaging, labeling, transportation and storage of mineral waters. Rules for accepting mineral waters. Determination of organoleptic indicators. Requirements for labeling and advertising of special food products.

Definition, classification and characteristics of baby food products. State regulation of the production and circulation of baby food products. Packaging, labeling and certification of baby food products. Pharmaceutical care when choosing baby food products. Cosmetics. Classification of cosmetic products. Technical regulations for cosmetic products dated January 20, 2021 No. 65. General requirements for cosmetics. Packaging, labeling and storage of cosmetic products. Special food products, classification and characteristics. Classification, storage, labeling of essential oils. Disinfectants. Assortment. Release form. Packaging, labeling, transportation and storage of disinfectants. Repellents. Classification, labeling, storage. pharmaceutical care when dispensing repellents. Storage of medical leeches and care for them. oral care products. Toothbrushes, toothpastes, mouthwashes and irrigators. Pharmaceutical care when dispensing oral care products.

*Topic 23. Oxygen, nitrous oxide used in medicine. Product analysis of oxygen, respiratory and anesthetic equipment.*

Medical oxygen. Requirements for the quality of medical oxygen. Medical oxygen passport. Oxygen cylinders and oxygen pillows (assortment, marking, technical requirements, storage). Acceptance of oxygen cylinders and their return to the supplier. Reducer. Disinfection of oxygen pillows and mouthpieces after their use. Safety rules when working with oxygen. Accounting for released oxygen. Nitrous oxide. Acceptance of nitrous oxide cylinders from the supplier. Release of nitrous oxide by warehouses. Procedure for using nitrous oxide in cylinders in medical institutions. Storage and transportation of nitrous oxide cylinders. Oxygen-respiratory and anesthetic equipment: oxygen concentrators, oxygen inhalers and inhalation anesthesia devices. Product identification operations when accepting oxygen-respiratory and anesthetic equipment.

*Topic 24. Product analysis of inspection, endoscopy and introsopic devices.*

Product types, assortment of instruments for examination, endoscopy and introscopy. Classification of instruments for examination, endoscopy and introscopy by purpose. Methods of disinfection and sterilization of parts of instruments for examination, endoscopy and introscopy that come into contact with patients. Product analysis of instruments for examination, endoscopy and introscopy upon receipt. Care of instruments and their storage.

*Topic 25. Acceptance of goods at the pharmacy warehouse.*

Acceptance and release of goods, quality assessment, organization of storage and transportation. The process of movement of goods in the pharmacy network and commodity operations related to it. The procedure for drawing up contracts with suppliers of medical and pharmaceutical goods. Acceptance of goods to the pharmacy warehouse by quantity and quality. Release of goods from pharmacy warehouses.

*Topic 26. Organization of storage of medicines and medical devices.*

The main factors that affect the quality of pharmaceutical products. Requirements for drugs and their storage. Quality control, stability and shelf life of drugs. Storage requirements for different groups of drugs depending on their physicochemical properties. Assortment of medical devices. The main factors that affect the quality of medical products. Requirements for medical devices and their storage conditions. Quality control, shelf life.

*Topic 27. Prevention of the circulation of counterfeit medicines in Ukraine.*

Relevance and causes of falsification of medicines. Classification signs of falsification of medicines. Detection of falsified medicines during incoming quality control. Means of protecting packaging and labels of medicines from counterfeiting.

*Topic 28. Product analysis of diagnostic devices.*

Product types, assortment of diagnostic devices and apparatus. Classification of diagnostic devices by purpose. Methods of disinfection and sterilization of parts of diagnostic equipment that come into contact with patients. Product analysis of diagnostic devices upon receipt. Care of devices and their storage. Classification and structure of devices for measuring human blood pressure. Conducting a product analysis of devices for measuring blood pressure in pharmacies. Pharmaceutical care during the sale of devices for measuring blood pressure. Classification of means for controlling human body temperature. Structure of a medical maximum thermometer. Tests and test systems as pharmacy assortment products. Principle of operation, classification

and characteristics of tests for determining pregnancy. Glucometers, characteristics, purpose and principle of action.

