Odessa national medical university
Faculty of Pharmacy
Department of Drug technology

Syllabus of course «Technology of the drugs»

Amount:	Total -180, number of ECTS credits - 6.
Semester, year:	V-VI, III year of study
Days, time, place:	According to the timetable
Teacher (s):	Borisyuk I.Yu.- PhD, head of the department Kobernic A.O.-PhD, docent
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Workplace:	Odessa, st. Malinovsky, 37, Faculty of Pharmacy, Department of Drug Technology, 124 and 123
Consultations:	Face-to-face consultations: during quarantine measures are not provided. Online consultations: remotely on the 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 the study of the discipline is the main provisions and trends of the development of pharmaceutical technology in the countries of the world and in Ukraine; the assimilation of modern principles of normative documentation and technologies for the production of pharmaceuticals in different dosage forms using new groups of excipients and modern types of equipment in the pharmaceutical conditions.

Course prerequisites

Interdisciplinary connections: discipline is based on the study of physics, general and inorganic chemistry, physical and colloidal 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, biopharmaceuticals, standardization of medicines, technology of medicinal cosmetics, which involves the integration of teaching with the above mentioned disciplines for the formation of skills to apply knowledge in the process of further training and professional activities;

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

-together with other pharmaceutical disciplines and social sciences, medicine technology plays an important role in providing special technological training for professional activities.

The purpose of the teaching of the discipline «Technology of the drugs» is to acquire the theoretical foundations and practical skills of the higher education students in the conditions of pharmacies taking into account the requirements of proper pharmacy and production practice; rules for the preparation of technological documentation of medicinal products, rules for their storage and packaging; mastering the knowledge on the characteristics, classification and assortment of finished dosage forms; formation of theoretical knowledge and professional skills of higher education graduates by studying the influence of auxiliary substances on the quality of medicinal products, which makes it possible to more fully realize the scientific and creative potential of future specialists.

The main tasks of studying the discipline «Technology of the drugs» are:

1. assimilation of the requirements of the current normative documents (state-owned enterprises, GPP and current orders) to the organization of production activities of pharmacies in the manufacture of drug various pharmaceutical forms;
2. familiarization with the organization of the production of drugs in the conditions of a pharmacy;
3. use in the professional activity of normative legal and legislative acts of Ukraine, requirements of proper pharmacy practice (GPP) for the manufacture of drugs in the conditions of a pharmacy;
4. the formation of higher education students with knowledge of: the theoretical foundations of manufacturing technology various types of dosage forms, conducting prosthetic control, ways of improving the technology of pharmaceutical forms in the conditions of a pharmacy;
5. studying the effects of storage conditions and the type of packaging on the stability of dosage forms;
6. the study of equipment, including new devices and automatic lines, modern requirements for the production of pharmaceutical forms, including the requirements of the World Health Organization (WHO) for the purity of raw materials, production facilities and personnel.

Learning outcomes for discipline.

know:

1) pharmacy manufacturing technology;
2) main groups of biologically active substances of medicinal plant material;
3) stability and timing of drug storage;

4) biologically active and auxiliary substances of medicinal forms;

5) pharmaceutical incompatibilities (physical, chemical, pharmacological), methods of their elimination;

6) orders of the Ministry of Health of Ukraine on the release of narcotic, poisonous, intoxicating drugs and precursors;

7) compilation of the material balance of the production of medicines; theoretical foundations of extraction, mass transfer processes;

8) technology of water extracts from medicinal plant raw materials (infusions and decoctions), tinctures and extracts;

9) technology of manufacturing dosage forms for parenteral use;

10) chemical stability of glass, requirements for vials for injectable solutions;

11) requirements for containers, closures and packaging materials;

12) the technology of making soft dosage forms: liniments, creams, ointments, gels and pastes of various types in the pharmacies conditions;

13) classification of drugs and medical forms;

14) conditions of storage of poisonous and potent medicinal plant material;

15) general requirements for storage of medicines in pharmacies.

be able to:

1) To use regulatory legal acts regulating pharmaceutical activity in Ukraine;

2) to provide information about the material and technical base of the pharmacy;

3) to use regulatory and regulatory acts regulating pharmaceutical activity in Ukraine and abroad;

4) conduct research on pharmaceuticals development;

5) to draw up technological schemes and instructions for the manufacture of drugs "in stock" in the conditions of a pharmacy;

