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

Syllabus of the educational discipline
"Manufacturing pharmaceutical practice in drug technology"

Scope of the educational discipline	Total hours per discipline: 150 hours, 5 credits. Semesters: IX. 5 years.
Days, time, place of the academic discipline	According to the schedule of classes. Department of Pharmaceutical Chemistry and Drug Technology. Odesa, st. Marshal Malinovskyi, 37. Pharmaceutical faculty
Teacher (-s)	Docent Nataliya FIZOR
Contact Information	Help by phones: Nikitin Olexii, head teacher of the department 067-485-11-06 Klyvniak Iryna, senior laboratory assistant 048-777-98-28 Fizor Nataliya, docent 095-086-39-08 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.

ABSTRACT OF THE EDUCATIONAL DISCIPLINE

Subject of discipline study – is the acquisition of skills in the field of providing high-quality pharmaceutical care to patients, taking into account knowledge of the physical, physico-chemical and chemical properties of drugs, the main patterns of structure-activity dependence, avoiding possible interaction of drugs in the process of their manufacture and use, establishing the good quality of individual medicinal products means, their multi-component mixtures and ensuring their proper storage,

acquiring knowledge of basic methods of synthesis of medicines or extraction from natural raw materials; in the field of pharmaceutical analysis. The process of studying the discipline is aimed at forming elements of the following competencies.

Prerequisites: the discipline belongs to the mandatory disciplines and is based on the knowledge obtained during the study of general disciplines: Latin language, botany, analytical chemistry, pharmacy technology of drugs, pharmacognosy, pharmacology, pharmaceutical chemistry, toxicological chemistry.

Postrequisites: knowledge obtained after completing the study of this discipline is necessary for studying such disciplines as: industrial technology of medicines, biopharmacy, pharmaceutical biotechnology.

Goal – assimilation of the acquirers of the ability to act socially responsibly and civically; consolidation, deepening, expansion of theoretical knowledge on the industrial technology of drugs, as well as acquisition, assimilation and improvement of practical skills and abilities obtained at the university, learn your profession directly in production conditions, get practical work experience.

Tasks of the discipline: acquiring skills in the field of providing high-quality pharmaceutical care to patients, taking into account knowledge of the physical, physico-chemical and chemical properties of drugs, the main laws of structure-activity dependence, avoiding possible interaction of drugs in the process of their manufacture and use, establishing the good quality of individual drugs , their multicomponent mixtures and ensuring their proper storage, acquiring knowledge of basic methods of synthesis of medicines or extraction from natural raw materials; in the field of pharmaceutical analysis. The process of studying the discipline is aimed at forming elements of the following competencies.

Expected results:

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

- *Know:* technology and organize the production of medicines at pharmaceutical enterprises using the necessary equipment; evaluate the quality and stability of semi-finished products and finished products. determine the influence of environmental factors: moisture, temperature, light, etc. on the stability of medicines and medical products; requirements of GMP and other appropriate pharmaceutical practices and regulatory documents (orders, instructions, etc.) regarding the stages of development and industrial production of medicinal products; requirements for containers, closures and packaging materials.
- *Be able:* to carry out professional activities in social interaction based on humanistic and ethical principles; to identify future professional activity as socially significant for human health; apply knowledge from general and professional disciplines in professional activity; use the results of independent search, analysis and synthesis of information from various sources to solve typical tasks of professional activity; argue information for decision-making, bear responsibility for them in standard and non-standard professional situations; adhere to the principles of deontology and ethics in professional activity; perform professional activities using creative methods and approaches; to carry out professional

activities using reference scientific literature, information technologies, "Information databases", Internet resources, software and other information and communication technologies; to use methods of evaluating performance quality indicators; identify reserves for improving labor efficiency; objectively use the advanced foreign experience of pharmaceutical manufacturers in the technology of drug production.

- *to master skills:* skills to improve the technological process, to be able to estimate the losses and output of the finished product, to draw up a material balance and a technological scheme for the production of medicinal products in industrial conditions.

DESCRIPTION OF THE EDUCATIONAL DISCIPLINE

Forms and methods of education. The course will be taught in the form of practical classes (60 hours) and organization of students' independent work (90 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

Topic 1. General acquaintance with the pharmaceutical enterprise; rules of internal procedure. Instruction on the rules of safety and occupational health and safety.
Topic 2. Production of solid dosage forms according to GMP requirements (tablets, granules, dragees).
Topic 3. Production of solid dosage forms according to GMP requirements (capsules in a gelatin shell).
Topic 4. Production of sterile medicinal products according to GMP requirements (medicinal forms for injections in ampoules, vials, infusion solutions in containers, etc.).
Topic 5. Production of soft dosage forms according to GMP requirements (ointments, gels, suspensions, emulsions, suppositories, plasters, etc.).
Topic 6. Production of phytochemicals according to GMP requirements.
Topic 7. Packaging and packaging of finished products.
Topic 8. Acquaintance with the work of the department of quality control of medicinal products and the central factory laboratory.

