

Odessa National Medical University
International Faculty
Department of Organization and Economics of Pharmacy

Syllabus course
Pharmaceutical and Medical commodity science

Volume	The volume of the academic discipline is 4 ECTS credits, 120 hours, of which 50 hours are telephone work with the teacher (lectures - 20 hours, practical classes - 30 hours), independent work of students - 70 hours
Semester, year of study	VII semester of the 4th year of study
Days, time, place	Scheduled Department of Organization and Economics of Pharmacy
Teacher (s)	Prof. Unhurian Liana Mikhailivna Sen.teacher Stepanova Oksana Anatolyevna
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Workplace	st. Malinovskogo, 37, Department of Organization and Economics of Pharmacy, room 212
Consultations	Consultations are held on Tuesdays from 14:30 to 16:00 and Saturdays from 9:00 to 13:00 according to the approved schedule

COMMUNICATION

Communication with students can be carried out by E-mail of the discipline teacher; Microsoft Teams and Zoom platforms; messengers Viber, Telergram, WhatsApp.

ANNOTATION OF THE COURSE

The subject of study of the academic discipline are the consumer properties of medicines, medical devices and parapharmaceuticals, their assortment, classification and coding, packaging and labeling rules, commodity operations associated with the organization of their transportation and storage.

Prerequisites and post-requisites of the course (Place of discipline in the educational program):

Interdisciplinary connections in the study of the academic discipline "Pharmaceutical and Medical Commodity Science" are based on general knowledge from such academic disciplines as "Introduction to Pharmacy", "Pharmaceutical Law and Legislation", "Fundamentals of Economics", "Technology of Drugs", "Ethics and Deontology in Pharmacy" , "Information Technologies in Pharmacy ".

The discipline lays the foundations for students to study pharmaceutical management and marketing, organization and economics of pharmacy, pharmacoeconomics, social pharmacy, providing for the integration of teaching with these disciplines to form the ability to apply knowledge of pharmaceutical and medical commodity science in the process of further education and in professional activity.

purpose of the course

The purpose of teaching the discipline "Pharmaceutical and Medical Commodity Science" is to train pharmacy workers and employees of the Medtekhnika system to perform professional commodity science functions related to providing medical institutions and the population with medicines and medical products, as well as training pharmacists in the skills of handling medical tools, devices and equipment.

discipline task:

The main tasks of studying the discipline are: assistance in the formation of professionally necessary knowledge, skills and abilities in accordance with the educational and qualification characteristics; providing a theoretical basis for further study of other pharmaceutical and economic disciplines of the curriculum; creation of a base that determines the professional competence and general erudition of pharmacists.

Expected results:

Program results (PLO) of instruction for discipline:

PLO 2. Apply knowledge of general and special disciplines in professional activities.

PLO 12. Analyze information obtained as a result of scientific research, generalize, systematize and use it in professional activities.

PLO 17. Use data from clinical, laboratory and instrumental studies to monitor the effectiveness and safety of medicinal products.

PLO 19. To predict and determine the influence of environmental factors on the quality of medicines and consumer characteristics of other goods in the pharmacy range during their storage.

PLO 20. To carry out a complex of organizational and managerial measures to provide the population and institutions of protection of doorways with medicines and other goods of the pharmacy range. Maintain records in pharmacies, administrative records, merchandise analysis processes.

PLO 24. Plan and implement professional activities based on the regulatory legal acts of Ukraine and recommendations of good pharmaceutical practices.

PLO 25. Promote health preservation, in particular disease prevention, rational prescription and use of medicines. To fulfill their professional duties in good faith, to comply with the norms of legislation regarding the promotion and advertising of medicines. Possess psychological communication skills to achieve trust and understanding with colleagues, doctors, patients, consumers.

PLO 27. Justify the technology and organize the production of drugs at pharmaceutical enterprises and draw up technical documentation for the production of drugs at pharmaceutical enterprises.

PLO 29. Ensure a competitive position and effective development of pharmaceutical organizations on the basis of research work on all elements of the marketing mix.

PLO 32. Determine the main organoleptic, physical, chemical, physicochemical and pharmacotechnological indicators of medicines, substantiate and choose methods for their standardization, carry out statistical processing of the results in accordance with the requirements of the current State Pharmacopoeia of Ukraine.

DESCRIPTION OF THE COURSE

Forms and methods of teaching

The course will be presented in the form of lectures (20 hours) and practical classes (30 hours), organization of students' independent work (70 hours). Problematic presentation, case studies, discussions, electronic (review, problem) lectures, presentations, business games, classes with the use of computer technology (situational tasks, test tasks) are used as teaching methods.

Content of the academic discipline

Topic № 1... Theoretical foundations of commodity science. Normative documentation in commodity analysis.

Topic № 2. Classification of goods. Product coding.

