

Odessa National Medical University
Faculty of Pharmacy
Department of Pharmaceutical Chemistry
Syllabus of course
Modern analytical laboratory practice

Amount	4 credits 120 hours
Semester, year of study	2 semester 1 year of study 4 semester 2 year of study
Days, time, place	Days, time and place are determined according to the approved schedule
Teachers	Nikitin Olexii Volodymyrovych, the senior teacher Shyshkin Ivan Olegovych, assistant
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Workplace	Department of Pharmaceutical Chemistry
Consultations	Consultations take place according to the approved schedule, both offline (face-to-face) and online, using ICT available to students and teachers

COMMUNICATION with students: E-mail, social networks, face-to-face meetings.

COURSE ANNOTATION

The subject of study of the discipline:

- organizational structure and staff of analytical control laboratories;
- system of receipt of samples for research and analysis;
- test system;
- evaluation of test results;
- rules of storage of samples;
- requirements for reagents and standard samples;
- tools and their calibration;
- safety issues in laboratories.

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

Postrequisites builds 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 the course: is the acquisition by students of the necessary theoretical knowledge and practical skills to apply state and international standards relating to the organization of chemical-analytical laboratories for quality control of medicines; assessment of the suitability of analysis methods, their reproducibility and establishing the limits of uncertainty of the obtained measurement results.

Tasks of discipline: to teach students the features of the production laboratory, knowledge of state and international standards, assessment of the suitability of methods of analysis, the ability to use state and international standards, conducting the necessary chemical analysis, choosing the most appropriate methods of analysis, effective determination of measurement results.

Expected results:

- know the subject and tasks of modern analytical laboratory practice ;;
- organization of quality control of finished drugs and medicinal substances;
- methods of quality improvement and improvement of analysis methods;
- main validation characteristics of analytical control methods;
- features of unification of quality control methods .;
- be able to work with regulations to ensure quality control of analytical laboratories;
- take and prepare samples for analysis;
- be able to use standard compounds in the development of methods of analysis;
- be able to validate analytical methods.

COURSE DESCRIPTION

Forms and methods of teaching

The course will be presented in the form of lectures (4 hours) and practical classes (4 hours), organization of independent work of students (112 hours)

The lectures use a multimedia presentation; in practical classes - teaching materials, situational tasks, individual tasks, to test the acquired knowledge and skills - test tasks, for independent work provided a list of necessary literature sources.

The content of the discipline

Topic 1. Technique of qualitative analysis by semi-micromethod. Basic operations of qualitative chemical analysis.

Topic 2. Determination of purity of medicinal substances. Methods for determining the boiling point, melting point, relative density of the substance and viscosity.

Topic 3. Gravimetric method of analysis. Deposition methods. Distillation methods. Selection methods.

Topic 4. Titrimetric analysis. Requirements for reactions used in titrimetric analysis. Classification of methods. Concentration of solutions, calculations in titrimetric analysis.

Topic 5. Reagents, reference solutions, buffer solutions. Starting standard substances for titrated solutions. Titrated solutions.

Topic 6. Non-aqueous titration. Titrants method. Methods of fixing the equivalence point.

Topic 7. Classification of physical and physico-chemical methods, methods of analysis. Potentiometric methods of analysis.

Topic 8. Voltammetry. Qualitative polarographic analysis. Quantitative polarographic analysis. Amperometry.

Topic 9. Conductometry. Classification of conductometric methods of analysis.

Topic 10. Photometric research methods.

Topic 11. Chromatographic methods of analysis.