6) to check and, if necessary, to correct one-time, daily and course doses of poisonous, narcotic, potent substances and norms for the release of narcotic substances and substances equated to them, taking into account individual features of a person (age, body weight, etc.);

7) to weigh, measure and dosage various kinds of medicines by weight and volume according to the word;

8) to prepare extractants of the required concentration, using various calculation methods;

9) stabilize pharmaceuticals, taking into account biological, physico-chemical, technological properties of active and auxiliary substances (list 1a), using the necessary reagents;

10) to prepare a variety of medicinal forms and intraperitoneal preparations (list 3) from medicinal and auxiliary substances;

11) to carry out sterilization of medical forms (list 3) taking into account physical and chemical properties and stability of medicinal substances;

12) make outlets for drugs made with poisonous, narcotic substances and substances equated with them;

13) to issue passports of written control for all manufactured medicines. To choose the optimum technology of manufacturing medical forms (list 3), using the necessary equipment;

14) to carry out the selection of auxiliary substances (stabilizers, emulsifiers, prolongers, ointments and suppository bases, fillers for tablets, etc.) for the manufacture of medical forms;

15) to develop technological regulations for the production of certain drugs by small series for frequently repeated prescriptions;

16) to draw up technological schemes and instructions for small-scale production of injection and infusion solutions in the conditions of small enterprises and hospital pharmacies;

17) to determine the technological and physical and chemical properties of powders and granules;

18) to prepare and test ampoules and vials for injectable solutions;

19) stabilize pharmaceuticals, taking into account the biological, physico-chemical, technological properties of active and auxiliary substances, using the necessary reagents to control the conditions of storage of raw materials and materials at the enterprises of the pharmaceutical profile.

COURSE DESCRIPTION

Thematic section 1. *State regulation of the manufacture of drugs in pharmacies. Solid dosage forms*

Theme 1. State regulation of the manufacture of drugs in pharmacies. General issues of drug technology.

Theme 2. Solid dosage forms. Manufacturing in the conditions of pharmacies of simple and complex powders with medicinal substances, differing in prescribed amount, bulk density and structure of particles.

Theme 3. Manufacturing of complex powders in pharmacy conditions with poisonous, narcotic and potent substances.

Theme 4. Production of complex powders with colorful, fragrant and hardly crushed substances.

Theme 5. Production of complex powders with extracts and semi-finished products.

Theme 6. Production of fees in pharmacy conditions.

Content section 2. *Liquid and extractive dosage forms*

Theme 7. Liquid dosage forms. Manufacturing of concentrated solutions.

Theme 8. Manufacturing of liquid dosage forms by mass-volume method by dissolving dry medicinal substances and use of concentrated solutions.

Theme 9. Special cases of making aqueous solutions. Drops.

Theme 10. Manufacturing of liquid dosage forms by dilution of standard pharmacopoeial liquids. Non-aqueous solutions.

Theme 11. High molecular weight - compounds solutions. Colloidal solutions.

Theme 12. Suspensions.

Theme 13. Emulsions.

Theme 14. Infusions and decoctions of medicinal plant material.

Theme 15. Slimes. RLF technology using extract concentrates.

Content section 3. *Soft medical forms. Suppositories*

Theme 16. Soft medical forms. Lineaments and ointments are homogeneous.

Theme 17. Ointments are heterogeneous.

Theme 18. Ointments combined. Creams. Gels.

Theme 19. Suppositories Manufacturing of suppositories by a method of pumping. Sticks. Pills.

Theme 20. Production of suppositories by pouring method.

Content section 4. *Medicinal forms that require aseptic conditions of production*

Theme 21. Requirements for the production of sterile and aseptic drugs in pharmacies.

Theme 22. Solutions for injections.

Theme 23. Solutions for injections that require stabilization.

Theme 24. Isotonic and infusion solutions. Solutions for injections with thermoplastic substances. Suspensions for injection.

Theme 25. Eye medicine forms.

Theme 26. Medicinal forms with antibiotics.

Theme 27. Children's and geriatric medical forms.

Sources of information:

Basic (base):

1. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.

2. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.

3. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 3. – 732 с.

4. Практикум по аптечной технологии лекарств : учеб. пособие для студ. вузов / А.И. Тихонов, С.А.Тихонова, С.М. Мусоев, Г.П. Пеклина, Л.А. Бондаренко,
А.Г. Башура, О.С. Шпичак, Е.Е. Богуцкая; под ред. А.И. Тихонова и С.А. Тихоновой. – Х.: Оригинал, 2016. – 462 с.