Topic № 3. Fundamentals of commodity analysis of medical and pharmaceutical products. Packaging, labeling and transportation of medical products.

Topic №4. Packaging, labeling and transportation of finished medicines. Tara. Closures for finished pharmaceutical products and parapharmaceutical products.

Topic № 5. Commodity research analysis of shipping containers.

Topic №6. Fundamentals of Materials Science for Medical and Pharmaceutical products.

Topic № 7. Metallic materials used in medicine and pharmacy.

Topic № 8. Commodity analysis of general surgical instruments: cutting, clamping, impression, probing and buzzing.

Topic № 9. Commodity analysis of special instruments: neurosurgical, ophthalmological and otorhinolaryngological.

Topic № 10. Commodity analysis of special instruments: urological, obstetric and gynecological.

Topic № 11. Commodity analysis of equipment for dentistry.

Topic № 12. Non-metallic materials used in medicine and pharmacy. Glass, ceramics and products from them.

Topic № 13. Non-metallic materials used in medicine and pharmacy. Rubber and rubber products. Commodity analysis of rubber products and patient care items.

Topic №14. Polymer materials and plastics used in pharmacy.

Topic №15. New directions in improving the consumer properties of pharmaceutical and medical products.

Topic № 16. Commodity analysis of suture materials and piercing surgical needles.

Topic № 17. Commodity analysis of instruments and apparatus for punctures, injections, transfusions and suction

Topic № 18. Commodity research analysis of goods of a limited range of pharmacy.

Topic №19. Spectacle optics. Commodity analysis of devices and means for research, correction and protection of the organs of vision.

Topic № 20. Commodity analysis of technical means for traumatology.

Topic №21. Commodity analysis of equipment for disinfection, pre-sterilization treatment and sterilization.

Topic № 22. Commodity research analysis of dressings and ready-made dressings.

Topic № 23. Oxygen, nitrous oxide, which are used in medicine. Commodity analysis of oxygen, respiratory and anesthetic equipment.

Topic № 24. Acceptance of goods at the pharmacy warehouse. Organization of storage of medicines and medical devices.

Topic № 25. Commodity analysis of technical equipment for laboratories and pharmacies.

Topic № 26. Commodity analysis of laboratory and pharmaceutical glass, products from it. Pharmacy equipment and means of small-scale mechanization

Topic № 27. Commodity analysis of technical means for the diagnosis of diseases.

Topic №28. Protection of the pharmaceutical market from counterfeit, sub-standard drugs and medical devices.

Topic № 29. Devices for examination, endoscopy and introscopy.

List of recommended literature

basic:

1. Pharmaceutical and medical commodity science: texts of lectures for students international faculty of full-time correspondence and distance learning /L. M. Unhurian, O.A. Stepanova, and others. ; for order. LM Unhurian // - Odessa: ONMeDU, 2019.- 107 pp.- Engl. lang. Access mode https://info.odmu.edu.ua/chair/economy_pharmacy/files/113/en

2. Pharmaceutical and medical commodity science: educational and methodical manual for students of the international faculty of full-time, part-time and distance learning Unhurian L.M., O.A. Stepanova, and others. ; for order. LM Unhurian // - Odessa: ONMeDU, 2020.- 130 pp.- Engl. lang.

3. Pharmaceutical and medical commodity science: atlas for students of the international faculty of full-time, part-time and distance learning L. M. Unhurian, O.A. Stepanova, and others. ; for order. LM Ungurian // - Odessa: ONMeDU, 2020.- 120 pp.- English lang.

4. Guide to Federal Pharmacy Law, 9-th Edition 9th Edition by Barry S. Reiss & Gary D. Hall (Author) 2015.

5. Pharmaceutical Packaging Technology 1st Edition by D. A. Dean (Editor), E. R. Evans (Editor), I. H. Hall (Editor) 646 p. 2014

6. Packaging of Pharmaceuticals and Healthcare Products / H. Lockhart, F. A. Paine. – London: Blackie academic& Professional - 230 p. 2017.
7. Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements: ISO 15223-1:2012– 23 p.
8. Pharmaceutical Law and Legislation: the textbook for applicants for higher education / A.A. Kotvitskaya, I.V. Kubarieva, A.V. Volkova et al. Kharkiv: NUPh : Golden Pages, 2019.204 p.

Further reading:

1. Good pharmacy practice in community and hospital pharmacy settings
<http://apps.who.int/medicinedocs/documents/s21088en/s21088en.pdf>
2. International health systems
http://www.pnhp.org/facts/international_health_systems.php?page=all
3. ISO 13485:2003 Medical devices – Quality management systems [Electronic resource]: 15. 15. Requirements for regulatory purposes. – Retrieved from:
http://www.iso.org/iso/catalogue_detail?csnumber=36786. (Reference date of 10.12.2017).
4. Standarts for quality of pharmacy services
<http://fip.org/files/fip/Statements/latest/Dossier%20004%20total.PDF>
5. Fundamentals of biological physics and medical equipment: textbook (high school I-III r. A.) / L.F. Emchik. - seconded., Rev. for students of higher medical institutions of I-III levels of accreditation All-Ukrainian specialized publishing house "Medicine" 2014.- 392 p. Ukrainian language.

