Odessa National Medical University

Faculty of Pharmacy
Department of General Pharmacy with a course in clinical pharmacology

The syllabus of the discipline " PHYSICO-CHEMICAL IN CREATION OF DRUGS "

Amount	credits (ECTS) - 3	total number of hours - 90 lectures - 1 0 seminar classes - 2 0 independent work - 6 0
Year of study	3	
Semester	5	
Days, time, place	The time and place (number of the lecture hall, auditorium, laboratory, studio, etc.) of the discipline is determined in accordance with the approved schedule.	
Teachers	Nikogosyan LR, Head of the Department, Doctor of Medical Sciences, Professor Berbek VL, Associate Professor, Candidate of Pharmaceutical Sciences, Gromova MI, Assistant	
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COMMUNICATION info.odmu.edu.ua/chair/general_pharmacy/
Microsoft Teams

COURSE ANNOTATION

The subject of study of the discipline

The subject of the discipline is the formation of students' knowledge system based on the basic laws of physical and colloid chemistry, necessary to understand the nature and mechanism of the processes underlying the creation of new high-performance technologies of drugs and improving existing ones, and the role of physicochemical analysis in this process. .

Prerequisites and post requisites of the course

The discipline is based on the theoretical principles of physics, mathematics, botany, human anatomy and physiology, microbiology, inorganic, analytical, organic, physical and colloid chemistry and other disciplines and integrates with these disciplines;

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 drugs, drug technology, which integrates teaching with the above disciplines to develop skills in further learning and in professional activities;

the discipline lays the foundations for the preparation of the future pharmacist for logical thinking, analysis and forecasting through a system of physicochemical concepts, definitions, the formation of skills for the study of pharmaceutical chemistry and technology of drugs, as well as preparation for independent work;

together with other pharmaceutical disciplines and social sciences, the course "Physico-chemical analysis in the development of drugs" plays an important role in providing training for professional activities, opens up new opportunities for professional activity of the pharmaceutical industry, and allows you to choose different options for creation and analysis effective scientifically sound, economically feasible and environmentally friendly drugs.

The purpose of the course

The purpose of teaching the elective course "Physico-chemical analysis in the development of drugs" is to acquaint students with the theoretical and practical foundations of physico-chemical analysis and coverage of modern requirements for evaluating the therapeutic efficacy of drugs and physico-chemical research methods in developing their composition and technology.

Tasks of discipline

The main objectives of the discipline "Physico-chemical analysis in the development of drugs" are to acquire theoretical knowledge and practical skills in physico-chemical features of drugs, which are necessary for a specialist in the pharmaceutical industry to ensure the development of drugs of various forms; 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; use in normative activity of normative-legal and legislative acts of Ukraine; formation of skills of application by the basic receptions and methods of research of physicochemical properties of compounds for the decision of applied problems in pharmaceutical practice; solving problems to predict the predominant direction of biochemical processes in order to develop methods for obtaining drugs.

Expected results

The student must know:

- Methods of the structure determination of organic compounds, physical and physicochemical methods chemical methods; types of chemical analysis; instrumental methods of analysis; methods of qualitative and quantitative analysis of drugs; cleanliness tests; state regulation of the quality of medicines and medicinal plant raw materials;

- Electrochemistry; potentiometric analysis; quality indicators of parenteral, solid, soft and aerosol dosage forms, stability and shelf life of drugs; analysis of purified water and water injection; methods for determining microbial contamination of medicinal raw materials and finished drugs;
- Qualitative analysis of cations and anions; medicines of inorganic nature; elemental analysis and analysis by functional groups; functional analysis of organic compounds by functional groups; general methods of analysis of inorganic and organic drug compounds;
- Chromatographic methods for identification, purity and quantitative research content drugs; light propagation in matter, methods of luminescent analysis; optical activity and specific rotation. Magnetic properties of substances; transfer phenomena. Real gases; gravimetric method of analysis; functional analysis of organic compounds; basic concepts of titrimetric analysis; spectral methods of analysis; components and impurities of fatty and essential oils, methods of their production.

The student must be able to:

- Conduct research on the pharmaceutical development of medicines and cosmetics. Carry out qualitative and quantitative rapid analysis of active substances that are part of drugs using the necessary equipment (refractometer, polarimeter, etc.). Carry out identification, determination of impurities and quantitative content of medicinal substances, biologically active substances of medicinal plants and poisons isolated from biological material, using physico-chemical methods: thin layer chromatography; polarimetry, refractometry, spectrophotometry, spectroscopy, photoelectric colorimetry, high performance liquid chromatography, gas chromatography, fluorometry.
- Determine the stability of medicines and medical devices during storage during the established shelf life.
- Determine cations and anions of active substances of inorganic nature in raw materials, intermediates and finished products by chemical methods; to determine the functional groups of active substances of organic nature in raw materials, intermediate products, finished products

COURSE DESCRIPTION

Forms and methods of teaching

The course would oud set out in the form of lectures (10 hrs.) And a seminar classes (20 hrs.), Organizations with independent work of students (60 hrs.).

