

Odessa National Medical University
Faculty of Pharmacy
Department of Drug Technology

Syllabus course
«Industrial practice from drugs technology»

Amount	Total number of hours – 120; number of ECTS credits - 4.
Semester, year	VII semester, IV year of study
Days, time, place	According to the approved schedule
Teacher	Candidate of Pharmacy sciences, docent Fizor N.S., Candidate of Biological sciences, as. Valivodz I. P., as. Akisheva A. S.
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Work place	Odessa, Malinovsky Street, 37, Department of Drug Technology, office 122, 123
Consultations	<i>Online consultations</i> : remotely on the Microsoft Teams platform

COMMUNICATION

Communication in the audience on schedule. Other types of communication: face-to-face consultation on a schedule, remotely on the Microsoft Teams platform and with the help of an e-mail lecturer. The solution of "working issues" is possible by the specified phone number.

COURSE ANNOTATION

Subject of study of the discipline «Industrial practice in drug technology»: the main provisions and trends in the development of pharmaceutical technology in the world and in Ukraine; mastering modern principles of regulatory documentation and technologies for the production of pharmaceuticals in various dosage forms with the use of new groups of excipients and modern types of equipment in pharmacies.

Course prerequisites: the discipline belongs to the compulsory disciplines and is based on the knowledge gained in the study of general disciplines: Latin, botany, analytical chemistry, pharmaceutical technology, pharmacognosy, pharmacology, pharmaceutical chemistry, toxicological chemistry.

Postrequisites of the course: knowledge gained after the study of this discipline is necessary for the study of such disciplines as: industrial technology of medicines, biopharmacy, pharmaceutical biotechnology.

The purpose of the course is to consolidate, deepen, expand theoretical knowledge of pharmacy technology of drugs, as well as to acquire, master and improve

practical skills and abilities acquired in higher education, to master their profession directly in production conditions, gain practical experience.

Tasks of the discipline:

- mastering the requirements of current regulations (SPU, GPP and current orders) to organize the production activities of pharmacies for the manufacture of drugs in various dosage forms;
- use in professional activity of normative-legal and legislative acts of Ukraine, requirements of good pharmacy practice (GPP) for the manufacture of drugs in pharmacies;
- perfect mastery of all technological operations for the preparation of various dosage forms, their packaging, registration for release, quality control.
- study of pharmacy equipment, including new ones, devices, modern requirements for the production of dosage forms, including the requirements of the World Health Organization (WHO) for the purity of raw materials, production facilities and personnel.

Expected results:

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

Know:

- requirements of current regulations (SPU, GPP and current orders) to the organization of production activities of pharmacies for the manufacture of drugs in various dosage forms;
- theoretical bases of technology of manufacturing of different types of dosage forms, carrying out of step-by-step control, ways of improvement of technology of dosage forms in pharmaceutical conditions;
- the influence of storage conditions and type of packaging on the stability of dosage forms;

Be able:

- use regulations governing pharmaceutical activities in Ukraine and abroad;
- compile information on the material and technical base of the pharmacy and pharmacy;
- draw up technological schemes and instructions for the manufacture of drugs «in stock» in a pharmacy;
- determine in prescriptions and eliminate incompatibilities of biologically active substances and medicinal plant raw materials: physical, chemical and physico-chemical in accordance with list 1a; pharmacological according to list 1b;
- check and, if necessary, correct single, daily and course doses of toxic, narcotic, potent substances and the norms of release of narcotic and similar substances, taking into account individual characteristics (age, body weight, etc.);
- weigh and measure, dose a variety of drugs by weight and volume according to the prescription;
- prepare extractants of the required concentration, using various calculation

methods;

- stabilize pharmaceuticals, taking into account the biological, physicochemical, technological properties of active substances and excipients, using the necessary reagents;
- prepare various dosage forms and in-pharmacy preparations from medicinal and excipients;
- sterilize dosage forms taking into account the physicochemical properties and stability of drugs;
- draw up manufactured medicines with poisonous, narcotic and similar substances;
- draw up written control passports for all manufactured medicines; choose the optimal technology for the manufacture of dosage forms, using the necessary equipment.

COURSE DESCRIPTION

Module volume: total number of hours - 120, practical classes - 60 hours, independent work - 60 hours; number of ECTS credits - 4.

In addition practical work, individual and group consultations are provided.

The content of the discipline

Topic 1. Familiarity with the production facilities of the pharmacy. Passing of instruction on safety, sanitary mode, observance of the pharmaceutical order.

Topic 2. Familiarity with obtaining purified water, quality control.

Topic 3. Preparation of solid dosage forms according to doctors' prescriptions and requirements of hospital institutions. Evaluate the quality of the prepared drug.

Topic 4. Preparation of liquid dosage forms (solutions, potions, etc.) according to prescriptions and requirements of hospitals. Assess the quality of the prepared drug in accordance with the analytical and regulatory documentation.

Topic 5. Preparation of soft dosage forms (liniments, ointments) according to doctors' prescriptions and requirements of hospital institutions. Evaluate the quality of the prepared drug.

Topic 6. Preparation of soft dosage forms (suppositories) according to doctors' prescriptions and requirements of hospital institutions. Evaluate the quality of the prepared drug.

Topic 7. Preparation of aseptic dosage forms according to doctors' prescriptions and requirements of hospital institutions. Assess the quality of the prepared drug according to (AND).

Topic 8. Preparation of ophthalmic dosage forms according to doctors' prescriptions and requirements of hospital institutions. Assess the quality of the prepared drug according to (AND).

