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

Syllabus of the educational discipline
" MANUFACTURING PRACTICE IN PHARMACEUTICAL CHEMISTRY "

Scope of the educational discipline	Total hours per discipline: 120 hours, 4,0 credits. Semesters: X. 5th year.
Days, time, place of the education discipline	According to the schedule of classes. Department of Pharmaceutical Chemistry. Odesa, st. Marshal Malinovskyi, 37. Pharmacy establishments.
Teacher (-s)	Gelmboldt Volodymyr. doctor of chemical science, professor, head of the department. Docent, PhD. Lozhichevska Tatyana. Senior Lecturer Nikitin Olexii. Assistant Lytvynchuk Iryna.
Contact Information	Help by phones: Nikitin Olexii, head teacher of the department 067-485-11-06 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.

ABSTRACT OF THE EDUCATIONAL DISCIPLINE

Subject of discipline study – familiarization with the pharmaceutical enterprise, the quality control of medicines and the organization of the workplace of the pharmacist-analyst. Production and analysis of titrated and working solutions. Analysis

of medicinal products using chemical and physico-chemical methods and preparation of results in the form of appropriate documentation. Express analysis of dosage forms. Compilation of a report on production practice, design of a diary and compilation of credit and course work.

Prerequisites: inorganic chemistry, organic chemistry, analytical chemistry, pharmacology, physical and colloidal chemistry, pharmacy and drug manufacturing technology, pharmaceutical chemistry and integrates with these disciplines.

Postrequisites: lays the foundations for passing state certification.

Goal – are consolidate and expand theoretical knowledge and practical skills in the chemistry of drugs, their standardization and quality control of drugs and their technological forms, familiarization with the latest drugs that enter the pharmacy; to bring students as close as possible to their specialty, to teach them to use all the theoretical knowledge and practical skills they have acquired in the chemistry of medicinal products in working with medicines and patients, to ensure the rigor and accuracy of quality control of medicines and their dispensing.

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 the basic methods of drug synthesis or extraction from natural raw materials, in the field of pharmaceutical analysis.

Expected results:

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

- *Know:* to know the state policy and state management in the field of creation, production and quality control of medicines; to know chemical formulas, Latin and chemical names of medicinal products, their properties, extraction and synthesis methods; to know the analytical and functional groups that are part of drug molecules and the chemistry of identification reactions; to know the methods of identification reactions, research on purity; to know the methods of quantitative determination of medicinal products; to know the methods of qualitative and quantitative express analysis of medicinal forms; to know the use of medicines in medicine. The connection between the structure and action of drugs;
- *Be able:* be able to independently make titrated solutions from amounts of reagents and fixanals, set the correction factor and titer for these solutions; be able to make reference solutions, solutions of indicators and reagents; to be able to determine the good quality of medicines and dosage forms (presence of impurities of chlorides, sulfates, nitrates, mercury, arsenic, etc.); to be able to determine the solubility of medicines; be able to apply physical and physico-chemical methods of analysis (refractometry, polarimetry, spectrophotometry, chromatography in a thin layer of sorbent) and have skills in working with appropriate equipment; to be able to carry out drug identification reactions by cations; to be able to carry out drug identification reactions by analytical

and functional groups; to be able to carry out quantitative determination of medicinal products by methods of acid-base titration in aqueous and non-aqueous solvents, bromatometry, complexonometry, iodometry, argentometry, etc.; to be able to conduct research on the pharmaco-technological indicators of medicinal products; be able to calculate the results of the analysis (equivalent mass, active substance content, mass deviation); be able to draw a conclusion about the compliance of medicinal products with the requirements of the pharmacopoeial article or QCT; be able to analyze pharmaceutical forms of industrial production (solutions for injections, tablets, ointments, etc.).

- *to master skills:* the ability to abstract thinking, analysis and synthesis, the ability to learn and be modernly educated; knowledge and understanding of the subject area and understanding of professional activity; ability to apply knowledge in practical situations; the ability to communicate in the state language; ability to adapt and act in a new situation; with determination and persistence in relation to assigned tasks and assumed responsibilities.

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 (60 hours).

Teaching methods are used during practical classes: laboratory equipment, reagents, educational methodical materials, situational tasks, individual tasks, test tasks to check acquired knowledge and skills, a list of necessary literary sources is provided for independent work.

Content of the education discipline

Topic 1. Modern methods of pharmaceutical analysis. Classification and characteristics. Peculiarities of pharmaceutical analysis are related to the intended use of drugs and the professional responsibility of the pharmacist. State principles and provisions regulating the quality of medicinal products.