Recommended literature list:

Basic:

1. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products". — 2nd edition. —

Addendum 1. — Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicinal Products", 2016. — 360 p.
2. Excipients in the production of drugs: training. manual for students higher pharmacy education closing / O.A. Ruban, I.M. Pertsev, S.A. Kutsenko, Yu.S. Oily; under the editorship I.M. Pepper - Kh.: Golden Pages, 2016. - 720 p.
3. Provision, quality control and standardization of medicinal products: Educational and methodological manual / Ed. Professor N. O. Vetyutneva. - Vinnytsia, PP "TD" Edelweiss and K", 2016. - 505 p.
4. Industrial technology of medicines: a basic textbook for students. higher education pharmacy institution (pharmacology) / E. V. Gladukh, O. A. Ruban, I. V. Saiko [and others] - Kh.: NFaU: Original, 2016. - 632 p.
5. Industrial technology of medicines: a basic textbook for students. higher education pharmacy institution (pharmacology) / E.V. Gladukh, O.A. Ruban, I.V. Saiko [and others].; under the editorship E.V. Hladukha, V.I. Chuyeshova - Kind. 2nd, ex. and added - X: National Institute of Scientific Research: Novy svit-2000, 2018. - 526 p.
6. Technological equipment of the biotechnological and pharmaceutical industry: a textbook [for higher education. education closed.] M.V. Stasevich, A.O. Mylianych., L.S. Strelnikov, T.V. Krutskikh, I.R. Buchkevich, O.I. Guziova Zaitsev, I.O., O.P. Strelets ., Gladukh E.V., Novikov V.P. - Lviv: "New World-2000", 2018. - 410 p.
7. Pharmaceutical development as a stage of the creation of medicinal products: a study guide for extracurricular work of third-level higher education students (Ph.D.) / T. G. Yarnykh, O. I. Tikhonov, I. V. Gerasimova, H. M. Melnyk – Kh.: NFaU , 2018. – 38 p.
8. European Pharmacopoeia. 9th edition. Council of Europe, Strasbourg, 2017.
9. Pharmacy-based Technology of Drugs: the manual for students of English-speaking applicants of higher education of “Pharmacy” specialty / – Kh.: NUPh, 2019.

Additional:

1. 1. Baula O. P., Derkach T. M. Quality assurance of medicinal products of herbal origin: state and prospects. Pharmaceutical journal. 2017. No. 2. P.79-78.
2. Medicines. Process validation.ST-N MOZ 42-3.5:2016.– Officer. kind. - K.: Ministry of Health of Ukraine, 2016. - 31 p. – (Instruction of the Ministry of Health of Ukraine).
3. Medicines. Guidelines for the production of finished medicinal products.ST-N MOZ 42-3.4:2020. - Officer. kind. - K.: Ministry of Health of Ukraine, 2020. - 37 p. – (Instruction of the Ministry of Health of Ukraine).
4. Medicines. Good Manufacturing Practice. ST-N MOZU 42-4.0:2020 - Officer. kind. - K.: Ministry of Health of Ukraine, 2020. - 338 p. – (Instruction of the Ministry of Health of Ukraine).
5. Medicines. Principles of good practice for the distribution of active substances for medicinal products for humans. ST-N of the Ministry of Health of Ukraine 42-

5.2:2020 - K.: Ministry of Health of Ukraine, 2020. - 28 p. – (Instruction of the Ministry of Health of Ukraine)
6. Study guide for independent preparation of students of the Faculty of Pharmacy for the licensing test exam "Step - 2. Pharmacy" / edited by I.Yu. Borysiuk, N.S. Fizor, A.V. Zamkova - Odesa.: ONMedU, 2019. – 88 p.
7. Normative and legal regulation of pharmaceutical and biotechnological enterprises: textbook/ M.V. Stasevich [and others]; Lviv Polytechnic, National University of Lviv: Novy svit— 2000, 2018. — 288 p.
8. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. J // Health Econ. - 2016. - Vol. 12; 47. - P. 20-33

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: I*ndependent performance of all types of work, tasks, forms of control provided for by 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.