Odessa National Medical University
Faculty of Pharmacy
Department of Pharmaceutical Chemistry

Syllabus of course
Industrial Practice of Pharmaceutical Chemistry

Amount	6 credits 180 hours
Semester, year of study	10 semester 5 year of study
Days, time, place	Days, time and place are determined according to the approved schedule
Teachers	Osiychuk Olga Volodymyrivna, Ph.D., associate professor Lytvynchuk Iryna Viktorivna, 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: acquaintance with the pharmaceutical enterprise, quality control of medicines and the organization of a workplace of the pharmacist-analyst. Preparation and analysis of titrated and working solutions. Analysis of drugs using chemical and physico-chemical methods and registration of results in the form of appropriate documentation. Express analysis of dosage forms. Compilation of a report on production practice, registration of the diary and preparation of the test and course work.

Prerequisites: inorganic chemistry, organic chemistry, analytical chemistry, pharmacology, physical and colloid chemistry, pharmaceutical and factory technology of drugs, pharmaceutical chemistry and integrates with these disciplines.

The purpose of the course:

-consolidate and expand theoretical knowledge and practical skills in drug chemistry, their standardization and quality control of drugs and their technological forms, acquaintance with the latest drugs that come to the pharmacy;

-to bring students as close as possible to their specialty, to teach them to use all the theoretical knowledge and practical skills acquired in the chemistry of medicines in

working with drugs and patients, to ensure the rigor and accuracy of quality control of drugs and their release.

Tasks of discipline: acquisition of skills in providing quality pharmaceutical care to patients taking into account knowledge of physical, physicochemical and chemical properties of drugs, the basic patterns of dependence of "structure-activity", avoiding possible interaction of drugs in their manufacture and use, establishing the quality of individual drugs , their multicomponent mixtures and ensuring their proper storage, acquiring knowledge of the basic methods of synthesis of drugs or extraction from natural raw materials; in the field of pharmaceutical analysis.

Expected results:

- know the state policy and public administration in the field of creation, production and quality control of medicines;
- know the chemical formulas, Latin and chemical names of drugs, their properties, methods of extraction and synthesis;
- know the analytical and functional groups that are part of the molecules of drugs, and the chemistry of identification reactions;
- know the methods of identification reactions, research on purity;
- know the methods of quantitative determination of drugs;
- know the methods of qualitative and quantitative rapid analysis of dosage forms;
- know the use of drugs in medicine. Relationship between the structure and action of drugs;
- be able to independently make titrated solutions from samples of reagents and fixants, set the correction factor and titer for these solutions;
- be able to make reference solutions, solutions of indicators and reagents;
- be able to determine the benignity of drugs and dosage forms (the presence of impurities of chlorides, sulfates, nitrates, mercury, arsenic, etc.);
- be able to determine the solubility of drugs;
- be able to apply physical and physico-chemical methods of analysis (refractometry, polarimetry, spectrophotometry, chromatography in a thin layer of sorbent) and have the skills to work with appropriate equipment;
- be able to carry out reactions of identification of drugs by cations;
- be able to carry out drug identification reactions by analytical-functional groups;
- be able to quantify drugs by acid-base titration in aqueous and non-aqueous solvents, bromatometry, complexometry, iodometry, argentometry, etc .;
- be able to conduct research on pharmaco-technological parameters of drugs.
- be able to calculate the results of the analysis (equivalent mass, content of active substance, deviation in mass);
- be able to draw a conclusion about the compliance of drugs with the

requirements of the pharmacopoeial article or AND.

– be able to analyze the dosage forms of industrial production (solutions for injections, tablets, ointments, etc.).

COURSE DESCRIPTION

Forms and methods of teaching

The course will be presented in the form of practical classes (60 hours) and the organization of independent work of students (120 hours)

The practical classes use laboratory equipment, reagents, 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. Modern methods of pharmaceutical analysis. Classification and characteristics.

Topic 2. General pharmacopoeial methods of analysis. General provisions on chemical methods of drug analysis.

