

МИНОБРНАУКИ РОССИИ

**Федеральное государственное бюджетное образовательное
учреждение высшего образования "Пермский
государственный национальный исследовательский
университет"**

Кафедра фармакологии и фармации

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Рабочая программа дисциплины
INDUSTRIAL MEDICINE TECHNOLOGY
Код УМК 93086

Утверждено
Протокол №6
от «23» марта 2020 г.

Пермь, 2020

1. Наименование дисциплины

Industrial Medicine Technology

2. Место дисциплины в структуре образовательной программы

Дисциплина входит в Блок « С.1 » образовательной программы по направлениям подготовки (специальностям):

Специальность: **33.05.01** Фармация

направленность Программа широкого профиля (для иностранных граждан)

3. Планируемые результаты обучения по дисциплине

В результате освоения дисциплины **Industrial Medicine Technology** у обучающегося должны быть сформированы следующие компетенции:

33.05.01 Фармация (направленность : Программа широкого профиля (для иностранных граждан))

ОПК.3 способность осваивать новые технологии и применять их для проведения естественнонаучных исследований

ПК.20 готовность к участию во внедрении новых методов и методик в сфере разработки, производства и обращения лекарственных средств

4. Объем и содержание дисциплины

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|---|--|
| Направления подготовки | 33.05.01 Фармация (направленность: Программа широкого профиля (для иностранных граждан)) |
| форма обучения | очная |
| №№ триместров, выделенных для изучения дисциплины | 13 |
| Объем дисциплины (з.е.) | 8 |
| Объем дисциплины (ак.час.) | 288 |
| Контактная работа с преподавателем (ак.час.), в том числе: | 112 |
| Проведение лекционных занятий | 14 |
| Проведение практических занятий, семинаров | 56 |
| Проведение лабораторных работ, занятий по иностранному языку | 42 |
| Самостоятельная работа (ак.час.) | 176 |
| Формы текущего контроля | Защищаемое контрольное мероприятие (2) Итоговое контрольное мероприятие (1) |
| Формы промежуточной аттестации | Экзамен (13 триместр) |

5. Аннотированное описание содержания разделов и тем дисциплины

Industrial drug technology as a science. Technology of dosage forms. Structure, goals and objectives. GMP rules. The main regulatory and technical documentation governing the production of drugs

Modern theoretical concept of pharmaceutical technology: unity of laws of influence of pharmaceutical factors in the process of creation of medicinal, preventive, rehabilitation and diagnostic means. The structure of pharmaceutical technology as a discipline, its sections: drugs and excipients, basic processes and devices of pharmaceutical technology, technology of dosage forms, machinery and equipment of pharmaceutical industries, Standardization of quality of medicines. Dependence of the quality of dosage forms on the standard of medicines. State Pharmacopoeia, Pharmacopoeia article, Temporary Pharmacopoeia Article. A brief history of domestic Pharmacopoeia. Pharmacopoeia regulation of production and quality of drugs, excipients and dosage forms. State Pharmacopoeia of the Russian Federation, international Pharmacopoeia, USA, Great Britain, Germany, etc. Rationing of drug formulations. Recipe of officinal and trunk. Indicators and standards of quality of initial components and finished drugs. Rationing of manufacturing conditions and technological processes of production of medicines. Rules of GMP, Pharmacopoeia article, Temporary Pharmacopoeia Article, technological regulations, orders of the Ministry of health, instructions for the manufacture and quality control of dosage forms in pharmacies, other regulatory documentation, sources of information. Organization of quality system of production of medicines.

The main processes and devices used in the manufacture of dosage forms and preparations. Classifications. Machines and apparatus. Thermal processes in the pharmaceutical industry

Types of basic processes of pharmaceutical technology on various grounds: mechanical, hydromechanical, thermal, mass transfer, etc. the Role and relationship of typical processes of pharmaceutical technology. General concepts of machines and apparatuses. Basic concepts of transfer mechanisms. Law of equilibrium. Thermodynamic equilibrium. The direction and driving force of the process. Mechanical processes and apparatus. Hydromechanical processes and devices. Thermal processes and apparatus. Mass transfer processes and devices. Vacuum evaporators: ball, tubular, free circulation, natural circulation, forced circulation, film, rotary. Vacuum-evaporating installation. Side effects of evaporation: formation of inlays, temperature losses, spray and foam, hydraulic, hydrostatic depression. By addressing.