*Topic 29. Product analysis of medical equipment.*

Electrotherapeutic equipment. Ultrasound therapy devices. Phototherapeutic equipment. Product types and purpose of medical equipment. Assortment and technical requirements. Methods of disinfection of parts of medical equipment that come into contact with the patient. Product analysis of medical equipment upon receipt (compliance of the device with the accompanying documentation, completeness, integrity of packaging, compliance with labeling). Care of devices and their storage

*Topic 30. Modern medical products.*

Rehabilitation and orthopedic devices. Types of exoskeletons Implantable medical devices and active implantable devices. Biomaterials for implants. Artificial joints, breast implants, hips. Cochlear implants. Modern medical devices and technologies used in ophthalmology. Smart contact lenses. Drug-eluting contact lenses. Remote monitoring systems for progressive diseases. Cybersecurity in medical device quality systems. Safety and ethics.

*List of recommended literature:*

*Main:*

1. Medical and pharmaceutical commodity science: a textbook for students of higher educational institutions / I.I. Baranova, S.M. Kovalenko, D.V. Semeniv and others. - Kharkiv: National University of Physics and Technology: Golden Pages, 2017. - 320 p.
2. Medical and pharmaceutical commodity science: a textbook for students of higher educational institutions / I.I. Baranova, S.M. Kovalenko, Y.O. Bospala, T.V. Dyudyun, S.O. Mamedova. – Kh.: NPhU: Original, 2016.- 304 p.
3. Commodity science at a pharmaceutical enterprise; teaching aids for applicants for higher education of the second (master's) level in the specialty "Pharmacy" / I.I. Baranova, S.M. Kovalenko, S.V. Breusova and others.-Kharkiv: National University of Pharmacy, 2018.-160 p.
4. Gromovyk B. P. Practical course on medical and pharmaceutical commodity science. Part 2. Pharmaceutical commodity science: a textbook for teachers / B.P. Gromovyk, N.B. Yarko, I.Ya. Gorodetska. - Lviv: Prostir M, 2018. -139 p.
5. Medical and pharmaceutical commodity science: teaching manual. / O.B. Kalushka, T.A. Groshovyi, A.V. Znayevska, M.B. Demchuk. - Ternopil: TSMU, 2017. - 484 p.
6. Pharmaceutical and medical commodity science: lecture texts for students of the Faculty of Pharmacy of full-time, part-time and distance learning / L. M. Unguryan, O. A. Stepanova, and others; ed. L. M. Unguryan // – Odesa: ONMeDU, 2020.- 216 p.- Language Ukrainian. Access mode [https://info.odmu.edu.ua/chair/economy\\_pharmacy/files/113/ua](https://info.odmu.edu.ua/chair/economy_pharmacy/files/113/ua)
7. Pharmaceutical and medical commodity science: a practical course for students of the Faculty of Pharmacy of full-time, part-time and distance learning / L. M. Unguryan, O. A. Stepanova, et al.; edited by L. M. Unguryan // – Odesa: ONMeDU, 2019- 136 p.- Ukrainian language.
8. Pharmaceutical and medical commodity science: a teaching and methodological manual for students of the Faculty of Pharmacy of full-time, part-time and distance learning / L. M. Unguryan, O. A. Stepanova, et al. ; ed. L. M. Unguryan // – Odesa: ONMeDU, 2020.- 230 p.- Language Ukrainian.
9. Pharmaceutical and medical commodity science: an atlas for students of the Faculty of Pharmacy of full-time, part-time and distance learning / L. M. Unguryan, O. A. Stepanova, and others; ed. L. M. Unguryan // – Odesa: ONMeDU, 2020.- 120 p.- Ukrainian.
10. Rymarchuk K. M. Fundamentals of pharmaceutical and medical commodity science: educational manual / K. M. Rymarchuk. – Kyiv: Medicine, 2015. – 118 p. : table.