Information resources:

1. European Pharmacopoeia. <https://www.edqm.eu/en/european-pharmacopoeia-ph-eur-10th-edition>
2. U.S. Food and Drug Administration. <https://www.fda.gov/>
3. World Health Organization (WHO) i <https://www.who.int/>
4. European Medicines Agency (EMA) <https://www.ema.europa.eu/en>
5. European Directorate for the Quality of Medicines and HealthCare (EDQM), <https://www.edqm.eu/>
6. Harmonized System (HS) Codes <https://www.trade.gov/harmonized-system-hs-codes>
https://eltident.com/wp-content/uploads/2016/12/41_suturmanual-5.pdf
7. DSTU ISO 780-2001. Package, image labeling for operating with goods.
8. ISO 37:1994, Rubber; vulcanized or thermoplastic — Determination of tensile stress-strain properties.
9. ISO 188:1982, Rubber; vulcanized - Accelerated ageing or heat-resistance tests.
10. ISO 2859-1:1989, Sampling procedures for inspection by attributes — Part 7: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot

inspection. ISO 4648:1991, Rubber, vulcanized or thermoplastic -Determination of dimensions of test pieces and products for test purposes.

11. ISO 7000:1989, Graphical symbols for use on equipment — Index and synopsis.
12. Legislation of Ukraine [Electronic resource]. - Access mode <http://zakon.rada.gov.ua/laws>
13. Normative-directive documents of the Ministry of Health of Ukraine [Electronic resource]. - Access mode: / [http:// mozdocs.kiev.ua](http://mozdocs.kiev.ua)
14. State Service of Ukraine for Medicines and Drug Control <https://www.dls.gov.ua/>
15. Medicines of Ukraine. All about medicines and their quality <https://lick.ukr/>
16. Compendium online. [Electronic resource]. - Access mode:<https://compendium.com.ua/bad/>.
17. Weekly "Pharmacy" [Electronic resource]. - Access mode:<https://www.apteka.ua/>
18. Search base for drugs [Electronic resource]. - Access mode:<https://tabletki.ua/uk/>.
19. Search base for drugs [Electronic resource]. - Access mode:<http://likicontrol.com.ua/>.

EVALUATION

There are various forms of control for classes (oral, written, combined, testing, practical skills, etc.). The results of the academic progress for students exhibited in the form of evaluation on a national scale, 200-point scale, ECTS and have standardized generic assessment criteria:

Criteria for assessing the student's current learning activity

<p>grade "excellent" ("5") grade "excellent" ("5") is given to a student who systematically worked during the term, has showed versatile and deep knowledge of the program content during the graded test, is able to successfully complete the tasks provided for by the program, has mastered the content of the main and additional literature, realized the relationship of individual sections of the discipline, their importance for the future profession, identified creative ability to understand and use educational and program materials, showed the ability to independently replenish and update knowledge; high level of competence (creative)</p>

<p>grade "good" ("4") is given to a student who has revealed complete knowledge of the educational and program materials, successfully completes the tasks provided for by the program, has mastered the basic literature recommended by the program, has shown a sufficient level of knowledge in the discipline and is capable of independently updating and replenishing them in the course of further education and professional activity; the level of competence is sufficient (constructive - variation)</p>

<p>grade "satisfactory" ("3") is given to a student who has revealed knowledge of the basic educational and program materials in the amount necessary for further training and subsequent work in the profession, copes with the tasks provided for by the program, made some mistakes in the answers on the exam and when performing the exam tasks, but has the necessary knowledge to overcome mistakes made under the guidance of a scientific and pedagogical worker; the level of competence is medium</p>

(reproductive).
grade "unsatisfactory" ("2") is given to a student who did not reveal sufficient knowledge of the basic educational and program materials, made fundamental mistakes in performing the tasks provided for in the program, cannot use knowledge in further training without the help of a teacher, could not master the skills of independent work, the level of competence is low (reciprocal-productive).

Current control

Current control is carried out at each practical class through oral questioning or written control. After studying each section, based on the control of theoretical knowledge, practical skills and abilities, the control of the acquisition of practical skills is carried out. The student's current educational activity is assessed in a practical class on a 4-point (traditional) scale.

Final control

The form of the final control is a graded test, which is assessed on a 4-point scale.