Extraction phytopreparations

Extraction of medicinal raw materials.

Theoretical bases of extraction of medicinal raw materials with cellular structure. Raw material preparation. Extractants. Requirements to them, nomenclature, justification of choice. Methods of extraction, ways of intensification. Extraction herbal remedies. Classifications. Characteristic. Extraction herbal remedies: herbal, total as purified preparations of individual substances. Technological schemes of obtaining. Industrial methods of extraction – maceration, percolation, repercolation, and circulating counter-current extraction. Methods of intensification. Equipment for extraction.

Tinctures. Definition. Characteristic. Evaporation. Preparations from fresh raw materials.

Place among the other extraction agents. Technological scheme of production, equipment. Extraction methods, purification methods. Quality indicators of tinctures, evaluation methods. Special occasions of preparation. The use of evaporation in pharmaceutical technology. Vacuum evaporation. Schematic diagrams of vacuum evaporators. Varieties of vacuum evaporators. Side effects of evaporation and methods of compensation. Preparations from fresh raw materials. Characteristics, classification. Feature of manufacture. Juices, tinctures, extracts. Technological scheme. Stabilization and preservation of juices. Nomenclature.

Extracts

Production of extracts (liquid, thick, dry). Technological and hardware schemes

Most refined (overall) herbal remedies. Classification. Preparations of individual substances from medicinal plant raw materials.

Place the most refined (overall) herbal remedies among other ekstraktsionnyh herbal remedies. Technological schemes of obtaining. Equipment for carrying out processes of liquid extraction, adsorption and other ways of purification of extracts. Classification and characteristics of preparations of individual substances from medicinal plant raw materials. Their place among the extraction of herbal remedies. Technological schemes of obtaining. Purification of extracts from ballast substances, separation of the amount of purified substances, isolation of individual.

Medicines from animal raw materials.

Characteristics of the preparations. Raw materials, their selection, preservation, processing features. Classifications. Technology of preparations of dried glands and tissues. Features of technology of extraction organopreparations for internal application. Enzyme preparation. Cell preparations. Technology of organopreparations for parenteral administration. Highly effective methods of purification: Athene chromatography, gelfiltration, etc. Drugs for injection: adencorticotropic hormone, pituitrin, etc.

Tinctures. Liquid, thick and dry extracts

Mass transfer processes. Theoretical bases of extraction. Extractants: classification, obtaining. Methods of extraction, ways of intensification. General characteristics of the process and features of extraction in liquid — solid and liquid — liquid systems. The main methods of extraction: single extraction, multiple cross-current solvent, multiple countercurrent, circulating. Extractors. Classification. Device and principle of operation of mixing-settling and differential-contact (spray, rotary-disk, pulsation, centrifugal) extractors. Extraction in liquid-liquid system. Production of tinctures. Production of extracts (liquid, thick, dry). The technological and hardware circuits. Recovery and rectification of alcohol.

Neogalenic preparations

The most purified (total) herbal remedies. Herbal preparations of individual substances. Definition. Characteristic. Properties. Their place among other herbal remedies. Nomenclature. Classification of drugs (glycosides, alkaloids, flavonoids, etc.). The general technological scheme of obtaining preparations of individual substances. Methods of isolation, purification and separation of the sum of individual substances. Recrystallization. Equipment for carrying out liquid extraction processes, adsorption and other ways of cleaning extracts. Dosage forms of drugs of individual substances. Private technology.

From fresh plant materials. Biogenic stimulant preparations. Organopreparations

Preparations from fresh vegetable raw materials. Characteristic. Classification. Technology. Nomenclature: aloe juice and others. Technological scheme of juice production. Cleaning and stabilization of juices. Private technology. Standardization of preparations from fresh vegetable raw materials. Storage. Preparations of biogenic stimulants. Characteristic. Technology. Nomenclature: aloe extract liquid and others. Preparations from animal raw materials: characteristics, classification. Raw materials, their selection, preservation, processing features. Technology of preparations of dried glands and tissues. Features of technology of extraction organopreparations for internal application. Enzyme preparation. Cell preparations. Technology of organopreparations for parenteral administration. Highly effective methods of purification: affine chromatography, gelfiltration, etc. Insulin. Drugs for injection: adrenocorticotropic hormone, pituitrin, etc. Nomenclature: thyroïdin, Pancreatin, lidase, ATP.

