МИНОБРНАУКИ РОССИИ

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

Кафедра фармакологии и фармации

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Программа производственной практики

PRACTICE IN PHARMACEUTICAL TECHNOLOGY

Код УМК 93096

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

Пермь, 2020

1. Вид практики, способ и форма проведения практики

Вид практики **производственная**
Тип практики **практика по фармацевтической технологии**
Способ проведения практики **стационарная, выездная**
Форма (формы) проведения практики **дискретная**

2. Место практики в структуре образовательной программы

Производственная практика « Practice in pharmaceutical technology » входит в обязательную часть Блока « С.2 » образовательной программы по направлениям подготовки (специальностям):

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

Цель практики :

Consolidation and deepening of theoretical knowledge gained in the educational process, practical skills in the manufacture of drugs. Obtaining more complete knowledge about the working conditions of a pharmacist-technologist, acquiring initial practical experience in the specialty and developing students' professional skills in taking prescriptions, manufacturing medicines, controlling their quality and dispensing, which are necessary for solving specific problems in the practical activities of a pharmacist-technologist in conditions of pharmacies, control and analytical laboratories, pharmacy warehouses and laboratories of pharmaceutical enterprises.

Задачи практики :

Tasks of the production practice:
1) to teach students the rules for receiving prescriptions in the workplace of a pharmacist-technologist;
2) To teach technological skills in the manufacture of dosage forms and their packaging;
3) To teach to make out the finished dosage form for vacation.

3. Перечень планируемых результатов обучения

В результате прохождения практики **Practice in pharmaceutical technology** у обучающегося должны быть сформированы следующие компетенции:

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

ПК.2 Способен к осуществлению технологических процессов при изготовлении лекарственных препаратов в условиях аптечных организаций

Индикаторы

ПК.2.1 Готовит лекарственные препараты по рецептам и требованиям в условиях аптечных организаций

ПК.2.3 Осуществляет упаковку и маркировку изготовленных лекарственных препаратов

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

УК.2 Способен управлять проектом, организовывать и руководить работой команды

Индикаторы

УК.2.3 Разрабатывает мероприятия по реализации проекта на разных этапах его жизненного цикла, вносит корректировки в ходе реализации проекта

4. Содержание и объем практики, формы отчетности

The practice of pharmaceutical technology is the formation and development of graduates in the specialty “Pharmacy” of competencies aimed at consolidating the theoretical knowledge and practical skills in taking prescriptions, preparing medicines, controlling their quality and supply necessary for solving specific tasks in practical activities of a pharmacist .

Направления подготовки	33.05.01 Фармация (направленность: Программа широкого профиля (для иностранных граждан))
форма обучения	очная
№№ триместров, выделенных для прохождения практики	14
Объем практики (з.е.)	6
Объем практики (ак.час.)	216
Форма отчетности	Экзамен (14 триместр)

Примерный график прохождения практики

Количество часов	Содержание работ	Место проведения
Instructing		
54	Familiarization with the pharmacy. Safety training, sanitary and hygienic regimen and pharmaceutical compliance. Acquaintance with the sanitary regime in the pharmacy. Acquaintance with weighing devices and filling machines, types of containers and packaging material. Participation in the packaging and packaging of powders, aqueous solutions for internal and external use and liquid medicines on non-aqueous solvents. Acquaintance with the methods of weighing and measuring liquid preparations, filtering and filtering. Taking part in the manufacture of intra-pharmacy blanks. Packaging and preparation of drugs in accordance with the requirements.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Manufacturing of dosage forms according to recipes (requirements)		
54	Production of dosage forms according to prescriptions (requirements), including: solid dosage forms (powders, fees); liquid dosage forms (solutions of low molecular weight compounds, colloidal solutions, suspensions, emulsions, aqueous extracts, liniments); mild dosage forms (ointments, suppositories, pills); aseptically manufactured dosage forms (for injection); aseptically manufactured dosage forms (ophthalmic, with antibiotics, etc.).	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Production of concentrated solutions, semi-finished products, intra-pharmaceutical preparations and aromatic waters		
54	Rules for the manufacture of semi-finished products, intra-pharmacy blanks, fragrant waters. Registration in relevant magazines and registration.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state

