Odessa National Medical University
Faculty of Pharmacy
Department of General Pharmacy with the Course of Clinical Pharmacology

Syllabus of the academic discipline "STANDARDIZATION OF DRUGS"

Volume	credits (ECTS) - 3 total hours - 90
Year of study	five
Semester	nine
Days, time, place	In accordance with the approved schedule of classes.
Teachers	Nikogosyan L.R., Head of the Department, Doctor of Medical Sciences, Professor Berbek V.L., Associate Professor, PhD in Pharmaceutical Sciences, Matyushkina M.V., PhD in Pharmaceutical Sciences, Assistant
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Consulting	according to the schedule of the department

COMMUNICATION info.odmu.edu.ua / chair / general_pharmacy / Microsoft Teams

ANNOTATION OF THE COURSE

The subject of study of the discipline "Standardization of medicines" is the formation of a system of knowledge among students based on the basic laws of physical, analytical and pharmaceutical chemistry, necessary to understand the nature and mechanism of the processes that underlie the creation of new highly effective methods of quality control of medicinal substances and the improvement of existing ones, and the role of chemical analysis in the process of ensuring the appropriate quality level of FPP.

Prerequisites and post - requisites of the course: "Pharmaceutical Law and Legislation", "Pharmacognosy", "Organization and Economics of Pharmacy", "Pharmaceutical and Medical Commodity Science", "Pharmaceutical Management and Marketing", "Labor Protection and Labor Protection in the Industry", "Technology of Medicinal funds", "Pharmaceutical Chemistry".

The goal of teaching the discipline "Standardization of Medicines" is to acquire the ability to standardize pharmaceutical products at all stages of its

life cycle: from development, research, registration and production to wholesale and retail sales.

The main objectives of studying the discipline "Standardization of medicines" are:

✓⋯Acquisition of theoretical knowledge and practical skills in physicochemical and pharmaceutical methods of analysis of medicinal substances, which are necessary for a specialist in the pharmaceutical industry to ensure the quality of medicinal products of various forms of release;

✓⋯study of properties and methods of analysis of various dosage forms and their application in the creation of new drugs;

✓⋯mastering the theoretical foundations of modern methods of drug quality control;

✓⋯conducting tests by which the quality of FPP is assessed;

✓⋯identification of drugs;

✓⋯determination of the quantitative content by various methods of analysis;

✓⋯implementation Validation of Analytical Procedures on basic to validated characteristics;

✓⋯preparation of validation master plans (VMP)

✓⋯use in professional activity of the normative-legal and legislative acts of Ukraine concerning the quality of FPP;

✓⋯statistical processing of the obtained analysis results;

✓⋯development of MQL on FPP;

✓⋯conducting pharmacological, microbiological tests, according to which the quality of FPP is assessed;

✓⋯selection of main and additional quality indicators for FPP depending on the type of dosage form.

Expected results

The student should know:

- basic principles of organizing pharmaceutical provision of the population; the main mechanisms of state regulation of pharmaceutical activities; requirements of regulatory documents (orders, manuals, etc.) for the development of medicines and processing of technological documentation; rules for the development of technological documentation.
- state regulation of the quality of medicines and medicinal herbal raw materials; state regulation of the quality of medicines; quality indicators of parenteral, solid, soft and aerosol dosage forms, stability and shelf life of medicines;

The student should be able to:

- use in professional activity knowledge of the regulatory and legal acts of Ukraine and recommendations of good pharmaceutical practices, carry out activities for the development and execution of

documentation for a clear certainty of technological processes for the manufacture and production of medicines in accordance with the rules of good practices.

- organize, provide and carry out the analysis of medicines and medicinal herbal raw materials in pharmacies and control and analytical laboratories of pharmaceutical enterprises in accordance with the requirements of the State Pharmacopoeia and other regulatory legal acts.
- organize and carry out quality control of medicines in accordance with the requirements of the State Pharmacopoeia of Ukraine and good practices, determine the methods of sampling for the control of medicines in accordance with the current requirements and carry out their certification, prevent the spread of counterfeit medicines.
- To develop methods for quality control of medicines, pharmaceutical substances, medicinal plant raw materials and excipients using physical, physicochemical and chemical control methods.