Topic 3. Tests for the maximum content of impurities. Pharmacopoeial reactions for the detection of impurities in drugs.

Topic 4 Tests for the maximum content of impurities. Analysis of purified water. Physico-chemical properties of water.

Topic 5. General principles of drug identification.

Topic 6. Features of pharmaceutical use. analysis in quality control of drugs manufactured in a pharmacy. Analysis of the concentration of solutions.

Topic 7. Features of pharmaceutical use. analysis in quality control of drugs manufactured in a pharmacy. Analysis of unstable drugs.

Topic 8. Analysis of unstable drugs, as well as perishable drugs. Analysis of 5% alcohol iodine solution.

Topic 9. Analysis of unstable drugs, as well as perishable drugs. Analysis of drops of ammonia-anise

Topic 10. Features of pharmaceutical use. analysis in quality control of drugs manufactured in a pharmacy. Preparation and analysis of injectable dosage forms.

Topic 11. Processing of auxiliary material, personal hygiene of aseptic unit workers.

Topic 12. Features of preparation and analysis of dosage forms for injections. Chemical analysis of 50% analgin solution for injection.

Topic 13. Features of preparation and analysis of dosage forms for injections. Chemical analysis of 5% aminocaproic acid solution

Topic 14. Features of preparation, analysis and storage of children's medicines, including for newborns.

Topic 15. Features of the use of pharmaceutical analysis in quality control of drugs manufactured in pharmacies. Analysis of a solution of glutamic acid 1%

Topic 16. Features of the use of pharmaceutical analysis in quality control of drugs manufactured in pharmacies. Analysis of dibazole 0.005, glucose 0.2.

Topic 17. Features of the use of pharmaceutical analysis in drug quality control. Analysis of eye drops.

Analysis of a solution of zinc sulfate 0.25%

Topic 18. Features of the use of pharmaceutical analysis in drug quality control. Analysis of alcohol solutions. Calculations, examples.
Topic 19. Features of the use of pharmaceutical analysis in drug quality control. Qualitative express analysis of drugs.
Topic 20. Quality control and chemical-pharmaceutical examination of vegetable raw materials.

List of recommended reading

1. State Pharmacopoeia of Ukraine: in 3 volumes / State Enterprise "Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines". 2nd type. - Kharkiv: State Enterprise "Ukrainian Scientific and Pharmacopoeial Center for Quality of Medicines". Vol. 1, 2015. - 1128 p., Vol. 2, 2014. - 724 p., Vol. 3, 2014. - 732 p.
2. Pharmaceutical chemistry / P.O. Bezugliy, V.A. Georgiyants, I.S. Gritsenko, I.V. ta in .: for ed. ON. Angleless. - Vinnytsya: Nova Knyga, 2017 .-- 456 p.
3. Medical chemistry: navch. posib. for students of the most important pawns / I. C. Grytsenko, S.G. Taran, L.O. Perechoda and oth. .; gen. ed. I.S. Grytsenka. - Kharkiv: NUPh: Zoloti Storinky, 2017 .-- 552s.
4. From substance to drug: Textbook. manual / [Bezugly P.A., Bolotov V.V., Gritsenko I.S., etc.]; under ed. V.P. Chernykha - H .: NUPh Publishing House: Zoloti Storinky, 2005. - 1244 p.
5. Turkevych M., Vladimirska O., Lesyk R. Pharmaceutical chemistry (steroid hormones, their synthetic substitutes and heterocyclic compounds as drugs). Textbook. - Vinnytsia: New Book, 2003. – 464 p.
6. V.G. Belikov. Pharmaceutical chemistry. - M .: "MEDpress-inform", 2008. – 615 p.
7. Pharmaceutical chemistry: edited by A.P. Arzamastsev. - 3rd ed. - M .: GEOTAR-Media, 2006. – 635 p.
8. Tsurcan O.O. Pharmaceutical chemistry. Analysis of drugs by functional groups: textbook. way. / O.O. Tsurcan, I.V. Nigencovska, O.O. Glushachenko. - K .: BCB «Medicine», 2012. - 152 p.
9. 9. Orlov V.D., Lipson V.V., Ivanov V.V. Medical Chemistry // Folio. - 2005.- 464 p.