Control event number 1

Industrial drug technology as a science. The modern concept of industrial technology of drugs. Technology of dosage forms. Structure, goals and objectives. GMP rules. The main regulatory and technical documentation

governing the production of drugs. Extraction dosage forms of industrial production. Technological and hardware schemes for the production of extraction preparations.

Medical solutions, syrups, suspensions and emulsions of industrial production

Medical solutions. Technological and apparatus scheme for the production of aqueous solutions. Standardization. Syrups. Suspensions and emulsions. Technological and hardware production schemes. Standardization. The solution of situational problems at the rate of industrial technology of drugs (material balance, the rule of mixing).

Soft dosage forms of industrial production. Suppositories

Ointments. Definition Characteristic. Classifications. Compositions. Excipients. Basics, their classification according to composition, physicochemical, technological properties, according to the degree of relationship with medicinal substances. Technological schemes for producing ointments of various types. Methods of introducing drugs into the base. Suppositories. Definition Characterization of the rectal route of administration of dosage forms. Types of rectal dosage forms. Types of suppositories, their classification. Compositions. Excipients, classification and nomenclature. The basis for suppositories: lipophilic, hydrophilic, diphilic. Technological schemes. Ways to improve.

Sterile dosage forms of industrial production

Features of industrial production of solutions for parenteral administration. Characteristic. Types of dosage forms. General requirements. Comparative characteristic. Definition, characteristics of the dosage form, application. Water preparation. Requirements for ampoule glass. Dressing ampoules and preparing them for filling with solutions. Equipment.

Amputation.

Methods of washing ampoules, their drying sterilization. Preparation of injection solutions, cleaning of mechanical contaminants. Equipment. Methods of filling ampoules with solutions. Sealing ampoules and checking the integrity of the package. Sterilization. Standardization. Quality indicators of solutions in ampoules. Quality inspections. Nomenclature.

Eye dosage forms of industrial production.

Characteristics and classification. Drops, ointments, films, ocular therapeutic systems. Standardization. Nomenclature. Equipment used. Technological scheme.

Injectable dosage forms of industrial production. Production of ampoules and vials for injectable dosage forms

Features of the industrial production of solutions for parenteral administration. Characteristic. Types of dosage forms. General requirements. Comparative characteristics. Definition, characterization of the dosage form, application. Water treatment. Requirements for ampoule glass. The manufacture of ampoules and their preparation for filling with solutions. Equipment. Methods for washing ampoules, their sterilization drying. Preparation of injection solutions, cleaning from mechanical impurities. Equipment.

Sterilization methods. Purification of injection solutions. Infusion solutions. Filling and sealing ampoules. Quality assessment of injectable dosage forms

Preparation of solutions for injection. Private technology of ampouled solutions. Stabilization and purification of injection solutions in a factory environment. Methods of filling ampoules with solutions. Sealing of ampoules and checking the tightness of the package. Sterilization. Standardization. Quality indicators of solutions in ampoules. Braquerage. Technological and equipment schemes for the production of injection solutions. Infusion solutions for industrial production, emulsions and suspensions for parenteral administration. Technological

features of obtaining a 0.5% solution of novocaine, 20% glucose solution, 5% ascorbic acid solution, 25% magnesium sulfate solution.

Ophthalmic dosage forms of industrial production

Ophthalmic dosage forms of industrial production (drops, ointments, films, ocular therapeutic systems). Characterization and classification. Standardization. Nomenclature. Ophthalmic medicinal films, equipment used, technological scheme. Promising drug form for the eyes.

Control event number 2

Medical solutions, syrups, suspensions and emulsions of industrial production. Soft dosage forms of industrial production. Suppositories. Injectable dosage forms of industrial production. Production of ampoules and vials for injectable dosage forms. Sterilization methods. Purification of injection solutions. Infusion solutions. Filling and sealing ampoules. Quality assessment of injectable dosage forms. Ophthalmic dosage forms of industrial production.