DESCRIPTION OF THE COURSE

Forms and methods of teaching

For full-time students the course will be presented in the form of lectures (10 h.) and practical (40 h.) lessons, the organization of independent work of students (40 h.).

For students of the correspondence form of training will be presented in the form of lectures (4 h.) and practical (40 hours) lessons, the organization of independent work of students (80 h.).

The following teaching methods are used: *verbal* - story, explanation, conversation, instruction, lecture, discussion; *visual* - demonstration of films, visual equipment (means of small-scale mechanization), illustrations, materials, demonstration of operations and processes of drug manufacture in the conditions of pharmacies and industrial enterprises; *practical methods* - practical exercises; *inductive methods* (generalization of the results of observations and experiments). Preference is given to active and interactive methods and multimedia teaching (multimedia lectures, educational films).

Content of the academic discipline

Topic 1. Standardization of pharmaceutical products. Quality control of medicines. Quality parameters used for drug standardization.

Topic 2. Standardization of solid drugs.

Topic 3. Standardization of liquid medicines.

Topic 4. Standardization of soft drugs.

Topic 5. Standardization of medicinal products and drugs based on them.

List of recommended literature

Basic (basic)

1. 1. Skoog, Douglas A.; West, Donald M.; Holler, F. James; Crouch, Stanley R.. Fundamentals of Analytical Chemistry. Belmont: Brooks/Cole, Cengage Learning. - 2014.
2. Bard, A.J.; Faulkner, L.R. Electrochemical Methods: Fundamentals and Applications. New York: John Wiley & Sons, 2nd Edition, - 2000.
3. Adams RP. Identification of Essential Oil Components By Gas Chromatography/Mass Spectrometry. Allured Pub Corp., - 2007.
4. Adlard ER, Handley AJ. Gas chromatographic techniques and applications. London: Sheffield Academic, - 2001.

Auxiliary

1. Barry EF, Grob RE. Modern practice of gas chromatography. New York: Wiley-Interscience, - 2004.
2. Callister, WD. Materials Science and Engineering – An Introduction. London: John Wiley and Sons. – 2000.

Yao, N, ed. Focused Ion Beam Systems: Basics and Applications. Cambridge, UK: Cambridge University Press. – 2007.

Informational resources

- Lecture materials, methodological developments for seminars and an independent robot and at the Department of General Pharmacy. URL : http: // http://info.odmu.edu.ua/chair/general_pharmacy/.
- Official website of the Ministry of Health of Ukraine www.moz.gov.ua
- Website library ONMedU the URL : http://libblog.odmu.edu.ua
- Site of the journal "Pharmacist Practitioner" URL : fp.com.ua
- Official site of the magazine "Pharmacist" URL : www.provisor.com.ua
- Compendium: Medicines . URL: http://compendium.com.ua/
- State Register of Medicines of Ukraine. URL : http://www.drlz.com.ua/
- Database "Equalizer" LLC "Business-Credit" URL : http://eq.bck.com.ua/

GRADE

<table>
<tr><td colspan="2">Current control</td></tr>
<tr><td colspan="2">Carried out on each seminary class according to specific goals. The form of assessment of the current educational activity is standardized and include control of theoretical training, which is conducted by the survey, the implementation of situational problems, as well as a test of writing of the survey.
The results of the current control is an indicator of the level of assimilation of students of educational programs and perform independent work. For each topic the student must obtain est e GCC on a 4-point (traditional) scale with a view of the approved criteria.</td></tr>
<tr><td>Verification of learning outcomes</td><td>By Criteria for per couple</td></tr>
<tr><td>Test Control Evaluations</td><td>2 - < 80%
3 - 80 - 89%
4 - 90 - 95%
5 - 96 - 100%</td></tr>
<tr><td>Assessment of the oral response</td><td>2 - The student does not reproduce Scholastic first material has a vague idea of the object study
3 - The student has difficulty in reproducing the main educational material, with errors and inaccuracies he defines the basic concepts and definitions of the topic
4 - The student demonstrates knowledge and understanding of the main provisions of the educational material
5 - The student has systemic, solid knowledge within the requirements of the curriculum, consciously uses them in standard and non-standard situations . Knows how to independently analyze, evaluate, generalize obsessed material</td></tr>
<tr><td colspan="2">Final control</td></tr>
<tr><td>General grading system</td><td>Participation in work during the semester 100% on a 200-point scale</td></tr>
<tr><td>Grading scales</td><td>traditional 4-point scale, multi -point (200-point)</td></tr>
</table>