EVALUATION

During the study of the discipline various forms of lesson control are used (oral, written, combined, testing, practical skills, etc.). The results of students' academic performance are presented in the form of assessment on the national scale, 200-point and ECTS scale and have standardized generalized criteria for assessing knowledge.

Assessment of knowledge is on a national scale:

- a grade "excellent" is given to a student who systematically worked during the term, showed during the test versatile and deep knowledge of the program material, is able to successfully perform the tasks provided by the program, mastered the content of basic and additional literature, realized the relationship of individual sections of the discipline importance for the future profession, showed creative abilities in understanding and using educational material, showed the ability to independently update and replenish knowledge; level of competence - high (creative);

- a grade "good" is given to a student who has shown full knowledge of the curriculum, successfully completes the tasks provided by the program, mastered the basic literature recommended by the program, showed a sufficient level of knowledge in the discipline and is able to independently update and update during further study and professional activity; level of competence - sufficient (constructive-variable);
- a grade "satisfactory" is given to the student who has shown knowledge of the basic educational program material in the volume necessary for the further training and the subsequent work on a profession, copes with performance of the tasks provided by the program, has made separate mistakes in answers on examination and at performance of examination tasks, but has the necessary knowledge to overcome mistakes under the guidance of a researcher; level of competence - average (reproductive);
- a grade "unsatisfactory" is given to the student who did not show sufficient knowledge of the basic educational and program material, made fundamental mistakes in performance of the tasks provided by the program, cannot use the knowledge at the further training without the help of the lecturer/tutor, failed to master skills of independent work; the level of competence is low (receptive-productive).

Methods of current control:

- control (observation) over the student's performance of practical tasks in the workplace during the internship;
- periodic inspection of the diary of industrial practice;
- conversation with the head of the practice from the institution and the student during the internship.

Forms and methods of final control

At the end of the internship the student must prepare the following documentation:

- written report, which contains generalized (final) data on the work done during the practice, as well as conclusions and suggestions;
- diary of industrial practice, signed by the head of practice from the institution and certified by the seal and signature of the head of the institution;
- feedback on the student's work signed by a pharmacist-analyst or head of institution.

The student makes a final test of industrial practice with the protection of the diary and practice report.

Conversion of a traditional grade from a discipline on a multi-point scale.

The multi-point scale characterizes the actual success of each student in mastering the discipline. Conversion of the traditional grade from the discipline to 200-point is performed by the information and computer center of the university program "Contingent" according to the formula:

Average score of success (current / discipline) x 40

national assessment	marks
«5»	185-200
«4»	151-184
«3»	120-150

The ECTS rating scale evaluates the achievements of students in the discipline who study in one course of one specialty, in accordance with the points obtained by them, by ranking, namely:

Scale ECTS	Statistical index
«A»	The best 10 % of students
«B»	Next 25 % of students
«C»	Next 30 %of students
«D»	Next 25 % of students
«E»	The last 10% of students

The ECTS scale establishes the student's belonging to the group of the best or worst among the reference group of classmates (faculty, specialty), ie his rating. When converting from a multi-point scale, as a rule, the limits of grades "A", "B", "C", "D", "E" do not coincide with the limits of grades "5", "4", "3" on the traditional scale. A grade of "A" on the ECTS scale cannot be equal to a grade of "excellent", and a grade of "B" - a grade of "good" and so on.

Students who have received grades "Fx" and "F" ("2") are not included in the list of ranked students. Such students automatically receive a score of "E" after re-assembly.

The grade "Fx" is given to students who have scored the minimum number of points for the current educational activity, but who do not pass the final control.

Grade "F" is given to students who have attended all classes in the discipline, but did not score an average score (3.00) for current academic activities and are not admitted to the final control.

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.