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 обязательную часть Блока « 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.4 Способен осуществлять профессиональную деятельность с учетом конкретных экономических, экологических, социальных факторов в рамках системы нормативно-правового регулирования сферы обращения лекарственных средств

Индикаторы

ОПК.4.1 Учитывает при принятии управленческих решений экономические и социальные факторы, оказывающие влияние на финансово-хозяйственную деятельность фармацевтических организаций

ПК.8 Способен к осуществлению технологических процессов при промышленном производстве и изготовлении лекарственных средств

Индикаторы

ПК.8.1 Осуществляет и сопровождает процесс при промышленном производстве лекарственных средств

ПК.8.2 Контролирует содержание помещений, процесс эксплуатации и техническое обслуживание оборудования

4. Объем и содержание дисциплины

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: adenocorticotropic 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: thyroidin, 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 tabletting. 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 аудиторные 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 с

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. Индикаторы и критерии их оценивания

ОПК.4

Способен осуществлять профессиональную деятельность с учетом конкретных экономических, экологических, социальных факторов в рамках системы нормативно-правового регулирования сферы обращения лекарственных средств

Компетенция (индикатор)	Планируемые результаты обучения	Критерии оценивания результатов обучения
ОПК.4.1 Учитывает при принятии управленческих решений экономические и социальные факторы, оказывающие влияние на финансово-хозяйственную деятельность фармацевтических организаций	Know: economic and social factors that affect the financial and economic activities of pharmaceutical organizations, which must be taken into account when making management decisions. To be able: to apply the acquired knowledge for making management decisions in the implementation of financial and economic activities of pharmaceutical organizations. Own: theoretical knowledge about the rules of management decision-making taking into account economic and social factors that affect the financial and economic activities of pharmaceutical organizations; skills of presentation of independent point of view, analysis and logical thinking in the field of management decisions.	**Неудовлетворител** Knowledge is unsystematic, fragmentary. The answers made gross, fundamental mistakes. Difficulties in making management decisions that affect the financial and economic activities of pharmaceutical organizations. Errors in the classification of management decisions, the description of the structure and technology of the decision-making process, the lack of consideration of economic and social factors. Difficulties and mistakes are not eliminated after leading questions of the teacher. **Удовлетворительн** Knowledge of the main provisions of the program. The answer is not complete, without justification and explanation. Poor knowledge of economic and social factors that need to be taken into account when making management decisions. Significant difficulties in theoretical issues relating to the classification of management decisions, the description of the structure and technology of the decision - making process that affect the financial and economic activities of pharmaceutical organizations. Errors are eliminated by additional questions of the teacher. **Хорошо** Full knowledge of the training material provided by the program, 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.

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		Отлично Comprehensive in-depth knowledge on the issue of management decisions affecting the financial and economic activities of pharmaceutical organizations, accounting for economic and social factors. The answer is justified, reasoned.

ПК.8

Способен к осуществлению технологических процессов при промышленном производстве и изготовлении лекарственных средств

Компетенция (индикатор)	Планируемые результаты обучения	Критерии оценивания результатов обучения
ПК.8.2 Контролирует содержание помещений, процесс эксплуатации и техническое обслуживание оборудования	To know: rules and norms of sanitary and hygienic regime, rules of aseptic conditions of manufacture of medicines; technological process of manufacture of medicines in the conditions of pharmacy and industrial production; the device and principles of modern laboratory and production equipment; normative documentation regulating the manufacture, production and quality of medicines in pharmacies and pharmaceutical enterprises. Be able to: apply in practice the basic requirements for the manufacture of medicines; use laboratory and technological equipment; evaluate the technical characteristics of pharmaceutical equipment and machines; comply with the rules of labor protection and safety. Own: the rules and regulations of the sanitary-hygienic regime, the rules for ensuring aseptic conditions for the manufacture of medicines; the technological process for the manufacture of medicines in a pharmacy and industrial production; skills to	**Неудовлетворител** Knowledge is unsystematic, fragmentary. The answers made gross, fundamental mistakes. Difficulties in understanding the device and principle of operation of modern laboratory and production equipment, operation and maintenance. Sketchy knowledge about the conditions of aseptic technological process and its compliance with modern requirements for the organization of production GMP. Difficulties and mistakes are not eliminated after leading questions of the teacher. **Удовлетворительн** Poor knowledge of the characteristics of the content of production facilities, ensuring the required class of cleanliness of premises, requirements for personnel, overalls, significant difficulties in theoretical issues relating to the device and the principle of operation of modern laboratory and production equipment, the operation and maintenance process. Errors are eliminated by additional questions of the teacher. **Хорошо** Full knowledge of the training material provided by the program, 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. **Отлично** Comprehensive in-depth knowledge of the