Solid Dosage Forms

Tablets. Definition. Characteristic. Types of tablets.

Composition and methods for the preparation of tablets. Theoretical bases of tableting. Technological schemes of production of tablets. Pressing tablets. Tablet machines: rotary and percussion, their device, the principle of operation. Coated tablets. Methods of coating tablets with shells: pelleting and suspension, pressed coatings, film. Quality indicators of tablets and their rationing. Granules. Dragee. The microgranules. Microcapsules. Characteristics, purpose. Technological schemes of reception of drops and as microdrops. Methods of microgranulation and microcapsulation. Apparatus. Medical capsules. Definition. Characteristics, purpose. Methods for obtaining hard and soft capsules. Spansule.

Tableted preparations. Studying the properties of pressed materials. Tablet technology

Tablets. Classification. Technological properties of powders. The theoretical foundations of tableting. Methods for producing tablets. Direct pressing. Tablet machines: rotary and percussion, their device, principle of operation.

Technology for the production of tablets with preliminary granulation. Coating tablets

Technology for producing tablets with preliminary granulation of mixtures. The technological scheme for the production of tablets using dry and wet granulation of tableted masses. Methods for coating tablets with coatings: coated and suspension, extruded and film coatings. Technological scheme of production.

Trituration tablets. Evaluation of the quality of tablets. Ways to improve the pills. Granules. Dragee

Trituration tablets. Quality indicators of tablets and their rationing. Ways to improve the pills. Granules. Dragee. Packaging solid dosage forms.

Encapsulated drugs. Microcapsules

Hard gelatin capsules. Soft gelatin capsules. Characteristic. Technological scheme of production. Standardization. Nomenclature. Spansula. Microgranules. Microcapsules Characteristic, purpose. Technological schemes for obtaining dragees and microdrags. Methods of microgranulation and microencapsulation. Devices. Standardization. Nomenclature

Prospects for creating a new generation of dosage forms and therapeutic systems. Aerodispersed dosage forms

Creation and preclinical testing of drugs. Ways of search and development of new drugs. Experimental study and clinical trials of drugs. Ways to improve traditional medicines. Biotechnology of traditional medicines and medicines of the future. State and prospects of development of production of therapeutic systems. The main

directions of improvement of technology and quality of ointments. New solid dosage forms of prolonged action. Nanotechnology in the preparation of dosage forms. Characteristics of aerosol dosage forms. Features of manufacturing technology of drugs under pressure. The device and the principle of operation of the aerosol can. Propellants, classification, requirements. The new aerosol packaging. Sprays.

Modern tests and devices for biopharmaceutical evaluation of dosage forms and systems. Methodology for the development of ND for the production of finished drugs

Bioavailability and therapeutic equivalence of drugs. Methods for determining absolute and relative bioavailability. Pharmaceutical factors and their role in obtaining therapeutically equivalent standard drugs. In vitro tests to determine dissolution and release of drugs from dosage forms. Principles of modeling the processes of release and absorption of drugs from dosage forms. Tests for biopharmaceutical research, devices. Interpretation of results obtained in vitro and in vivo. Stages. Bioobjects. Preparation of medicinal and prophylactic agents by biosynthesis and biotransformation.

Exam

A list of exam questions is attached.

6. Методические указания для обучающихся по освоению дисциплины

Освоение дисциплины требует систематического изучения всех тем в той последовательности, в какой они указаны в рабочей программе.

Основными видами учебной работы являются аудиторские занятия. Их цель - расширить базовые знания обучающихся по осваиваемой дисциплине и систему теоретических ориентиров для последующего более глубокого освоения программного материала в ходе самостоятельной работы. Обучающемуся важно помнить, что контактная работа с преподавателем эффективно помогает ему овладеть программным материалом благодаря расстановке необходимых акцентов и удержанию внимания интонационными модуляциями голоса, а также подключением аудио-визуального механизма восприятия информации.