A graded test is carried out at the last practical class based on the results of the final interview with the obligatory performance by the student of all types of work stipulated by the work curriculum (subject to attending all classes, receiving a positive assessment to control the development of practical skills) and rated for current educational activities on average not less 3.00.

The means of diagnosing the assimilation of the material is the control of the implementation of practical skills (2 situational tasks), an oral answer to 2 theoretical questions.

The grade received for the answer on the graded test and the average current academic performance in the study of the discipline are used to calculate the arithmetic mean, which is the overall grade for the discipline.

In the student's record book, the teacher enters the grade for the discipline on the traditional and 200-point scale.

A multi-point scale characterizes the actual progress of each student in mastering the academic discipline. The conversion of the traditional grade in the discipline into a 200-point grade is carried out by the information and computing center of the university by the "Contingent" program according to the formula:

$$\text{grade point average (current / by discipline) x 40}$$

national grade	points
«5»	185-200
«4»	151-184
«3»	120-150

ECTS scale

The ECTS rating scale evaluates the achievements of students in the discipline who study in one course of one specialty, according to the points they received, by ranking, namely:

ECTS score	Statistical indicator
"A"	top 10% of students
"B"	next 25% of students
"C"	next 30% of students
"D"	next 25% of students
"E"	the remaining 10% of students

The ECTS scale establishes the student's belonging to the group of the best or worst among the reference group of fellow students (faculty, specialty), that is his rating. When converting from a multi-point scale, as a rule, the boundaries of grades "A", "B", "C", "D", "E" do not coincide with the boundaries of grades "5", "4", "3" on the traditional scale. The "A" grade on the ECTS scale cannot be equal to the "excellent" grade, and the "B" grade - the "good" grade, etc.

Students who have received grades "FX" and "F" ("2") are not included in the list of ranking students. Such students, after retaking, automatically receive an "E" score.

The mark "FX" is given to students who have scored the minimum number of points for the current educational activity, but who are not credited with the final control. Grade "F" is given to students, attended all classroom lessons in the discipline, but did not score an average score (3.00) for the current educational activity and were not admitted to the final control.

Independent work of students.

Independent work in the study of the discipline is provided by methodological developments for the independent work of students, visual teaching aids (presentations, educational films etc.), the information resource of the department, the topic of independent tasks for each task, algorithms for the implementation of practical skills, algorithms for self- and mutual control of knowledge

Independent work of students, which is provided by the topic of the class along with classroom work, is assessed during the current control of the topic in the corresponding practical class. The assimilation of topics that are taken out only for independent work is checked during a graded test.

COURSE POLICY

Deadline and retake policy

Students for education are expected to attend all lectures and practical classes. If they missed classes, it is necessary to make-up them (according to the schedule posted on the information stand of the department and according to the permission of the dean's office, if necessary).

The retake of the control of the acquisition of practical skills is carried out during the semester on an individual basis with the determination of the time of the training.

Retake of unsatisfactory grades is carried out during the term of studying the discipline, provided that the average score for the current educational activity is less than 3.00 (carried out according to the schedule posted on the information stand of the department).

Academic Virtue Policy

Respect for academic virtue by education seekers includes:

- independent fulfillment of educational tasks, tasks of current and final control (current controls and discipline exam) of learning outcomes (for persons with special educational needs, this requirement is applied taking into account their individual needs and capabilities);

- links to sources of information when using ideas, developments, statements, information;

- provision of reliable information about the results of their own (scientific, creative) activities, the research methods used and sources of information.

It is unacceptable in educational activities for participants in the educational process to use prohibited auxiliary materials or technical means (crib notes, earpieces, phones, smartphones, tablets, etc.) during control events.

For violation of academic virtue, education seekers may be held liable for such academic responsibility

- decrease in the results of assessment (control work, exam);
- re-passing the assessment (test, exam);
- appointment of additional control measures (additional individual tasks, control works, tests, etc.).

Attendance policy

Attendance at lectures and practical classes is compulsory. If you are more than 15 minutes late, the lesson is considered missed and requires working out.

Mobile devices

During practical exercises, the use of a smartphone, tablet or other device for storing and processing information is allowed only with the permission of the tutor.

When conducting any form of control, the use of mobile devices and their accessories is strictly prohibited.

Audience behavior

During the classes it is allowed: to leave the audience for a short time, if necessary and with the permission of the teacher; photograph presentation slides; actively participate in the class.

During the lessons it is prohibited: to eat (except for persons whose special medical condition requires another - in this case, medical confirmation is required), smoking, drinking alcoholic and low-alcohol drinks or drugs; use obscene language or use words that offend the honor and dignity of colleagues and faculty; gamble; damage the material and technical base of the university (spoil inventory, equipment;

furniture, walls, floors, litter premises and territories), make noise, shout or listen to loud music in classrooms and even in the corridors during classes.