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

interactive methods and multimedia learning (multimedia lectures, educational films).

The content of the discipline

Topic 1. Subject, tasks and methods of the discipline "Physico-chemical analysis in the creation of drugs", the main stages of development and place among other sciences. The role of basic sciences in the development of therapeutically effective drugs.

The concept of drug substance and dosage form. Types of dosage forms. The path from molecules to drugs. Security issues. Advantages and disadvantages of traditional medicines. Problems develop new forms of known drugs or problems permeability solubilization, targeted delivery, controlling the speed of flow in the body, reducing toxicity, administration, production, patent protection.

Topic 2. Basic classifications and concepts of technology of dosage forms; biopharmaceutical classification system and basics of pharmacokinetics.

Classification of medicinal substances. Methods of influencing the properties of dosage forms without changing the chemical composition of the substance. Pharmaceutical production: technology of dosage forms; biopharmacy; pharmacokinetics; bioavailability, pharmacodynamics. Requirements for excipients. Pharmaceutical factors influencing therapeutic activity (effective drug release). Elements of pharmacokinetics. The scheme of the path of the drug in the body.

Topic 3. The structure of research on the development and biopharmaceutical screening of drugs of liquid, solid and soft forms, ophthalmic, nasal drugs, drugs based on nanoparticles.

Liquid dosage forms. The doctrine of solutions is the basis for the preparation of most liquid drugs. Dissolution as a physicochemical process. Physico-chemical bases of obtaining emulsions and suspensions. Physical and chemical nature of infusions and decoctions. Solid dosage forms. Excipients in the manufacture of tablets and capsules. Properties of medicinal substances and bases in rectal and mild dosage forms. The structure of research to develop the optimal composition, technology and methods of quality control of drugs of various forms of release.

Topic 4. Pharmaco- technological methods for assessing the release of drugs from drugs.

Static and dynamic methods for studying the decay of solid dosage forms. Methods and devices for studying dissolution and its kinetics. Passage of drugs through membranes. Physico-chemical, microbiological and methods of physico-chemical detection in the study of the release of drugs from soft and rectal dosage forms.

Topic 5. Review of modern research methods and their hardware used in the development of innovative dosage forms and subsequent product control.

Thermal analysis. Melting diagrams of binary mixtures, their analysis: determination of the number and nature of phases, the limits of their existence, the nature of the interaction of components, the stability of the formed substances.

Conductometry. Schematic diagram of the conductometer. Direct conductometry is a method of determining various physicochemical quantities based on the electrical conductivity of the solution. Application of conductometric titration in pharmaceutical practice.

EMF method. The essence of potentiometric definitions is the doctrine of the origin of the electrode potential and the dependence of the latter on the concentration of ions that determine the potential. Determination of pH and other physicochemical characteristics in the study and analysis of drugs.

Polarography. Kinetic regularities of electrochemical reactions as a basis of a method of polarography. Qualitative and quantitative polarographic analysis.

Molecular spectroscopy. Atomic absorption and emission spectroscopy. Molecular optical spectroscopy: Infrared spectroscopy (ICS), visible and UV spectroscopy. Quantitative spectroscopic and spectrophotocolorimetric analysis. Application of photometric methods in biochemical, medical research and in the analysis of individual and combined drugs.

Chromatography. The essence of the method of chromatography. Principles of classification of chromatographic methods. Paper and thin layer chromatography. Ion exchange and gel chromatography.

List of recommended reading

Basic

1. Державна фармакопея України. – 1-е вид., Доповнення 3. – Х.: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2009. – 280 с.
2. Загальні методи аналізу якості лікарських препаратів: навч.-метод. посіб. для студентів 3,4,5 курсів фармац. ф-ту спеціальності «Фармація» / уклад. : Л. І. Кучеренко, І. А. Мазур, О. О. Портна [та ін.]. – Запоріжжя: [ЗДМУ], 2017. – 115 с.
3. Біофармація : підруч. для студ. вищих фармац. навч. закладів і фармац. ф–тів вищ. мед. навч. закладів IV рівня акредидації / О. І. Тихонов, Т. Г. Ярних, І. А. Зупанець, О. С. Данькевич, О. Є. Богуцька, Н. В. Бездітко, Ю. М. Азаренко, Ю. В. Левачкова. – Х. : Изд–во НФаУ : Золотые страницы, 2010. – 240 с.
4. Фармацевтичний аналіз: Навч. посіб. для студ. вищ. фармац. навч. закл. III-IV рівнів акредитації / П.О. Безуглий, В.О. Грудько, С.Г. Леонова та ін.; За ред. П.О. Безуглого. - Х.: Вид-во НФАУ; Золоті сторінки, 2001. - 240 с.