11. Fundamentals of medical and pharmaceutical commodity science: Teaching and methodical manual for higher medical (pharmaceutical) institutions. Approved by the Ministry of Health / O.G. Moroz, Zh.V. Osinska and others. — K., 2018. — 68 p.
12. Medical and pharmaceutical commodity science: methodological recommendations for independent work / I. I. Baranova, S. V. Breusova, S. M. Kovalenko and others. — Kh.: National University of Physics, 2017. — 140 p.
13. Fundamentals of law and legislation in pharmacy: national textbook for students of higher education. / A.A. Kotvitska, I.V. Kubareva, O.O. Surikov and others; edited by A.A. Kotvitska. — Kharkiv: National University of Pharmacy: Golden Pages, 2016. - 528 p. (National textbook).

*Additional:*

1. State Pharmacopoeia of Ukraine / State Enterprise “Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicinal Products”. — 2nd ed. — Supplement 2. — Kharkiv: State Enterprise “Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicinal Products”, 2018. — 336 p.
2. Organization of the activities of pharmacies to provide the population and healthcare institutions with medicines and pharmacy products Part 1: Textbook for full-time students / L.M. Unguryan, O.I. Belyaeva, M. S. Obrazenko and others. // Ed. L.M. Unguryan. — Odessa: Odessa National Medical University, 2020. - 92 p. Language: Ukrainian.
3. Pharmaceutical legislation (Regulatory acts on the organization of the work of pharmacy enterprises. Edited by Dr. of Pharmaceutical Sciences, Prof. T.A. Groshovoi — Ternopil: TSMU, 2013.— 468 p.
4. DSTU, TU, FS, TFS for medical devices.
5. Fundamentals of biological physics and medical equipment: textbook (Higher Medical Institutions I-III grades) / L.F. Yemchik. 2nd ed., revised for students of higher medical institutions of I-III accreditation levels All-Ukrainian Specialized Publishing House "Medicine" 2014.- 392 p. Language Ukrainian.
6. Fundamentals of pharmaceutical law. Album of schemes: a teaching aid for students of higher education. / O. O. Grin.-Uzhgorod: Publishing house of FOP Sabov A.M., 2020. - 211 p.

*Electronic information resources*

1. Legislation of Ukraine [Electronic resource]. - Access mode:<https://zakon.rada.gov.ua/laws>
2. Normative and directive documents of the Ministry of Health of Ukraine [Electronic resource]. - Access mode: [/http:// mozdocs.kiev.ua](http://mozdocs.kiev.ua)
3. State Service of Ukraine for Medicines and Drug Control <https://www.dls.gov.ua/>
4. State Register of Medicinal Products of Ukraine. [Electronic resource]. – Access mode:<http://www.drlz.com.ua/ibp/ddsite.nsf/all/shlist?opendocument>.
5. World Health Organization <https://www.who.int/ru>
6. Medicines of Ukraine. All about medicines and their quality.<https://xn--h1adc2i.xn--j1amh/>
7. Compendium online. [Electronic resource]. – Access mode: <https://compendium.com.ua/bad/>.
8. Weekly "Pharmacy" [Electronic resource]. – Access mode: <https://www.apteka.ua/>.
9. Drug search database [Electronic resource]. – Access mode:<https://tabletki.ua/uk/>.
10. Drug search database [Electronic resource]. – Access mode: <http://likicontrol.com.ua/>.
11. Medscape search database [Electronic resource]. – Access mode: [Medscapehttps://www.medscape.com/pharmacists](https://www.medscape.com/pharmacists).

## EVALUATION

*Forms and methods of current control:*

**Current control:** oral interview, testing, assessment of practical skills, solving situational problems, assessment of activity in the lesson.