	scale, ECTS rating scale	
Conditions for admission to final control	The student attended all lectures and seminars and received at least 120 points for current academic performance	
View the final control	*The technique of the final control*	*To the offset criteria*
Offset	All topics submitted to the current control must be credited. Grades from a 4- point scale are converted into points on a multi- point (200 point) scale in accordance with the Regulation "Criteria, rules and procedures for assessing the results of educational activities of students "	The maximum number of points is 200. The minimum number of points is 120
The calculation of the number of points is conducted on the basis of the obtained student assessments on a 4-point (national) scale of time studying the discipline, by calculations average arithmetic, rounded of to two digits after the decimal point. The resulting value is converted into points on a multi- point scale by the information and computing center of the university.		

Independent work of students:

- ✓⋯work with lecture material, which provides for the study of lecture notes and educational literature;
- ✓⋯search (selection) and review of literature and electronic sources of information on an individually set problem of the course;
- ✓⋯homework or home control work, involving problem solving, exercise and so on;
- ✓⋯study of material submitted for independent study;
- ✓⋯writing an abstract on a given problem;
- ✓⋯preparation for test.

COURSE POLICY

Deadline and retake policy

Students who have completed all types of work stipulated by the curriculum, completed all training sessions and, while studying the module, scored at least the minimum number of points are allowed to the final control.

Testing missed practical classes, regardless of the cause skipping, and consultations take place according to the cathedral graphics of consultation. Working off of the missed practical lessons is carried out with an entry in the journal of the development of the department and a mark on the permit form from the dean's office. Skipping a lecture without a good reason is worked out by a student through an interview with a lecturer, or a presentation of a missed topic. Retaking the current and final modules to improve the assessment is not allowed, except for cases stipulated by the "Regulations on the diploma is, the state sample with honors"

Academic Virtue Policy

Respect for academic virtue by education seekers includes:

♦⋯independent fulfillment 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 capabilities);

♦⋯links to sources of information when using ideas, developments, statements, information;

♦⋯observance of the norms of legislation on copyright and related rights;

♦⋯provision of reliable information about the results of one's own (scientific, creative) activities, used research methods and sources of information.

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

- the use of family or official ties to obtain a positive or highest mark in the implementation of any form of control of learning outcomes or advantages in scientific work;
- use of prohibited auxiliary materials or technical means (cribs, notes, earpieces, phones, smartphones, tablets, etc.) during control activities;
- passing the procedures for monitoring the learning outcomes by dummies.

For violation of academic virtue, education seekers may be held liable for such academic responsibility.

- decrease in the results of the assessment of control work, exams, tests, etc.;
- re-passing the assessment (tests, exams, tests, etc.);
- appointment of additional control measures (additional individual tasks, control papers, tests, etc.);
- re-passing the corresponding educational component of the educational program;
- additional verification of other works of authorship of the offender;
- deprivation of the right to participate in competitions for scholarships, grants, and the like;

- Post subject provides training funding (research), the institution that issued the grant to study (research), prospective employers, higher education of the applicant parents to completely m violation;
- exclusion from the ranking of applicants for an academic scholarship or the accrual of penalty points in such a ranking;
- deprivation of an academic scholarship;
- deprivation of tuition fees provided by the University;
- deductions from the University.

Policy on attendance and lateness: attendance at all classes: lectures, practical classes, current and final control is mandatory (exception: good reason). Delay by more than 5 minutes without a valid 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 stipulated by the curriculum.

Mobile devices: prohibited cheating is, under the control of knowledge (including the use of mobile technical communication).

Audience behavior:

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