Компетенция (индикатор)	Планируемые результаты обучения	Критерии оценивания результатов обучения
	select the optimal technological process and prepare the necessary technological equipment for the manufacture of drugs.	**Отлично** characteristics of the content of production facilities, ensuring the required class of cleanliness of premises, requirements for personnel, overalls, devices and principles of operation of modern laboratory and production equipment, operation and maintenance. The answer is justified, reasoned.
ПК.8.1 Осуществляет и сопровождает процесс при промышленном производстве лекарственных средств	Know: the basics of technological processes in the industrial production and manufacture of medicines; regulatory and legislative framework governing the production of medicines; the basics of Biopharmaceuticals and its role in modern technology of medicines; innovative medicines and their place in the system of drug supply; requirements for labeling, packaging and storage of pharmaceutical products; requirements of international standards for industrial production of medicines; sanitary requirements for the manufacture of drugs in the conditions of pharmaceutical organizations; types of interaction of drugs and types of drug incompatibility; Be able to: apply the acquired knowledge directly to the technological processes of industrial production of medicines;; choose the best technology and produce dosage forms of industrial production; organize the production of medicines and the manufacture of medicines; make the material balance for the individual components of the technological process; receive finished dosage forms on laboratory and industrial equipment; identify, prevent (if possible) pharmaceutical	**Неудовлетворител** Knowledge is unsystematic, fragmentary. The answers made gross, fundamental mistakes. Difficulties in understanding the basic processes and lack of knowledge of devices used in the industrial production of drugs. Errors in the preparation of technological sections of the industrial regulations for the production of finished dosage forms. Difficulties and mistakes are not eliminated after leading questions of the teacher. **Удовлетворительн** Knowledge of the main provisions of the program. The answer is not complete, without justification and explanation. Poor knowledge of the basic processes and devices used in the industrial production of drugs, significant difficulties in theoretical issues relating to the subject under consideration. Errors are eliminated by additional questions of the teacher. **Хорошо** Full knowledge of the training material provided by the program, 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. **Отлично** Comprehensive in-depth knowledge of the main processes and devices used in the industrial production of medicines. Full knowledge of the methodology for the preparation of technological sections of the industrial regulations for the production of finished dosage forms. The answer is justified, reasoned.

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	incompatibility; issue passports of written control; choose the packaging material and carry out labeling depending on the type of dosage form, route of administration and physico-chemical properties of drugs and excipients. Own: theoretical knowledge about industrial production and manufacture of medicines; rules of organization of production and quality control of medicines provided by GMP, GLP, GCP; knowledge on improvement of technology of production and manufacture of medicines; skills of drawing up technological sections of industrial regulations on production of finished dosage forms, including technological and hardware schemes of production of finished dosage forms; the ability to make the material balance and conducting calculations based on consumption rates of all types of technological process for manufacturing of various drugs in phases; requirements of the international standards for industrial production of drugs; technology of medicinal forms obtained in the conditions of pharmaceutical production; the skills of working with modern laboratory and production equipment; the technique of creating the necessary sanitation of pharmaceutical enterprises; skills packaging, design to release of dosage forms.	

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 (индикатор)	Мероприятие текущего контроля	Контролируемые элементы результатов обучения
ПК.8.2 Контролирует содержание помещений, процесс эксплуатации и техническое обслуживание оборудования **ПК.8.1** Осуществляет и сопровождает процесс при промышленном производстве 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.4.1 Учитывает при принятии управленческих решений экономические и социальные факторы, оказывающие влияние на финансово-хозяйственную деятельность фармацевтических организаций **ПК.8.2** Контролирует содержание помещений, процесс эксплуатации и техническое обслуживание оборудования **ПК.8.1** Осуществляет и сопровождает процесс при промышленном производстве 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 (индикатор)	Мероприятие текущего контроля	Контролируемые элементы результатов обучения
ОПК.4.1 Учитывает при принятии управленческих решений экономические и социальные факторы, оказывающие влияние на финансово-хозяйственную деятельность фармацевтических организаций **ПК.8.2** Контролирует содержание помещений, процесс эксплуатации и техническое обслуживание оборудования **ПК.8.1** Осуществляет и сопровождает процесс при промышленном производстве лекарственных средств	Exam **Итоговое контрольное мероприятие**	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.

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