**Final control:** Graded test

### Evaluation of current learning activities in a practical session:

1. Assessment of theoretical knowledge on the topic of the lesson:
  - methods: survey, solving a situational problem
  - maximum score – 5, minimum score – 3, unsatisfactory score – 2.
2. Assessment of practical skills on the topic of the lesson:
  - methods: assessing the correctness of performing practical skills
  - maximum score – 5, minimum score – 3, unsatisfactory score – 2.

The grade for one practical lesson is the arithmetic average of all components and can only have an integer value (5, 4, 3, 2), which is rounded using the statistical method.

### Criteria for ongoing assessment in a practical lesson

Rating	Evaluation criteria
Excellent "5"	The applicant is fluent in the material, actively participates in the discussion and solution of the situational/case problem, confidently demonstrates practical skills on the topic of the lesson, expresses his/her opinion on the topic of the lesson
Good "4"	The applicant has a good command of the material, participates in the discussion and solution of a situational/case problem, demonstrates certain practical skills on the topic of the lesson with some errors, and expresses his/her opinion on the topic of the lesson.
Satisfactory "3"	The applicant does not have sufficient knowledge of the material, participates uncertainly in the discussion and solution of the situational/case problem, and demonstrates practical skills on the topic of the lesson with significant errors.
Unsatisfactory "2"	The applicant does not possess the material, does not participate in the discussion and solution of the situational/case problem, does not demonstrate practical skills on the topic of the lesson

Only those applicants who have fulfilled the requirements of the curriculum in the discipline, have no academic debt, and their average score for current academic activity in the discipline is at least 3.00 are allowed to take the final test in the form of a Graded test.

### Assessment of students' learning outcomes during final control - differentiated assessment

Content of the assessed activity	Number of points
Answer to theoretical questions.	2
Completion of a practical task with evaluation of the results obtained	2
Solving a situational problem	1

*Template for a Graded test ticket:*

TICKET No. \_\_\_\_\_

1. Classification of medical instruments. General requirements, labeling, packaging, storage. General surgical instruments: classification, characteristics.
2. Mineral waters. Classification. Rules for receiving mineral waters. Packaging, labeling, transportation and storage of mineral waters.
3. Practical task #1. Analyze the proposed prescription for glasses or soft contact lenses. (The prescription is issued during the differentiated test)
4. Practical task No. 2. Conduct a product analysis of the proposed medical instrument in accordance with regulatory documentation. (The instrument is issued during the differentiated assessment)

**Criteria for evaluating the learning outcomes of applicants during final control - differentiated assessment**

<b>Rating</b>	<b>Evaluation criteria</b>
Excellent "5"	The student correctly, accurately and completely completed all the tasks of the examination ticket, clearly and logically answered the questions posed by the examiners. Thoroughly and comprehensively knows the content of theoretical questions, is fluent in professional and scientific terminology. Thinks logically and builds an answer, freely uses the acquired theoretical knowledge when analyzing practical tasks. When solving a situational problem, correctly interpreted the initial data, correctly answered all the questions posed and convincingly substantiated his point of view, could propose and justify an alternative solution to individual issues.
Good "4"	The candidate has sufficiently completed all the tasks of the examination ticket, clearly and logically answered the questions posed by the examiners. He knows the content of theoretical questions sufficiently deeply and comprehensively, possesses professional and scientific terminology. He thinks logically and builds an answer, uses the acquired theoretical knowledge when analyzing practical tasks. However, when presenting some questions, he lacks sufficient depth and argumentation, and makes minor errors that are eliminated by the candidate himself when the examiner points them out. When solving a situational problem, he made minor errors or inaccuracies in the interpretation of the initial data, answered all the questions posed without significant errors, fully substantiated his point of view, but the proposal of an alternative option caused difficulties.
Satisfactory "3"	The student incompletely completed all the tasks of the examination ticket, the answers to additional and leading questions are unclear, vague. Possesses the main volume of theoretical knowledge, inaccurately uses professional and scientific terminology. Experiences significant difficulties in constructing an independent logical answer, in applying theoretical knowledge when analyzing practical tasks. There are significant errors in the answers. When solving a situational task, he interpreted the initial data incorrectly, made inaccuracies in the answers to the questions, did not justify his answers and interpreted the wording correctly enough, experienced difficulties in completing the tasks and proposing alternative options.
Unsatisfactory "2"	The student did not complete the exam paper task, in most cases did not answer the examiners' additional and leading questions. Did not master the basic theoretical knowledge, showed a low level of proficiency in professional and scientific terminology. The answers to the questions are fragmentary, inconsistent, illogical, cannot apply theoretical knowledge when analyzing