Topic 2. General Pharmacopoeial methods of analysis. General provisions on chemical methods of drug analysis. State principles and provisions regulating the quality of medicinal products. Organization of quality control of medicinal products in Ukraine. State Pharmacopoeia of Ukraine. Modern strategies for creating innovative medicines. Pharmacopoeial analysis.

Topic 3. Testing for the limit content of impurities. Pharmacopoeial reactions for the detection of impurities in medicinal products.

Topic 4. Testing for the limit content of impurities. Analysis of physico-chemical properties of medicinal products as one of the elements of quality assessment of medicinal products. Analysis of purified water. Physical and chemical properties of water.

Topic 5. General principles of identification of medicinal substances. Identification of medicinal substances of inorganic nature. Identification of medicinal substances of organic nature by functional groups (functional analysis).

Topic 6. Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Analysis of concentration of solutions.
Topic 7. Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Analysis of unstable medicinal products.
Topic 8. Analysis of unstable medicinal products, as well as perishable medicinal products. Analysis of 5% alcohol iodine solution.
Topic 9. Analysis of unstable medicinal products, as well as perishable medicinal products. Analysis of aniseed drops.
Topic 10. Peculiarities of pharmaceutical use. analysis in the quality control of medicines manufactured in a pharmacy. Preparation and analysis of dosage forms for injections.
Topic 11. Processing of auxiliary material, personal hygiene of aseptic block workers.
Topic 12. Peculiarities of preparation and analysis of dosage forms for injections. Chemical analysis of 50% analgin solution for injections.
Topic 13. Peculiarities of preparation and analysis of dosage forms for injections. Chemical analysis of 5% aminocaproic acid solution.
Topic 14. Peculiarities of preparation, analysis and storage of children's medicines, including for newborns.
Topic 15. Peculiarities of the use of pharmaceutical analysis in quality control of medicinal products manufactured in a pharmacy. Analysis of 1% glutamic acid solution.
Topic 16. Peculiarities of the use of pharmaceutical analysis in quality control of medicinal products manufactured in a pharmacy. Analysis of dibazole 0.005, glucose 0.2.
Topic 17. Peculiarities of using pharmaceutical analysis in quality control of medicines. Analysis of eye drops. Analysis of 0.25% zinc sulfate solution.
Topic 18. Peculiarities of using pharmaceutical analysis in quality control of medicines. Analysis of alcohol solutions. Calculations, examples.
Topic 19. Peculiarities of using pharmaceutical analysis in quality control of medicines. Qualitative express analysis of medicines.
Topic 20. Quality control and chemical-pharmaceutical examination of plant raw materials.

Recommended literature list:

Basic:

1. Handbook of pharmaceutical chemictry Vol. 117 / L. Ohannesian, Antony J. Streeter. 2016. – 582 p.
2. Pharmaceutical Chemistry I – Laboratory Experiments and Commentary / Attila Almási, Zsuzsanna Rozmer, Pál Perjési. 2014. – 179 p.
3. Introduction to Pharmaceutical Chemical Analysis / S. Hansen, S. Pederson-Bjergaard, K. Rasmussen. 2012. – 496 p.
4. Chemical Analysis Modern Instrumentation Methods and Techniques 2nd Edition / F. Rouessac, A. Rouessac. 2007. – 599 p.
5. Pharmaceutical medicine analysis / Addis Ababa. 2005. – 554 p.

6. Analytical Chemistry Series / John M., Chalmers, Alan J. Handley. 2003. – 384 p.
7. HANDBOOK OF MODERN PHARMACEUTICAL ANALYSIS Vol. 3 / Satinder Ahuja, Stephen Scypinski. 2001. – 587 p.
8. Europian Pharmacopoeia 10th. 2019. – 4255 p.

Additional:

1. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.
2. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.
3. Державна Фармакопея України : в 3 т. / ДП «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Х. : Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 3. – 732 с.
4. Фармацевтична хімія / П.О. Безуглий, В.А. Георгіянц, І.С. Гриценко, І.В. та ін.: за ред. П.О. Безуглого. – Вінниця: Нова книга, 2017. – 456 с.
5. Фармацевтична хімія. Загальна та спеціальна фармацевтична хімія. Лікарські засоби неорганічної природи: лабораторно-практичні заняття. Навчальний посібник / Л.Г. Мішина. – Вінниця: ПП «ТД «Едельвейс і К»», 2010. – 384 с.

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 objective structured practical examination (OSPE) on the condition that he completes all the tasks provided for in the work program of the practice and the instructions of its supervisors, with the timely completion of the reporting documentation in the form of an electronic diary, and if for the current educational activity, he received at least 3.00 points.
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.