List of recommended reading

1. State Pharmacopoeia of Ukraine: in 3 volumes / SE "Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines". - 2nd type. - Kh. : State Enterprise "Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines", 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. : Derzhspozhyvstandart of Ukraine, 2007. – 24p. - (National standards of Ukraine).
3. Analytical chemistry: textbook. help way. for students. higher textbook lock / V.V. Bolotov, O.A. Evtifeeva, T.V. Zhukova, L. Yu. Klimenko, O.E. Mykytenko, V.P. Moroz, I. Yu. Petukhova; for general ed. V.V. Bolotov. - X. : NPhaU, 2014. - 320 c.
4. Pritchard E. Quality control in analytical chemistry / E. Pritchard, V. Barvik // Translated from English by Boldyrev IV-SPb. : TsOP "Profession", 2012.-320 p.
5. Wexler E.M. Quality Management. Tutorial. / Wexler EM, Rifa VM, Vasilevich LF -K. : VD "Professional", 2008. -320 p

EVALUATION

Methods of current control: current control is carried out at each practical lesson in accordance with the specific objectives of the topic. All practical classes use objective control over the performance of independent work, theoretical training and the acquisition of practical skills. The following means of diagnosing the level of preparation of students are used: oral examination, testing, solving situational problems.

A form of final discipline knowledges control is a test.

Students who have fully completed the curriculum in the discipline have no academic debt, their average grade point average is 3.00 or more, in the last class receive a credit, which is set as "passed" / "not credited".

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

Independent work of student is assessed during the current control of the topic in the relevant classroom. Assessment of topics that are submitted for self-study and are not included in the topics of classroom training, are controlled during the final tests and exam.

COURSE POLICY

Deadline and recompilation policy

Students who have completed all types of work provided for in the initial program, completed all training sessions and scored at least the minimum number of points during the study of the module are admitted to the final control.

Rehearsals of missed practical classes, regardless of the reason for admission, and consultations take place in accordance with the departmental schedule of rehearsals and consultations. The practice of missed practical classes is carried out with an entry in the journal of the department's work and a mark on the permit form from the dean's office. Skipping a lecture without a good reason is completed by the student through an interview with the lecturer, or a presentation of the missed topic. Rearrangement of the current and final modules in order to increase the assessment is not allowed,

except for situations provided by the "Regulations on the diploma of the state standard with honors"

Academic Integrity Policy

Adherence to academic integrity by students provides:

- ♦ independent performance of educational tasks, tasks of current and final control of learning outcomes (for persons with special educational needs this requirement is applied taking into account their individual needs and opportunities);
- ♦ links to sources of information in the case of the use of ideas, developments, statements, information;
- ♦ compliance with the legislation on copyright and related rights;
- ♦ providing reliable information about the results of their own (scientific, creative) activities, used research methods and sources of information.

They are unacceptable in educational activities for participants in the educational process:

- the use of family or business ties to obtain a positive or higher assessment in the implementation of any form of control over learning outcomes or advantages in scientific work;
- use of prohibited auxiliary materials or technical means (cheat sheets, abstracts, headphones, telephones, smartphones, tablets, etc.) during control measures;
- passing the procedures of control of learning outcomes by fictitious persons.

For violation of academic integrity, students may be held liable for such academic liability:

- reduction of results of assessment of control work, examination, credit, etc .;
- repeated assessment (test, exam, test, etc.);
- appointment of additional control measures (additional individual tasks, tests, tests, etc.);
- re-passing the relevant educational component of the educational program;
- conducting additional verification of other works by the infringer;
- deprivation of the right to participate in competitions for scholarships, grants, etc .;
- notification of the entity that finances the training (scientific research), the institution that issued the grant for training (research), potential employers, parents of the applicant for higher education about the violation;
- exclusion from the rating of applicants for an academic scholarship or accrual of penalty points in such a rating;
- deprivation of an academic scholarship;
- deprivation of tuition benefits provided by the University;
- expulsions from the University.

Attendance and lateness policy: attendance at all classes: lectures, practical classes, current and final control is mandatory (exception: good reason). Delay of more than 5 minutes without good reason is not allowed. Within two days, in any form convenient

for the student, inform the dean's office about the reasons that make it impossible to attend classes and perform other tasks provided by the curriculum.

Mobile devices: it is forbidden to write off during the control of knowledge (including the use of mobile technical means of information transfer).

Behavior in the audience:

- attend lectures, laboratory classes according to the schedule in bathrobes;
- do not be late for class;
- do not talk during classes;
- turn off your mobile phone.