	practical tasks. There are a significant number of gross errors in the answers. When solving a situational problem, could not interpret the initial data, or made significant errors in the answers; could not justify their decisions or did so unconvincingly. Did not offer alternative options.
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### **INDEPENDENT WORK OF HIGHER EDUCATION STUDENTS**

Independent work with recommended basic and additional literature, with electronic information resources, preparation for practical classes, preparation of reports.

The independent work of applicants consists of studying the material, as well as preparing for the performance and defense of practical work, preparing for current and final control, taking practice tests, and searching for information from literary sources and the Internet.

### **ACADEMIC DISCIPLINE POLICY**

#### *Deadline and resubmission policy:*

- Missed classes for non-respectable reasons are made up according to the schedule of the teacher on duty.
- Absences for valid reasons are made up according to an individual schedule with the permission of the dean's office.
- Recalculation of an unsatisfactory grade is carried out on consultation and practice days; in distance learning - on dates determined and agreed upon with the teacher.

#### *Academic Integrity Policy:*

It is mandatory for applicants to maintain academic integrity, namely:

- independent performance of all types of work, tasks, and forms of control provided for by the work program of this academic discipline;
- references to sources of information when using ideas, developments, statements, information;
- compliance with the norms of legislation on copyright and related rights;
- providing reliable information about the results of one's own educational (scientific) activities, research methods used and sources of information.

The following are unacceptable in educational activities for participants in the educational process:

- using family or work connections to obtain a positive or higher grade when exercising any form of control over academic performance or academic merit;
- use of prohibited auxiliary materials or technical means (cribs, notes, micro-headphones, telephones, smartphones, tablets, etc.) during control measures;
- passing procedures for monitoring learning outcomes by proxy persons.

For violation of academic integrity, students may be held accountable for the following academic responsibilities:

- decrease in the results of individual survey evaluation, test tasks, scores for solving situational tasks, individual task completion, test scores, etc.;
- re-taking the assessment (test tasks, situational tasks, individual tasks, test, etc.);
- assigning additional control measures (additional situational tasks, individual tasks, tests, etc.);
- conducting additional verification of other works authored by the infringer.

#### *Attendance and tardy policy:*

Health status: applicants with acute infectious diseases, including respiratory diseases, are not allowed to attend classes. Lateness to classes is not allowed. An applicant who is late for a class may attend it, but if the teacher has marked it "NB" in the journal, he must complete it in the general order.

#### *Using mobile devices:*

The use of any mobile devices is prohibited. If this clause is violated, the student must leave the class and the teacher will put a "nb" in the log, which he must work out in the general order.

Mobile devices may be used by students with the permission of the instructor if they are needed to complete the assignment.

*Behavior in the audience:*

The behavior of applicants and teachers in the classrooms must be professional and calm, strictly complying with the rules established Regulations on academic integrity and ethics of academic relations at Odessa National Medical University, in accordance with Code of Academic Ethics and University Community Relations of Odessa National Medical University, Regulations on the prevention and detection of academic plagiarism in the research and educational work of higher education students, scientists and teachers of Odessa National Medical University.