Самостоятельная работа преследует следующие цели:

- закрепление и совершенствование теоретических знаний, полученных на лекционных занятиях;
- формирование навыков подготовки текстовой составляющей информации учебного и научного назначения для размещения в различных информационных системах;
- совершенствование навыков поиска научных публикаций и образовательных ресурсов, размещенных в сети Интернет;
- самоконтроль освоения программного материала.

Обучающемуся необходимо помнить, что результаты самостоятельной работы контролируются преподавателем во время проведения мероприятий текущего контроля и учитываются при промежуточной аттестации.

Обучающимся с ОВЗ и инвалидов предоставляется возможность выбора форм проведения мероприятий текущего контроля, альтернативных формам, предусмотренным рабочей программой дисциплины. Предусматривается возможность увеличения в пределах 1 академического часа времени, отводимого на выполнение контрольных мероприятий.

Процедура оценивания результатов обучения инвалидов и лиц с ограниченными возможностями здоровья по дисциплине предусматривает предоставление информации в формах, адаптированных к ограничениям их здоровья и восприятия информации.

При проведении текущего контроля применяются оценочные средства, обеспечивающие передачу информации, от обучающегося к преподавателю, с учетом психофизиологических особенностей здоровья обучающихся.

7. Перечень учебно-методического обеспечения для самостоятельной работы обучающихся по дисциплине

При самостоятельной работе обучающимся следует использовать:

- конспекты лекций;
- литературу из перечня основной и дополнительной учебной литературы, необходимой для освоения дисциплины (модуля);
- текст лекций на электронных носителях;
- ресурсы информационно-телекоммуникационной сети "Интернет", необходимые для освоения дисциплины;
- лицензионное и свободно распространяемое программное обеспечение из перечня информационных технологий, используемых при осуществлении образовательного процесса по дисциплине;
- методические указания для обучающихся по освоению дисциплины.

8. Перечень основной и дополнительной учебной литературы

Основная:

1. Richard S. Larson Bioinformatics and Drug Discovery. Humana Press, 2006. Online ISBN 978-1-59259-964-6. Текст электронный // : <https://link.springer.com/book/10.1385/1592599648#toc>
<https://link.springer.com/book/10.1385/1592599648>
2. Yvonne Bouwman-Boer, V'Iain Fenton-May, Paul Le Brun Practical Pharmaceutics. An International Guideline for the Preparation, Care and Use of Medicinal Products. KNMP and Springer International Publishing Switzerland 2015. Online ISBN 978-3-319-15814-3. Текст электронный // :
<https://link.springer.com/book/10.1007/978-3-319-15814-3> <https://link.springer.com/book/10.1007/978-3-319-15814-3>

Дополнительная:

1. Volker Bühler Polyvinylpyrrolidone Excipients for Pharmaceuticals. Povidone, Crospovidone and Copovidone. Springer-Verlag Berlin Heidelberg, 2005. Online ISBN978-3-540-27090-4. Текст электронный // : <https://link.springer.com/book/10.1007/b138598> <https://link.springer.com/book/10.1007/b138598>
2. Ali R. Rajabi-Siahboomi Multiparticulate Drug Delivery. Formulation, Processing and Manufacturing. Controlled Release Society, 2017. Online ISBN 978-1-4939-7012-4. Текст электронный // :
<https://link.springer.com/book/10.1007/978-1-4939-7012-4#toc> <https://link.springer.com/book/10.1007/978-1-4939-7012-4>

9. Перечень ресурсов сети Интернет, необходимых для освоения дисциплины

<http://www.consultant.ru/> Справочно-правовая система Консультант+
<https://pubchem.ncbi.nlm.nih.gov/> База данных химических соединений
<http://www.rlsnet.ru/> Регистр лекарственных средств
<http://www.iprbookshop.ru/> Электронно-библиотечная система IPRbooks
<https://cyberleninka.ru/> Научная электронная библиотека «Киберленинка»
<http://grls.rosminzdrav.ru/Default.aspx> Реестр лекарственных средств

10. Перечень информационных технологий, используемых при осуществлении образовательного процесса по дисциплине

Образовательный процесс по дисциплине **Industrial Medicine Technology** предполагает использование следующего программного обеспечения и информационных справочных систем: Presentation materials (slides on the topics of lecture and practical classes).
On-line access to the Electronic Library System (ELS).
Access to the electronic informational and educational environment of the university;
Testing.

