MINISTRY OF HEALTH OF UKRAINE
ODESA NATIONAL MEDICAL UNIVERSITY
Department of Pharmaceutical Chemistry and Drug Technology

Syllabus of the educational discipline
"Technology of Drugs"

Scope of the educational discipline	Total hours per discipline: 360 hours, 12 credits. Semesters: V - VIII 3, 4 years.
Days, time, place of the academic discipline	According to the schedule of classes. Department of Pharmaceutical Chemistry. Odesa, st. Marshal Malinovskyi, 37.
Teacher (-s)	Docent, PhD. Nataliya Fizor. Docent, PhD. Alyona Zamkova Docent, PhD. Alona Tsisak Docent, PhD. Alona Kovpak Assistants: PhD Holubchyk Khrystyna, Shyshkin Ivan, Lytvynchuk Iryna, Ulizko Igor.
Contact Information	Help by phones: Nikitin Oleksii, senior lecturer of the department +380674851106 Docent, PhD. Nataliya Fizor +380950863908 Docent, PhD. Alyona Zamkova +380507425467 Klyvniak Iryna, senior laboratory assistant 0487779828 E-mail : pharmchemistry@onmedu.edu. ua Face-to-face consultations: from 2:00 p.m. to 5:00 p.m. every Thursday, from 9:00 a.m. to 2:00 p.m. every Saturday. Online consultations: from 4:00 p.m. to 6:00 p.m. every Thursday, from 9:00 a.m. to 2:00 p.m. every Saturday. The link to the online consultation is given to each group during the classes separately.

COMMUNICATION

Communication with applicants will be conducted in the classroom (face-to-face).

During distance learning, communication is carried out through the Microsoft Teams platform, as well as through e-mail correspondence, Viber messengers (through groups created in Viber for each group, separately through the head of the group), Telegram.

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ABSTRACT OF THE EDUCATIONAL DISCIPLINE

Subject of discipline study - the main provisions and trends in the development of pharmaceutical technology in the countries of the world and in Ukraine; assimilation of modern principles of regulatory documentation and production technologies of pharmaceuticals in various dosage forms with the use of new groups of excipients and modern types of equipment in pharmacy and industrial conditions.

Prerequisites: the discipline is based on the study of physics, general and inorganic chemistry, physical and colloidal chemistry, biology with the basics of genetics, medical and pharmaceutical commodity science, good practices in pharmacy, pharmaceutical chemistry, management and marketing in pharmacy, biopharmacy, standardization of medicinal products, technology of medicinal and cosmetic products.

Postrequisites: together with other pharmaceutical disciplines and social sciences, drug technology plays an important role in providing special technological training for professional activities.

Goal - Acquisition by the learner of knowledge and the formation of elements of professional competences in the field of pharmacy and industrial drug technology, acquisitionand improvement practical skills and competencies acquired during the study of previous disciplinesat the university.

Tasks of the discipline:

1. Assimilation of the requirements of current regulatory documents (SPhU, GPP and current orders) for the organization of production activities of pharmacies regarding the manufacture of medicinal products in various dosage forms.
2. Familiarization with the organization of the production of medicinal products in the conditions of pharmaceutical enterprises, in accordance with the requirements of Good Manufacturing Practice (GMP).
3. Use in professional activity of regulatory and legislative acts of Ukraine, requirements of good pharmacy practice (GPP) and good manufacturing practice (GMP) for the manufacture of pharmaceuticals in the conditions of pharmacies and industrial enterprises.
4. The formation of higher education students' knowledge on: theoretical foundations of the technology of manufacturing various types of dosage forms, conducting step- by-step control, ways of improving the technology of dosage forms in pharmacy and industrial conditions.
5. Study of the influence of storage conditions and type of packaging on the stability of dosage forms.
6. Study of industrial equipment, including new devices and automatic lines, modern requirements for the production of dosage forms, including the requirements of the World Health Organization (WHO) for the purity of raw materials, production premises and personnel.

Expected results:

As a result of studying the educational discipline, the applicant must:

- *Know:* requirements of GMP, GRP, other proper pharmaceutical practices and regulatory documents (orders, instructions, etc.) regarding the development and

Department of Pharmaceutical Chemistry and Drug Technology manufacture of medicinal products and the preparation of technological documentation; technology of pharmaceutical drugs; main groups of biologically active substances of medicinal plant raw materials; stability and shelf life of medicinal products; biologically active and auxiliary substances of medicinal forms; pharmaceutical incompatibilities (physical, chemical, pharmacological), methods of their elimination; orders of the Ministry of Health of Ukraine regarding the release of narcotic, poisonous, intoxicating drugs and precursors, know the requirements for containers, sealing means and packaging materials.

