

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 Biological sciences, senior teacher Zamkovaya A. V.
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Work place	Odessa, Malinovsky Street, 37, Department of Drug Technology, office.122
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

The subject of study of the discipline «Industrial practice from drugs 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 industrial conditions.

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.

Post-requisites of the course: knowledge gained after studying 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 teach students the ability to act socially responsible and civic consciously; consolidation, deepening, expansion of theoretical knowledge of industrial drug technology, as well as the acquisition, acquisition and improvement of practical skills and abilities acquired in higher education, to master their profession

directly in the production environment, to gain practical experience.

Tasks of the discipline:

- mastering the requirements of current regulations (SPU, GMP and current orders) to the organization of production activities of enterprises for the manufacture of drugs in various dosage forms;
- use in professional activity of normative-legal and legislative acts of Ukraine, requirements of good industrial practice (GMP) to manufacture of medicinal products in factory conditions;
- perfect mastery of all technological operations for the preparation of various dosage forms in industrial conditions, their packaging, registration for release, quality control.
- study of industrial equipment, including new, 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:

- 1) know the requirements of GMP and other good pharmaceutical practices and regulations (orders, guidelines, etc.) for the development and industrial manufacture of medicines;
- 2) know the requirements for containers, closures and packaging materials.
- 3) technology and organize the production of medicines at pharmaceutical companies, using the necessary equipment;
- 4) assess the quality and stability of intermediates and finished products. determine the influence of environmental factors: moisture, temperature, light, etc. on the stability of drugs and medical devices;

Be able:

- 1) to carry out professional activities in social interaction based on humanistic and ethical principles; identify future professional activities as socially significant for human health;
- 2) apply knowledge in professional activities;
- 3) use the results of independent search, analysis and synthesis of information from various sources to solve typical problems of professional activity;
- 4) argue information for decision-making, be responsible for them in standard and non-standard professional situations; adhere to the principles of deontology and ethics in professional activities;
- 5) perform professional activities using creative methods and approaches;
- 6) carry out professional activities using reference scientific literature, information technology, "Information databases", navigation systems, Internet resources, software and other information and communication technologies;
- 7) use methods of assessing performance indicators; identify reserves to increase labor efficiency;
- 8) analyze the information obtained as a result of scientific research, summarize,

- systematize and use it in professional activities;
- 9) plan and implement professional activities on the basis of regulations of Ukraine and recommendations of good pharmaceutical practices;
 - 10) develop and draw up technological regulations for the production (manufacture) of drugs in pharmacies and pharmaceutical companies;
 - 11) substantiate the technology and organize the production of medicines at pharmaceutical enterprises;
 - 12) to carry out step-by-step control of medicines;
 - 13) to study the influence of environmental factors on the stability of drugs;
 - 14) substantiate the technology and organize the production of medicines at pharmaceutical enterprises, using the necessary equipment;
 - 15) assess the quality and stability of intermediates and finished products. Determine the influence of environmental factors: moisture, temperature, light, etc. on the stability of drugs and medical devices;
 - 16) objectively use the best foreign experience of pharmaceutical manufacturers;
 - 17) be able to reasonably select the necessary excipients in the composition of the drugs being developed.

Have:

- 1) skills to improve the technological process, to be able to assess the losses and yield of the finished product, to compile a material balance and technological scheme of production of drugs in industrial conditions.

COURSE DESCRIPTION

Module volume: total number of hours - 120, practical classes - 40 hours, independent work - 80 hours; number of ECTS credits - 4.

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

The content of the discipline

Topic 1. General acquaintance with the pharmaceutical company; internal regulations. Instruction on the rules of safety and labor protection.

Topic 2. Production of solid dosage forms according to GMP requirements (tablets, granules, pills).

Topic 3. Production of solid dosage forms according to GMP requirements (capsules in a gelatin shell).

Topic 4. Production of sterile drugs according to GMP requirements (dosage forms for injection in ampoules, vials, infusion solutions in containers, etc.).

Topic 5. Production of soft dosage forms according to GMP requirements (ointments, gels, suspensions, emulsions, suppositories, patches, etc.).

Topic 6. Production of phytochemicals according to GMP requirements.

Topic 7. Packing and packaging of finished products.

Topic 8. Familiarity with the work of the department of quality control of drugs and the central factory laboratory.

List of main recommended literature:

- Промислова технологія лікарських засобів: базовий підручник для студ. вищ. навч.закладу (фармац. ф-тів) / Є. В. Гладух, О. А. Рубан, І. В. Сайко [та ін.] – Х. : НФаУ : Оригінал, 2016. – 632 с. : іл.
- Практикум з промислової технології лікарських засобів: навч. посіб. для студ. вищ. навч. закладів зі спеціальності «Фармація» / О.А. Рубан, Д.І. Дмитрієвський, Л.М. Хохлова [та ін.]; за ред. О.А. Рубан. – Х.: НФаУ; Оригінал, 2015. – 320 с.
- Промислова технологія лікарських засобів: навч. посіб. для самостійної роботи студентів / О.А. Рубан, В.Д. Рибачук, Л.М. Хохлова та ін. – Х.: НФаУ, 2015. – 120 с.
- Промислова технологія лікарських засобів. Навчальний посібник для самостійної роботи студентів: опрацьоване та доповнене. / Сост. О.А. Рубан, В.Д. Рибачук, Л. М. Хохлова, Ю. С. Маслій та ін. – Х.: НФаУ, 2015. - 120 с.
- Навчальний посібник з підготовки до підсумкового модульного контролю та Державної атестації з Промислової технології лікарських засобів для студентів денного та заочного відділення спеціальності «Фармація» / Під ред. О.А. Рубан. – Х.: НФаУ, 2016. – 80 с.
- Навчальний посібник для самостійної підготовки студентів фармацевтичного факультету до ліцензійного інтегрованого іспиту «Крок 2. Фармація» / О.А. Рубан, В.Д. Рибачук, Л.М. Хохлова, Д.С. Пуляєв – Х.: НФаУ, 2016. – 63 с.
- Допоміжні речовини у виробництві ліків: навч. посіб. 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.
- Сучасні фармацевтичні технології: навч. посіб. до лабораторних занять магістрантів денної, вечірньої та заочної форми навчання спеціальності 8.110201 «Фармація» / під ред. О.А. Рубан. – Х.: Вид-во НФаУ, 2016. – 256 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:

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.