The list of necessary licensed and (or) free software:

1. Office suite of applications "LibreOffice".
2. An application that allows you to view and play media content of PDF files "Adobe Acrobat Reader DC".
3. Programs, demonstrations of video materials (player) "WindowsMediaPlayer".
4. The program for viewing Internet content (browser) "Google Chrome".

При освоении материала и выполнения заданий по дисциплине рекомендуется использование материалов, размещенных в Личных кабинетах обучающихся ЕТИС ПГНИУ (**student.psu.ru**).

При организации дистанционной работы и проведении занятий в режиме онлайн могут использоваться:

- система видеоконференцсвязи на основе платформы BigBlueButton (<https://bigbluebutton.org/>).
- система LMS Moodle (<http://e-learn.psu.ru/>), которая поддерживает возможность использования текстовых материалов и презентаций, аудио- и видеоконтент, а так же тесты, проверяемые задания, задания для совместной работы.
- система тестирования Indigo (<https://indigotech.ru/>).

11. Описание материально-технической базы, необходимой для осуществления образовательного процесса по дисциплине

1. Lectures - an Audience equipped with presentation equipment (projector, screen, computer / laptop) with the appropriate software.
2. Seminar type classes (seminars, practical classes) - an Audience equipped with presentation equipment (projector, screen, computer/laptop) with appropriate software, chalk (s) or marker Board.
3. Laboratory classes - laboratory "Pharmaceutical technology", equipped with specialized equipment. The composition of the equipment is defined in the Passport of the laboratory.
4. Independent work-the Audience for independent work, equipped with computer equipment with the ability to connect to the Internet, provided with access to the electronic information and educational environment of the University.

Premises of the Scientific library PSU.

Помещения научной библиотеки ПГНИУ для обеспечения самостоятельной работы обучающихся:

1. Научно-библиографический отдел, корп.1, ауд. 142. Оборудован 3 персональными компьютера

доступом к локальной и глобальной компьютерным сетям.

2. Читальный зал гуманитарной литературы, корп. 2, ауд. 418. Оборудован 7 персональными компьютерами с доступом к локальной и глобальной компьютерным сетям.

3. Читальный зал естественной литературы, корп.6, ауд. 107а. Оборудован 5 персональными компьютерами с доступом к локальной и глобальной компьютерным сетям.

4. Отдел иностранной литературы, корп.2 ауд. 207. Оборудован 1 персональным компьютером с доступом к локальной и глобальной компьютерным сетям.

5. Библиотека юридического факультета, корп.9, ауд. 4. Оборудована 11 персональными компьютерами с доступом к локальной и глобальной компьютерным сетям.

6. Читальный зал географического факультета, корп.8, ауд. 419. Оборудован 6 персональными компьютерами с доступом к локальной и глобальной компьютерным сетям.

Все компьютеры, установленные в помещениях научной библиотеки, оснащены следующим программным обеспечением:

Операционная система ALT Linux;

Офисный пакет Libreoffice.

Справочно-правовая система «КонсультантПлюс»