Topic 9. Carrying out of intrapharmacy preparation of medicines and semi-finished products with them. Detection of frequently prescribed medication prescriptions.

Topic 10. Identify physical, chemical and pharmacological incompatibilities, the possibility of preparation and release of drugs, taking into account compatibility.

List of main recommended literature:

1. Тихонов О. І. Аптечна технологія ліків : підруч. для студентів вищ. навч. закл. / О. І. Тихонов, Т. Г. Ярних. - 5-е вид. - Вінниця : Нова кн., 2019. - 535 с.
2. Аптечна технологія ліків: метод. рек. для самостійної роботи здобувачів вищої освіти спеціальності «Фармація, промислова фармація» денної та заочної форми навчання / Н. П. Половко [та ін.]. – Х. : Вид-во НФаУ, 2018. – 72 с.
3. Виробнича практика з аптечної технології ліків: метод. рек. з підготовки до підсумкового модульного контролю здобувачів вищої освіти спеціальності «Фармація» денної та заочної форми навчання / Н. П. Половко, Л. І. Вишневська, Т. М. Зубченко, Т. М. Ковалева. – Х.: Вид-во НФаУ, 2018. – 27 с.
4. Введение в фармацию. Практические занятия в аптеке по технологии лекарств: метод. рек. к практическим занятиям для соискателей высшего образования специальности «Фармация, промышленная фармация» дневной и заочной формы обучения / Н. П. Половко, Л. И. Вишневская, Т. Н. Зубченко, Т. Н. Ковалева. – Х.: Изд-во НФаУ. 2018. – 34 с.
5. Технология гомогенных жидких лекарственных средств в условиях аптек: учебное пособие для внеаудиторной работы соискателей высшего образования специальности «Фармация» факультета по подготовке иностранных граждан / Н. П. Половко, Л. И. Вишневская, Е. Е. Богуцкая, М. В. Марченко; под ред. Н. П. Половко и Л. И. Вишневской – Х.: Оригинал, 2018. – 124 с.
6. Технология суппозиторий в условиях аптек: учебное пособие для внеаудиторной работы соискателей высшего образования специальности «Фармация» факультета по подготовке иностранных граждан / Н. П. Половко, Л. И. Вишневская, Е.В. Семченко; Под редакцией проф. Половко Н. П., проф. Вишневской Л. И. – Х. : Изд-во НФаУ, 2018. – 68 с.
7. Допоміжні речовини у виробництві ліків : навч. посібн. для студ. вищ. фармац. навч. закл. / О.А. Рубан, І.М. Перцев, С.А. Куценко, Ю.С. Маслій; за ред. І.М. Перцева. – Х.: Золоті сторінки, 2016. – 720 с.
8. Навчальний посібник для самостійної підготовки студентів фармацевтичного факультету до ліцензійного тестового іспиту «Крок - 2. Фармація» / під редакцією І.Ю. Борисюк, Н.С. Фізор, А.В. Замкова - Одеса.: ОНМедУ, 2019. – 88 с.

EVALUATION

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

Current success. Evaluation of the success of studying the topics of the discipline is performed on a traditional 4-point scale. At the practical (laboratory) lesson students must be interviewed at least once for 2-3 practical (laboratory) lessons (not more than

75% of students), and at the seminar - at least once for 3-4 lessons (not more than 50) % of students). At the end of the semester (cycle) the number of grades for students in the group should be the same on average. At the end of each lesson, the teacher must announce the students' grades, make an appropriate entry in the Journal of attendance and student performance and Information on the performance and attendance of students. At the end of the study, the current performance is calculated - the average current score (arithmetic mean of all current grades on a traditional scale, rounded to two decimal places). In the last practical lesson, the teacher is obliged to provide information to students about the results of their current academic performance and academic debt (if any), as well as when completing the curriculum in the discipline to fill in the student's record book. To increase the average score in the discipline, the current grades "3" or "4" are not rearranged.

The differential test is set at the last lesson of the discipline based on the results of the final interview with the mandatory performance by the student of all types of work provided for in the working curriculum and evaluated for the current educational activity on average not less than 3.00. The grade obtained for the answer on the differential test and the score of the average current performance during the study of the discipline are used to calculate the arithmetic mean, which is the overall grade for the discipline. In the student's record book the teacher enters the grade in the discipline on the traditional and 200-point scales. No bonus points are accrued.

Independent work of students: on the topics of independent work - writing essays and preparing presentations. Assessment of independent work is performed on the traditional 4-point scale, the deadline - during the course of the discipline.

COURSE POLICY («rules of the game»):

Deadline and recompilation policy. The final control is carried out in the audience in the penultimate week. In case of absence or low result, the final written control is rescheduled once in the last week on the day of the scheduled consultation (Thursday 15.00-16.00). In case of non-compliance with the policy on deadlines and rescheduling, control measures are considered not passed.

Academic Integrity Policy: the course involves the writing of abstracts (SRS) that will be tested for academic integrity (according to the Regulations on the Commission on Academic Integrity of Odessa National Medical University).

Attendance and lateness policy: attendance practical classes is mandatory, lateness is not desirable. Points for attending classes are not accrued. An important reason for absence from classes is an illness, which is confirmed by a certificate from a doctor (hospital).

Mobile devices: with the permission of the teacher it is allowed to use a smartphone, tablet or other device for storing and processing information.

Behavior in the audience or remotely on the Microsoft Teams platform: active, business and creative atmosphere.