Be able:

- Use methods of evaluating quality indicators of pharmaceuticals.
- Carry out the manufacture of medicines from solid dosage form (DF) in the conditions of pharmacies and industry.
- Carry out the manufacture of medicines in soft DF in the conditions of pharmacies and industry.
- Carry out the manufacture of medicinal products in liquid DF in the conditions of pharmacies and industry.
- Carry out the production of sterile non-sterile medicinal products in the conditions of pharmacies and industry.
- Carry out the production of medical preparations under pressure in industrial conditions, TTS and nano- and radiopreparations.
- Develop and formalize technological regulatory documentation for the production (manufacturing) of medicinal products in pharmacies and pharmaceutical enterprises.
- Choose a rational technology, manufacture medicines in various dosage forms according to doctors' prescriptions and orders of medical institutions, prepare them for release. Perform technological operations: weigh, measure, dose various medicinal products by weight, volume, etc.
- To substantiate the technology of production of medicinal products at pharmaceutical enterprises.
- Carry out constant quality control of medicinal products and packaging.
- To study the influence of environmental factors on the stability of medicinal products.
- To be able to reasonably select the necessary auxiliary substances in the composition of the drugs being developed.
- Objectively use the advanced foreign experience of pharmaceutical manufacturers in the technology of drug production in the conditions of pharmacies and industry.
- To comply with the requirements of ethics, bioethics and deontology in the production of medicines.

to master skills:

- Be able to skillfully use pharmacy and industrial equipment in compliance with all safety rules.
- Be able to plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of proper pharmaceutical practices.

- Choose a rational technology for the production of medicinal products in various dosage forms, carry out step-by-step control of medicinal products at each stage of production;
- Assess the quality and stability of semi-finished products and finished products.
- Carry out professional communication in the state language, use oral communication skills in a foreign language, Latin, analyzing specialized texts and translating foreign language information sources.
- To carry out professional activities using information technologies, "Information databases", navigation systems, Internet resources, software and other information and communication technologies.
- Adhere to the norms of communication in professional interaction with colleagues, management, consumers, work effectively in a team.

DESCRIPTION OF THE EDUCATIONAL DISCIPLINE

Forms and methods of education. The course will be taught in the form of lectures (40 hours) and practical classes (170 hours), organization of students' independent work (150 hours).

Teaching methods are used during practical classes: multimedia presentation is used in lectures; in practical classes - educational methodical materials, situational tasks, individual tasks, laboratory equipment, to test acquired knowledge and skills - test and calculation tasks, for independent work a list of necessary literary sources is provided.

Content of the education discipline

Subsection 1. Pharmacy technology of drugs

Topic 1. State regulation of drug production in pharmacies. General issues of drug technology.
Topic2. Solid dosage forms. Production in pharmacies of simple and complex powders with medicinal substances that differ in prescribed quantity, bulk mass and structure of particles.
Topic3. Production of complex powders with poisonous, narcotic and potent substances in pharmacies.
Topic 4. Production of complex powders with colored, odorous and difficult to grind substances.
Topic 5. Production of complex powders with extracts and semi-finished products. Topic 6. Production of herbs collection in the conditions of a pharmacy Topic 7. Liquid dosage forms. Production of concentrated solutions.
Topic 8. Production of liquid medicinal forms by the mass-volume method by dissolving dry medicinal substances and using concentrated solutions.
Topic 9. Special cases of production of aqueous solutions. Drops.
Topic 10. Production of liquid dosage forms by diluting standard pharmacopoeial liquids. Non-aqueous solutions.
Topic 11. HMWC solutions. Colloidal solutions.

Topic 12. Suspensions.
Topic 13. Emulsions.
Topic 14. Infusions and decoctions from medicinal plant raw materials.
Topic 15. Mucus. LDF technology using extracts-concentrates.
Topic 16. Soft dosage forms. Homogeneous liniments and ointments
Topic 17. Heterogeneous ointments
Topic 18. Combined ointments. Creams. Gels
Topic 19. Suppositories. Production of suppositories by the rolling method. Sticks. Pills
Topic 20. Production of suppositories by pouring method
Topic 21. Requirements for the manufacture of sterile and aseptic medicinal products in pharmacies
Topic 22. Solutions for injections
Topic 23. Solutions for injections that require stabilization
Topic 24. Isotonic and infusion solutions. Solutions for injections with thermolabile substances. Suspensions for injections
Topic 25. Ocular dosage forms
Topic 26. Medicinal forms with antibiotics
Topic 27. Children's and geriatric dosage forms
Section 2.Industrial technology of medicines.
Topic 28.Normative documentation in the production of FDF
Topic 29. Requirements for sterile products. Determination of the main indicators of the quality of ampoule glass.
Topic 30. Industrial production of injection solutions.
Topic 31. Industrial production of infusion solutions.
Topic 32. Industrial production of eye, ear and nasal dosage forms.
Topic 33. Theoretical foundations of extraction
Topic 34. Production of tinctures. Alcoholmetry
Topic 35. Production of liquid extracts
Topic 36. Production of thick and dry extracts. Intensification of extraction processes Topic 37. Production of drugs under pressure.
Topic 38. Physico-chemical and technological properties of powders and granules. Topic 39. Production of tablets by the method of direct pressing and with preliminary granulation.
Topic 40. Industrial production of coated tablets. Quality control.
Topic 41. Production of medical capsules.
Topic 42. Industrial production of soft medicines.
Topic 43. Industrial production of suppositories.
Topic 44. Production of plasters and TTS.
Topic 45. Production of nano- and radiopharmaceuticals.