**Фонды оценочных средств для аттестации по дисциплине
Industrial Medicine Technology**

**Планируемые результаты обучения по дисциплине для формирования компетенции и
критерии их оценивания**

| Компетенция | Планируемые результаты обучения | Критерии оценивания результатов обучения |
|--|---|--|
| <p>ПК.20 готовность к участию во внедрении новых методов и методик в сфере разработки, производства и обращения лекарственных средств</p> | <p>Know: new methods and techniques in the field of development, production and circulation of medicines; Actual problems and the latest developments in the field of pharmaceutical production. Be able to: introduce methods and techniques in the field of development, production and circulation of medicines; to qualitatively carry out various methods of production and manufacture of medicines; make changes to the course of scientific research to optimize the manufacturing technology of the dosage form. Own: basic techniques for the production and manufacture of medicines; new methods and techniques in the field of development, production and circulation of medicines.</p> | <p align="center">Неудовлетворител</p> <p>The knowledge is unsystematic, fragmentary. Gross, fundamental errors were made in the answers. Difficulties in understanding the characteristics of sterile dosage forms and dosage forms manufactured under aseptic conditions, on ensuring the required class of cleanliness of the premises, requirements for personnel, work clothing, equipment, significant difficulties in theoretical issues relating to the periods considered by the subject. Difficulties and errors are not resolved after leading questions of the teacher.</p> <p align="center">Удовлетворительн</p> <p>Knowledge of the main provisions of the program. The answer is not complete, without justification and explanation. Weak knowledge of the characteristics of sterile dosage forms and dosage forms manufactured under aseptic conditions, about ensuring the required class of cleanliness of the premises, requirements for personnel, work clothing, equipment, significant difficulties in theoretical issues relating to the periods under consideration. Errors are eliminated by additional questions of the teacher.</p> <p align="center">Хорошо</p> <p>Full knowledge of the training material provided for by the program, the successful completion of all tasks provided by the forms of current control. The answer is justified, reasoned. Minor errors, inaccuracies, which are corrected after the comments of the teacher.</p> <p align="center">Отлично</p> <p>Comprehensive in-depth knowledge of the characteristics of sterile dosage forms and</p> |

| Компетенция | Планируемые результаты обучения | Критерии оценивания результатов обучения |
|--|---|--|
| | | <p style="text-align: center;">Отлично</p> <p>dosage forms manufactured under aseptic conditions, on ensuring the required class of cleanliness of the premises, requirements for personnel, work clothing, equipment. The answer is justified, reasoned.</p> |
| <p>ОПК.3 способность осваивать новые технологии и применять их для проведения естественнонаучных исследований</p> | <p>Know: the technologies used to conduct science research. Be able to: apply technology to conduct natural science research. Own: skills in the development of new technologies for conducting natural science research.</p> | <p style="text-align: center;">Неудовлетворител</p> <p>The knowledge is unsystematic, fragmentary. Gross, fundamental errors were made in the answers. Difficulties in understanding the fundamentals of the industrial technology of drugs. Difficulties and errors are not resolved after leading questions of the teacher.</p> <p style="text-align: center;">Удовлетворительн</p> <p>Knowledge of the main provisions of the program. The answer is not complete, without justification and explanation. Weak knowledge of the industrial technology of drugs, significant difficulties in theoretical issues relating to the periods considered by the subject. Errors are eliminated by additional questions of the teacher.</p> <p style="text-align: center;">Хорошо</p> <p>Full knowledge of the training material provided for by the program, the successful completion of all tasks provided by the forms of current control. The answer is justified, reasoned. Minor errors, inaccuracies, which are corrected after the comments of the teacher.</p> <p style="text-align: center;">Отлично</p> <p>Comprehensive in-depth knowledge of industrial drug technology. The answer is justified, reasoned.</p> |

Оценочные средства текущего контроля и промежуточной аттестации

Схема доставки : Базовая

Вид мероприятия промежуточной аттестации : Экзамен

Способ проведения мероприятия промежуточной аттестации : Оценка по дисциплине в рамках промежуточной аттестации определяется на основе баллов, набранных обучающимся на контрольных мероприятиях, проводимых в течение учебного периода.

Максимальное количество баллов : 100

Конвертация баллов в отметки

«отлично» - от 81 до 100

«хорошо» - от 61 до 80

«удовлетворительно» - от 50 до 60

«неудовлетворительно» / «незачтено» менее 50 балла

| Компетенция | Мероприятие текущего контроля | Контролируемые элементы результатов обучения |
|--|---|--|
| ОПК.3 способность осваивать новые технологии и применять их для проведения естественнонаучных исследований ПК.20 готовность к участию во внедрении новых методов и методик в сфере разработки, производства и обращения лекарственных средств | Control event number 1 Защищаемое контрольное мероприятие | Industrial drug technology as a science. The modern concept of industrial technology of drugs. Technology of dosage forms. Structure, goals and objectives. GMP rules. The main regulatory and technical documentation governing the production of drugs. Extraction dosage forms of industrial production. Technological and hardware schemes for the production of extraction preparations. |
| ОПК.3 способность осваивать новые технологии и применять их для проведения естественнонаучных исследований ПК.20 готовность к участию во внедрении новых методов и методик в сфере разработки, производства и обращения лекарственных средств | Control event number 2 Защищаемое контрольное мероприятие | Medical solutions, syrups, suspensions and emulsions of industrial production. Soft dosage forms of industrial production. Suppositories. Injectable dosage forms of industrial production. Production of ampoules and vials for injectable dosage forms. Sterilization methods. Purification of injection solutions. Infusion solutions. Filling and sealing ampoules. Quality assessment of injectable dosage forms. Ophthalmic dosage forms of industrial production. |