Auxiliary

1. Допоміжні речовини в технології ліків: вплив на технологічні, споживчі, економічні характеристики і терапевтичну ефективність : навч. посібник для студ. вищ. фармац. навч. закладів / І. М. Перцев, Д. І. Дмитрієвський, В. Д.

Рибачук, В. М. Хоменко, О. П. Гудзенко, О. М. Котенко, Ю. С. Маслій. – Х. : Золоті сторінки, 2010. – 600 с.
2. Фармацевтичні та медико-біологічні аспекти ліків: навч. посіб. для студ., магістрів, асп., викл., наук. співроб. та спеціалістів фармації / І.М.Перцев, О.Х.Пімінов, М.М.Слободянюк [та ін.]; за ред. І.М.Перцева ; Нац. фармац. ун-т. - 2-ге вид., перероб. та доп. - Вінниця : Н. Кн., 2007. - 725 с. : іл., табл.
3. Фармацевтична хімія: Підручник для студ. вищ. фармац. навч. закл. і фармац. ф-тів вищ.мед. навч. закл. / За заг. ред. П.О.Безуглого. – Вінниця, НОВА КНИГА, 2011. – 560 с.

Information resources

- Лекційні матеріали, методичні розробки для семінарських занять та самостійної роботи на кафедрі загальної фармації: Режим доступу : http:// http://info.odmu.edu.ua/chair/general_pharmacy/.
- www.moz.gov.ua – офіційний сайт Міністерства охорони здоров'я України
- http://onmedu.edu.ua – офіційний сайт Одеського національного фармацевтичного університету
- http://libblog.odmu.edu.ua – сайт бібліотеки ОНМедУ
- fp.com.ua – сайт журналу «Фармацевт практик»
- www.provisor.com.ua – офіційний сайт журналу «Провізор»
- Компендиум: лекарственные препараты. − [Електроний ресурс]. – Режим доступу: http://compendium.com.ua/ − станом на 10.10.2016 р.
- Державний реєстр лікарських засобів України. − [Електроний ресурс]. – Режим доступу: http://www.drlz.com.ua/ − станом на 10.01.2017 р.
- База даних «Еквалайзер» ТОВ «Бізнес-Кредит» – [Електроний ресурс]. – Режим доступу: http://eq.bck.com.ua/ − станом на 20.09.2016 р.

EVALUATION

General evaluation system	Participation in the work during the semester on a 200-point scale
Rating scales	traditional 4-point scale, multi-point (200-point) scale, ECTS rating scale
Conditions of admission to the final control	Students who have attended all classes provided by the curriculum, performed all types of work provided by the program and received grades sufficient to convert to a minimum number of points (not less than 120 points for current performance) are allowed to the final control .

Test	It consists in assessing the student's mastery of educational material solely on the basis of the results of his performance of certain types of work in practical classes and during independent work. The semester test is held at the last lesson of the discipline. The test in the discipline is set according to the results of the current control and is expressed on a two-point scale: "passed" or "not passed"	*The maximum number of points is 200.* *The minimum number of points is 120*

Independent work of students.

Students' independent work is a process of active, purposeful acquisition by a student of new knowledge and skills without the direct participation of teachers. VTS provides preparation of the student for current classroom activities and control activities according to the curriculum.

Basic VTS includes the following types of work:

- work with lecture material, which involves the elaboration of lecture notes and educational literature;
- search (selection) and review of literature and electronic sources of information on an individual problem of the course;
- homework or homework, which involves solving problems, performing exercises, etc .;
- study of the material submitted for independent processing;
- writing an abstract on a given problem;
- preparation for the test.

Results appear in this training activity students in the classroom and the quality of performed tests, tests made reports and other forms of current control.

COURSE POLICY

For successful mastering of the course the applicant of higher education is obliged:

- to take an active part in the educational process, in particular to properly study the educational material on each topic;
- not to miss lectures and practical classes without a good reason, and in case of illness to provide information;
- not to be late for lectures and practical classes;
- timely work off missed classes;
- prepare for practical classes and maintain feedback during them;
- timely and accurately perform tasks for VTS;
- turn off your mobile phone during lectures and practical classes;
- take part in control measures (current control, VTS control, final control), during which hints and write-offs are not allowed.

Any copying or reproduction of the results of someone else's work, unless the work has a group format, the use of materials downloaded from the Internet qualifies as a violation of the rules and regulations of academic integrity and involves bringing the perpetrator to justice under applicable regulations.

Failure to comply with and / or non-compliance with the course policy may result in a grade of "unsatisfactory".