Odessa National Medical University
Faculty of Pharmacy
Department of Drug Technology

Syllabus course

Drug technology

Amount	EDKS – 6 credits, 180 hours;
Semester, year of study	Semester V-VI, VII-VIII, III-IV cours
Days, time, place	In accordance with the approved schedule of classes
Teacher (s)	Borisyuk Iryna Yuriyivna - Ph.D. pharmaceutical science; Zamkovaya Alyona Victorovna - Ph.D. biological science
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Workplace	Odessa, street Malinowski, 37, Faculty of Pharmacy, Department of Drug Technology, room 119 and room 122
Consultations	Eye consultations: no quarantine measures are provided for the time being Online consultations: remotely on the Microsoft Teams platform
COMMUNICATION	
Phone	(0482) 34-14-74
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COMMUNICATION

Communication in the auditory on schedule. Other types of communication: schedule consultation on the principle «Face to face», distance 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 "Drugs technology" (industrial technology) are 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 pharmacy and industrial conditions.

Prerequisites of the course:

-discipline is based on the study of physics, general and inorganic chemistry, physical and colloid chemistry, biology with the basics of genetics;

-discipline is the basis for the study of medical and pharmaceutical commodity science, good practices in pharmacy, pharmaceutical chemistry, management and marketing in pharmacy, biopharmacy, standardization of medicines, technology of medicines cosmetics, which involves the integration of teaching with the above disciplines to develop knowledge in the process further training in professional activities;

-discipline lays the foundations of professional training, promotes the formation of technical and pharmaceutical thinking necessary for the pharmaceutical specialty;

Post-requisites of the course: together with other pharmaceutical disciplines and social sciences, drug technology plays an important role in providing special technological training for professional activities.

The aim of the course: is the mastering by students of higher education of theoretical bases and practical skills and abilities of manufacturing medicines in the conditions of pharmaceutical enterprises taking into account the requirements of industrial practice; rules for compiling technological documentation for the manufacture of drugs, rules for their storage and packaging; mastering knowledge of the characteristics, classification and range of finished dosage forms; formation of theoretical knowledge and professional skills in applicants for higher education by studying the impact of excipients on the quality of drugs, which allows more fully realize the scientific and creative potential of future professionals. Mastering the theory and practice of manufacturing dosage forms is necessary for a specialist to perform the duties of a specialist, as provided by legal procedure legislation and the relevant order of the Ministry of Health of Ukraine.

Tasks of the discipline:

1. 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;
2. acquaintance with the organization of production of medicines in the conditions of pharmaceutical enterprises, according to requirements of Good manufacturing practice (GMP);
3. formation of knowledge in higher education seekers on: theoretical foundations of technology for the manufacture of various types of dosage forms, step-by-step control, ways to improve the technology of dosage forms in pharmacy and industrial conditions;
4. study of the influence of storage conditions and type of packaging on the stability of dosage forms;
5. study of industrial equipment, including new, devices and automatic lines, 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 academic discipline, the applicant for education must:

Know:

1) know the requirements of GMP and other good pharmaceutical practices and regulatory documents (orders, manuals, etc.) for the development and industrial production of medicines;

2) know the requirements for containers, closures and packaging materials.

Be able to:

1. to carry out professional activities in social interaction based on humanistic and moral principles; identify future professional activities as socially significant for human health.
2. apply knowledge in professional activities.
3. to use the results of independent search, analysis and synthesis of information from various sources to solve typical tasks of professional activity.
4. to argue the information for making decisions, to be responsible for them in standard and non-standard professional situations; adhere to the principles of deontology and ethics in professional activities.
5. to carry out 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 for assessing performance indicators; to identify reserves for increasing labor efficiency.
8. analyze information obtained as a result of scientific research, generalize, systematize and use it in professional activities.
9. to plan and implement professional activities on the basis of regulatory legal acts of Ukraine and recommendations of good pharmaceutical practices.
10. to develop and execute technological normative documentation for the production (manufacture) of medicinal products in pharmacies and pharmaceutical enterprises.
11. to justify the technology and organize the production of medicines at pharmaceutical enterprises.
12. to carry out stepwise control of medicines.
13. to study the influence of environmental factors on the stability of drugs.
14. to substantiate the technology and organize the production of medicines at pharmaceutical enterprises, using the necessary equipment.
15. evaluate the quality and stability of semi-finished products and finished products. Determine the influence of environmental factors: moisture, temperature, light, etc. on the stability of medicines and medical devices.
16. to objectively use the advanced foreign experience of pharmaceutical manufacturers.
17. be able to reasonably select the necessary excipients in the composition of medicines being developed.

Master:

Acquire skills to improve the technological process, be able to estimate losses and yield of a finished product, draw up a material balance and a technological scheme for the production of drugs in an industrial environment.

COURSE DESCRIPTION

Module volume: total number of hours - 180 of them lectures - 20 hours, practical lessons - 80 hours, independent work - 80 hours.

In addition to the lecture and practical form of work, individual and group consultations are provided.