| Компетенция | Мероприятие текущего контроля | Контролируемые элементы результатов обучения |
|---|--|---|
| <p>ОПК.3 способность осваивать новые технологии и применять их для проведения естественнонаучных исследований</p> <p>ПК.20 готовность к участию во внедрении новых методов и методик в сфере разработки, производства и обращения лекарственных средств</p> | <p>Exam</p> <p>Итоговое контрольное мероприятие</p> | <p>Industrial technology of medicines as a science. Dosage Forms. Their classification and characteristics. The main processes and devices used in the manufacture of medicines. Preparation of raw materials. Modern devices and tests for biopharmaceutical evaluation of dosage forms and systems.</p> |

Спецификация мероприятий текущего контроля

Control event number 1

Продолжительность проведения мероприятия промежуточной аттестации: **10 часа**

Условия проведения мероприятия: **в часы самостоятельной работы**

Максимальный балл, выставляемый за мероприятие промежуточной аттестации: **30**

Проходной балл: **15**

| Показатели оценивания | Баллы |
|---|-------|
| Knowledge of the classification of machines and apparatus used in the manufacture of drugs | 3 |
| Knowledge of hardware circuits for the manufacture of drugs | 3 |
| Knowledge of the classification of extractants and their requirements | 3 |
| Knowledge of the basic rules of the organization of production of quality control of medicines (GMP) | 3 |
| Knowledge of extraction dosage forms of industrial production | 3 |
| Knowledge of the theoretical principles of evaporation | 3 |
| Knowledge of the theoretical principles of grinding | 3 |
| Knowledge of the theoretical foundations of dissolution | 3 |
| Knowledge of thermal processes in pharmaceutical production (heating, cooling, evaporation, drying, condensation, etc.) | 3 |
| Knowledge of production regulations, types, structure | 3 |

Control event number 2

Продолжительность проведения мероприятия промежуточной аттестации: **10 часа**

Условия проведения мероприятия: **в часы самостоятельной работы**

Максимальный балл, выставляемый за мероприятие промежуточной аттестации: **30**

Проходной балл: **15**

| Показатели оценивания | Баллы |
|---|-------|
| Knowledge of the technology of suspensions and emulsions of industrial production | 3 |
| Knowledge of the technological schemes for the production of parenteral solutions | |

| | |
|--|---|
| | 3 |
| Knowledge of the requirements for personnel, work clothing and equipment in rooms of cleanliness classes A, B, C and D according to GMP | 3 |
| Knowledge of solvent requirements and methods for their preparation | 3 |
| Knowledge of methods for diluting and strengthening standard solutions | 3 |
| Knowledge of the characteristics of sterile dosage forms and aseptically manufactured dosage forms | 3 |
| Knowledge of the main regulatory and technical documentation governing the production of drugs | 3 |
| Knowledge of GMP rules | 3 |
| Knowledge of methods for producing pyrogen-free water for the production of injection solutions | 3 |
| Knowledge of the characteristics of factory-made aqueous and non-aqueous solutions: Burov's liquid, 5% alcohol iodine solution, Lugol's solution on glycerin, etc. | 3 |

Exam

Продолжительность проведения мероприятия промежуточной аттестации: **30 часа**

Условия проведения мероприятия: **в часы самостоятельной работы**

Максимальный балл, выставляемый за мероприятие промежуточной аттестации: **40**

Проходной балл: **20**

| Показатели оценивания | Баллы |
|---|--------------|
| The answer to additional questions on the second ticket issue | 10 |
| Full answer to the first ticket question | 10 |
| Full answer to the second ticket question | 10 |
| The answer to additional questions on the topic of the first ticket issue | 10 |