 Recommended literature list:

Main:

1. Pharmacy — based technology of drugs: the manual for applicants of higher education / O. I. Tykhonov , T. G. Yarnykh, O. A. Rukhmakova, G. B. Yuryeva; ed. by O. I. Tykhonov and T. G. Yarnykh. - Kharkiv : NUPh : Golden Pages, 2019. - 488 p.
2. Workbook for Pharmacy-based Technology of Drugs: A tutorial for the 3-rd year Englishspeaking applicants of higher education of “Pharmacy” specialty / T. G. Yarnykh, O. I. Tykhonov, O. A. Rukhmakova, M. V. Buryak, V. V. Kovalyov, I. V. Herasymova - Kh.:NUPh, 2019. - 149 p.
3. Workbook for preparation to the licensed examination “KROK-2” in pharmacy- based technology of drugs: for English-speaking applicants of higher education of specialty “Pharmacy”: Practical aids. For individual work / T. G. Yarnykh, O. A. Rukhmakova, V. V.Kovalyov, M. V. Buryak - Kh.: NUPh, 2017. - 56 p.
4. Tests. Pharmacy-based technology of drugs: A handbook for the out-of-classwork of English applicants/ T. G. Yarnykh, O. I. Tykhonov, O. A. Rukhmakova, G. B. Yuryeva, M. V. Buryak, V.V.; ed. by T.G. Yarnykh. - Kh.: NUPh, 2019. - 156 p.
5. European Pharmacopoeia 8.0 [8th edition] / European Directorate for the Quality of Medicines & HealthCare. - Strasbourg, 2013. - 3638 p.
6. Handbook of Pharmaceutical Excipients, 6th edition / R.C. Rowe, P.J. Sheskey, M.E. Quinn. - Pharmaceutical Press and American Pharmacists Association, 2009. - 521 p.

Electronic information resources

1. www.moz.gov.ua is the official website of the Ministry of Health of Ukraine
2. www.fp.com.ua - the website of the magazine "Pharmacist Praktik"
3. www.provisor.com.ua - the official website of the magazine "Provisor"
4. State Register of Medicinal Products of Ukraine. - [Electronic resource]. - Access mode: http://www.drlz.com.ua/ - as of January 10, 2017.
5. Database "Equalizer" LLC "Business Credit" - [Electronic resource]. - Access mode: http://eq.bck.com.ua/ - as of September 20, 2016.**EVALUATING**

Forms and methods of current control: oral survey, testing, evaluation of practical skills, problem solving.

Current evaluation criteria in practical training

Evaluation	**Evaluation criteria**
“5”	The applicant takes an active part in the discussion of the most difficult questions on the topic of the lesson, gives at least 90% correct answers

	to standardized test tasks, answers written tasks without errors, performs practical work and issued a protocol.
“4”	The applicant participates in the discussion of the most difficult questions on the topic, gives at least 75% correct answers to standardized test tasks, makes some minor mistakes in the answers to written tasks, performs practical work and draws up a protocol.
“3”	The applicant participates in the discussion of the most difficult questions on the topic, gives at least 60% correct answers to standardized test tasks, makes significant mistakes in answers to written tasks, performs practical work and draws up a protocol.
“2”	The applicant does not participate in the discussion of complex questions on the topic, gives less than 60% correct answers to standardized test tasks, makes gross mistakes in answers to written tasks or does not give answers to them at all, does not perform practical work and does not draw up a protocol.

Forms and methods of final control: the applicant is admitted to the exam on the condition that the requirements of the educational program are met and if he received at least 3.00 points for the current educational activity and passed the test control of the "STEP-2" tests with at least 90% (50 tasks).

The test control is held in the Educational and Production Complex of Innovative Technologies of Learning, Informatization and Continuous Education of ONMedU in the last session on the eve of the exam.

Possibility and conditions of obtaining additional (bonus) points: not provided.

INDEPENDENT WORK OF HIGHER EDUCATION ACQUIRES

Independent work involves preparation for each practical session.

EDUCATIONAL DISCIPLINE POLICY

The policy on deadlines and rescheduling corresponds to the general rules at ONMedU. Absences of classes for non-respectable reasons will be worked out according to the schedule of the teacher on duty. Absences for valid reasons are worked out according to an individual schedule with the permission of the dean's office.

Observance of academic integrity by applicants is mandatory, namely: independent performance of all types of work, tasks, forms of control provided for by

Department of Pharmaceutical Chemistry and Drug Technology the work program of this educational discipline; references to sources of information in the case of using ideas, developments, statements, information; compliance with the legislation on copyright and related rights; provision of reliable information about the results of one's own educational (scientific) activity, used research methods and sources of information.

Attendance and Tardiness Policy:

Uniform: a medical gown that completely covers the outer clothing.

Equipment: notebook, pen.

State of health: applicants suffering from acute infectious diseases, including respiratory diseases, are not allowed to attend classes.

A student who is late for a class can attend it, but if the teacher has put "nb" (absent) in the journal, he must complete it in the general order.

Use of mobile devices:

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

Behavior in the audience:

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