5. Руководство к учебным занятиям по аптечной технологии лекарств : учеб. пособие для студентов вузов / Л.И. Вишневская, Н.П. Половко, Р.С. Корытнюк и [др.]. – Х.: НФаУ : Оригинал, 2016. – 378 с.

6. Тихонов О.І. Аптечна технологія ліків / О.І. Тихонов, Т.Г. Ярних. – Вінниця: Нова книга, 2016. – 536 с.

7. 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.

8. 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.

9. Технологія ліків. Навчально-методичний посібник: Навч. посіб. для студ. вищ. навч. зал./О.І. Тихонов, П.А. Логвін, С..О. Тихонова, О.В. Мазулін, Т.Г. Ярних, О.С. Шпичак, О.М. Котенко; за ред.. О.І. Тихонова. –Х.: Оригінал, 2009.-432 с. Тихонов, О. І. Аптечна технологія ліків / О. І. Тихонов, Т. Г. Ярних. – Вінниця: Нова книга, 2016. – 536 с.

10. 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.

11. Ярних, Т. Г. Екстемпоральна рецептура (технологія, аналіз, застосування): метод. рек. / Т. Г. Ярних, о. І. Тихонов, І. С. Гриценко та ін. – Х., 2015. –379 с.

12. Аптечна технологія ліків: навчальний посібник /упоряд.: Борисюк І.Ю., Фізор Н.С., Сущук Н.А., Мельник О.А., Молодан Ю.О. Одеса, ОНМедУ, 2021.-140с.

Additional literature:

1. Стандарт МОЗ України «Вимоги до виготовлення нестерильних лікарських засобів в умовах аптек» СТ-Н МОЗУ 42 – 4.5 : 2015 // За ред. проф. О.І. Тихонова і проф. Т.Г. Ярних. – Київ, 2015. – 109 с. (Затверджено наказом МОЗ України № 398 від от 01.07.2015).

2. Вимоги до виготовлення стерильних та асептичних лікарських засобів в умовах аптек [Електронний ресурс] : настанова СТ-Н МОЗУ 42-4.5:2015, затверджені Наказом МОЗ України № 398 від 01.07.15. – К., 2015. – 76 с.

3. Фармацевтична енциклопедія / Голова ред. ради та автор передмови В.П. Черних. – 3-тє вид., переробл. і доповн. – К.: «МОРІОН», 2016. – 1952 с.

Electronic resources:

1. Компендиум: лекарственные препараты. − [Електроний ресурс]. – Режим доступу: http://compendium.com.ua/ − станом на 10.10.2016 р. 39.

2. Державний реєстр лікарських засобів України. − [Електроний ресурс]. – Режим доступу: http://www.drlz.com.ua/ − станом на 10.01.2017 р.

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 (the 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.

Final credit. Students who have fully completed the curriculum in the discipline have no academic debt, their average score of current performance is 3.00 or more, in the last class receive a credit, which is set as «passed» / «not credited». Conversion of a traditional national score to a multi-point score (maximum 200 points) is required.

If a student receives a minimum grade point average of 3.00 for current performance, even if there are unsatisfactory grades, he receives a credit for the discipline.

For disciplines included in the integrated test exams Крок-1 and Крок-2, a mandatory component of the curriculum is the final test control of the discipline, which includes 50 test questions (30 minutes), as an indicator of students' acquisition of knowledge. Compilation of the final test control takes place at the last practical lesson in the discipline at ЦІАВКЯО according to the schedule of the educational department, approved by the rector of the university. The student must provide the correct answers by at least 90% (45 questions). A paper copy of the information on the results of test control in the discipline signed by the head of the Center is sent to the department. The teacher files a statement in the Journal of attendance and student performance and puts assessments of current performance for the last lesson in the discipline, converting the results on the following scale:

- grade «excellent» - 50 correct answers;
- grade «good» - 47-49 correct answers;
- assessment «satisfactory» - 45-46 correct answers;
- score «unsatisfactory» - 44 correct answers and less

A student who has not passed the final test control in the discipline is considered to have not completed the program in the discipline. At the last lesson of the discipline in the semester, the teacher is obliged to put «enrolled» in the student's record book.

The form of final control of knowledge in the discipline in the third year is a **differential test.**

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.

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 retake 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 the writing of abstracts (Independent work) 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, 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.

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.