

**MINISTRY OF HEALTH OF UKRAINE  
ODESA NATIONAL MEDICAL UNIVERSITY**

**Faculty of Pharmacy, International**

**Department of Pharmaceutical Chemistry and Drug Technology**

**Syllabus of the educational discipline  
"Modern analytical laboratory practice"**

<b>Scope of the educational discipline</b>	Total hours per discipline: 90 hours, 3,0 credits. Semesters: IV. 2 <sup>nd</sup> year.
<b>Days, time, place of the education discipline</b>	According to the schedule of classes. Department of Pharmaceutical Chemistry. Odesa, st. Marshal Malinovskyi, 37.
<b>Teacher (-s)</b>	Senior Lecturer Nikitin Olexii. Assistants: Lytvynchuk Iryna, PhD Holubchyk Khrystyna, Shyshkin Ivan.
<b>Contact Information</b>	Help by phones: Nikitin Olexii, head teacher of the department 067-485-11-06 Klyvniak Iryna, senior laboratory assistant 0487779828 E-mail: <a href="mailto:pharmchemistry@onmedu.edu.ua">pharmchemistry@onmedu.edu.ua</a> 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* – organizational structure and staff of analytical control laboratories, system of receiving samples for research and analysis, testing system, evaluation of test results, rules for storing samples, requirements for reagents and standard samples, instruments and their calibration, safety issues in laboratories.

*Prerequisites and postrequisites of the discipline (the place of the discipline in the educational program):*

*Prerequisites:* is based on knowledge of mathematics, physics and inorganic chemistry.

*Postrequisites:* lays the foundations for the study of analytical, pharmaceutical and toxicological chemistry and provides for the formation of skills in the application of acquired knowledge for the study of special disciplines and in professional activities.

*The purpose of discipline:* is the acquisition by students of the necessary theoretical knowledge and practical ability to apply state and international standards related to the organization of the work of chemical-analytical laboratories for the control of the quality of medicinal products; assessment of suitability of analysis methods, their reproducibility and establishment of uncertainty limits of the obtained measurement results.

*Tasks of the discipline:* to teach students the peculiarities of the production laboratory system, knowledge of state and international standards, assessment of the suitability of analysis methods; the ability to use state and international standards, conducting the necessary chemical-analytical studies, choosing the most suitable methods of analysis, effectively determining the correctness of the obtained measurement results.

*Expected results:*

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

*Know:*

- to know the subject and tasks of modern analytical laboratory practice;
- to know the organization of quality control of finished medicinal products and medicinal substances;
- to know methods of quality improvement and improvement of analysis methods;
- to know the main validation characteristics of analytical control methods;
- to know the features of the unification of quality control methods.

*Be able:*

- to be able to work with regulatory documents to ensure quality control of the work of analytical laboratories;
- to be able to select and prepare samples for analysis;
- to be able to use standard compounds in the development of analysis methods;
- to be able to carry out validation of analytical methods.

## **DESCRIPTION OF THE EDUCATIONAL DISCIPLINE**

*Forms and methods of education*

The course will be taught in the form of practical classes (30 hours) and organization of students' independent work (60 hours).

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

*Content of the education discipline*

Topic 1. The technique of qualitative analysis using the semi-micro method.

Topic 2. Basic operations of qualitative chemical analysis.

Topic 3. Determination of the purity of medicinal substances.

Topic 4. Methods of determining the boiling point, melting point, relative density of a substance and viscosity.

Topic 5. Gravimetric method of analysis. Deposition methods. Distillation methods. Selection methods.

Topic 6. Titrimetric analysis. Requirements for reactions used in titrimetric analysis. Classification of methods.

Topic 7 Concentration of solutions, calculations in titrimetric analysis.

Topic 8. Reagents, reference solutions, buffer solutions.

Topic 9. Initial standard substances for titrated solutions. Titrated solutions.

Topic 10. Non-aqueous titration. Titrants of the method. Methods of fixing the equivalence point.

Topic 11. Classification of physical and physicochemical methods, methods of analysis. Potentiometric methods of analysis.

Topic 12. Voltammetry. Qualitative polarographic analysis. Quantitative polarographic analysis. Amperometry.

Topic 13. Conductometry. Classification of conductometric methods of analysis.

Topic 14. Photometric research methods.

Topic 15. Chromatographic methods of analysis.

Recommended literature list:

**Basic:**

1. State Pharmacopoeia of Ukraine: in 3 volumes / SE "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products". - 2nd edition. - Kh.: State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2015. - Vol. 1. - 1128 p.
2. General requirements for the competence of testing and calibration laboratories: DSTU ISO17025:2006 –DSTU ISO17025:2006– [effective from 2007-07-01]. K.: Derzhspozhivstandard of Ukraine, 2007.–24p. (National standards of Ukraine).
3. Analytical chemistry: teaching. reference manual for students higher education closing / V. V. Bolotov, O. A. Yevtifeeva, T. V. Zhukova, L. Yu. Klymenko, O. E. Mykytenko, V. P. Moroz, I. Yu. Petukhova; in general ed. V. V. Bolotova. - Kh.: NFaU, 2014. - 320 p.
4. Prichard E. Quality control in analytical chemistry / E. Prichard, V. Barvyk // Translation from the English language under the editorship of I.V. Boldyrev–St. Petersburg: TsOP "Professiya", 2012.–320 p.
5. Veksler E. M. Quality management. Tutorial. / Veksler E. M., Ryfa V. M., Vasylevich L. F. - K.: "VD "Professional", 2008. -320 p. Pharmaceutical analysis: учеб. help for students high school institutions / P. A. Bezugly [and others]; under community ed.: V. A. Georgiyants. - Kharkiv: NFaU; The original. - 2016. - 541 p.

## EVALUATING

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

### Current evaluation criteria in practical training

<b>Evaluation</b>	<b>Evaluation criteria</b>
“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.
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*Forms and methods of final control:* applicants who have completed the training program in the discipline in full, have no academic debt, set their current grade point average to 3.00 or more, receive credit in the last lesson, which is presented as "credited" / "not credited".

If a student has received a minimum grade point average of 3.00 for the current performance, even in the case of unworked unsatisfactory grades, he receives credit for the discipline.

*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**

### *Deadlines and Rescheduling Policy:*

- Absences of classes for non-respectable reasons are worked out according to the schedule of the teacher on duty.
- Absences due to valid reasons are processed according to an individual schedule with the permission of the dean's office.

### *Academic Integrity Policy:*

Observance of academic integrity by applicants is mandatory, namely:

- independent 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.

Unacceptable in educational activities for participants of the educational process are:

- using family or work connections to obtain a positive or higher grade during any form of control of learning outcomes or advantages in scientific work;
- use of prohibited auxiliary materials or technical means (cheat sheets, notes, micro-earphones, telephones, smartphones, tablets, etc.) during control measures;
- passing procedures for control of training results by fake persons.

For violations of academic integrity, students may be held to such academic responsibility:

- a decrease in the results of assessment of test work, class assessment, exam, etc;
- repeated assessment (test, exam, etc.);
- appointment of additional control measures (additional individual tasks, control works, tests, etc.);
- conducting an additional inspection of other works authored by the violator.

### *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.