The content of the discipline

Topic 1. Normative documentation in the production of ready medicines

Topic 2. Requirements for sterile products. Determination of the main quality indicators of ampoule glass.

Topic 3. Industrial production of injectable solutions.

Topic 4. Industrial production of infusion solutions.

Topic 5. Industrial production of ophthalmic, ear and nasal dosage forms.

Topic 6. Technological schemes of production of ocular, ear and nasal drugs.

Topic 7. Production of tinctures. Alcoholometry.

Topic 8. Production of liquid extracts.

Topic 9. Production of thick and dry extracts. Intensification of extraction processes.

Topic 10. Production of drugs under pressure.

Topic 11. Physico-chemical and technological properties of powders and granules.

Topic 12. Production of tablets by direct compression and pre-granulation.

Topic 13. Industrial production of coated tablets. Quality control.

Topic 14. Production of medical capsules.

Topic 15. Industrial production of soft medicines.

Topic 16. Industrial production of suppositories.

Topic 17. Production of plasters and TTS.

Topic 18. Production of nano- and radiopharmaceuticals.

List of recommended reading

1. Industrial technology of medicines: a basic textbook for students. Higher. uch. pharmacy. institutions (pharmac. f-tiv) / E.V. Gladuh, A.A. Ruban, I.V. Saiko and others. - H .: NUPh: Original, 2016. - 632p. : To them. - (National Textbook Series)
2. Workshop on industrial technology of medicines specialty "Pharmacy" / Ed. Ruban OA - M .: НФаУ, 2015. - 374 c
3. Technology of industrial drugs: a textbook for students. higher textbook zakl .: in 2 hours / VI Chueshov, EV Gladukh, I.V. Saiko and others. - second ed., reworked. and ext. - M .: NUPh Original, 2012. - Part 1. - 694 p. : ill.
4. Technology of industrial drugs: a textbook for students. higher textbook zakl .: in 2 hours / VI Chueshov, EV Gladukh, IV Saiko and others. - second ed., reworked. and ext. - M .: NUPh Original, 2013. - Part 2. - 638 p. : ill.
5. Workshop on industrial technology of medicines: textbook. way. for students. higher textbook institutions in the specialty "Pharmacy" / OA Ruban, DI Dmitrievsky, LM Khokhlova [etc.]; for order. O. A. Ruban. - H.: НФаУ; Original, 2015. - 320 p.
6. Industrial technology of medicines: textbook. way. for independent work of students / OA Ruban, VD Rybachuk, LM Khokhlova and others. - H.: NFAU, 2015. - 120 p.

7. Excipients in the manufacture of drugs: textbook. way. for students. higher pharmacy. textbook lock / OA Ruban, IM Pertsev, SA Kutsenko, YS Masliy; for order. IM Pertsev. - H .: Golden Pages, 2016. - 720 p.
8. Technology of industrial drugs: textbook. for higher students. textbook lock : in 2 parts / VI Chuyeshov, EV Gladukh, IV Saiko and others. - 2nd ed., Reworked. and dop. - H .: NUPh: Original, 2013. - Part 2. - 638 p.
9. Modern pharmaceutical technologies: textbook. way. to laboratory classes of full-time, part-time and part-time undergraduates majoring in 8.110201 "Pharmacy" / ed. O. A. Ruban. - H .: NUPh Publishing House, 2016. - 256 p.

EVALUATION

- oral control (participation in creative conversations, answers during lectures) – current control in each classroom – the traditional 4-point scale. At the end of the course, the current performance is calculated as the average current score, ie the arithmetic mean of all grades obtained by the student on a traditional scale (example 4.75);
- independent work (performance of individual tasks and their defense during practical classes) – assessment is performed on the traditional 4-point scale, the deadline – during the course of the discipline.

Bonus points not provided.

Independent work of students: on the topics of independent work - writing abstracts and preparing presentations. Assessment of independent work is carried out according to the traditional 4-point scale, the term of completion is during the course of the discipline.

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 a grade on the national scale, 200-point and ECTS scale and have standardized generalized criteria for knowledge assessment: national scale:

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

- the 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 teacher, failed to master skills of independent work; level of competence - low (receptive-productive).

Final control in the form of tests is assessed on a two-point scale: - grade "credited" is given to a student who has completed the curriculum of the discipline, has no academic debt; level of competence - high (creative); - the grade "not credited" is given to a student who has not fulfilled the curriculum of the discipline, has an academic debt (average score below 3.0 and / or absences); the level of competence is low (receptive-productive).

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 grade point average (current / discipline) x 40

national assessment	
«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:

mark ECTS
«A»
«B»
«C»
«D»
«E»

The form of final control of knowledge in the discipline in the third year is a exam.

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 from 15.00 to 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 writing essays (IWS) 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 at lectures and practical classes is mandatory, delays are not desirable. Points for attending classes are not accrued. An important reason for absence from classes is a disease confirmed by a certificate from a doctor (hospital).

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

Behavior in the audience or remotely on the Microsoft Teams platform: active, business and creative atmosphere, in compliance with sanitary and epidemiological requirements.