Количество часов	Содержание работ	Место проведения
		University
Acceptance of prescriptions (requirements) and dispensing dosage forms for them. Release of toxic substances by the pharmacist		
54	Prescription drug requirements. Checking the doses of toxic and potent substances in dosage forms. Requirements and design.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University

5. Перечень учебной литературы, необходимой для проведения практики

Основная

1. Marianthi G. Ierapetritou, Rohit Ramachandran Process Simulation and Data Modeling in Solid Oral Drug Development and Manufacture. Springer Science+Business Media, New York, 2016. Online ISBN978-1-4939-2996-2. Текст электронный // : https://link.springer.com/book/10.1007/978-1-4939-2996-2#toc https://link.springer.com/book/10.1007/978-1-4939-2996-2

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

Дополнительная

1. Zaheer-Ud-Din Babar. Pharmacy Practice Research Methods / Zaheer-Ud-Din Babar // Publisher Name: Springer, Singapore. — 2020. — 265 p. — ISBN 978-981-15-2993-1. — [Электронный ресурс]. https://link.springer.com/book/10.1007/978-981-15-2993-1

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

6. Перечень ресурсов сети «Интернет», требуемых для проведения практики

При прохождении практики требуется использование следующих ресурсов сети «Интернет» :

http://www.pharmaceutical-technology.com News, views and contacts from the global Pharmaceutical industry

www.roszdravnadzor.ru Федеральная служба по надзору в сфере здравоохранения

www.consultant.ru Справочно-поисковая система Консультант+

www.iprbookshop.ru Электронно-библиотечная система IPRbooks

7. Перечень информационных технологий, используемых при проведении практики

Образовательный процесс по практике **Practice in pharmaceutical 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 (EDS)
access to the university's electronic educational information environment;
Internet services and electronic resources (search engines, email, professional thematic chats and forums, audio and video conferencing systems, online encyclopedias, etc.).
The list of necessary licensed and (or) free software:
1. An application that allows you to view and play the media content of Adobe Acrobat Reader DC PDF files.
2. Programs, demonstrations of video materials (player) "WindowsMediaPlayer".
3. The program for viewing Internet content (browser) "Google Chrome".
4. Office suite of applications "LibreOffice".

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/).

8. Описание материально-технической базы, необходимой для проведения практики

1. Lecture classes - An audience equipped with presentation equipment (projector, screen, computer / laptop) with appropriate software.
2. Seminar-type classes (seminars, workshops) - An audience equipped with presentation equipment (projector, screen, computer / laptop) with the appropriate software, chalk (s) or marker board.
3. Laboratory classes - Laboratory of Pharmaceutical Technology, equipped with specialized equipment. The composition of the equipment is defined in the passport of the laboratory.
4. Independent work - An 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 of PSNIU.

Assistant room of the prescription and production department, the workplace of the pharmacist-technologist for receiving recipes.

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»

9. Методические указания для обучающихся по освоению дисциплины

During practice, the student draws up a report (diary) indicating the type of work performed during the day.

1. Acquaintance with the organization of the production of drugs in the country. Based on the analysis of available literature and regulatory and technical documentation, provide in a diary data on the organization of production of drugs, the system of their organization and management, as well as monitoring the quality of pharmaceutical products.
2. Familiarity with the pharmacy and its functions. Describe in detail the production premises of the pharmacy in which the practice is performed, with the plan of the pharmacy, draw a diagram of the premises, indicate the principle of management of the pharmacy, the pharmacy staff. Give a detailed description of all the work performed in the pharmacy.
3. Acquaintance with the organization of the manufacture of drugs in the pharmacy. To characterize dosage forms manufactured in a pharmacy, provide names and set out the regulatory documents on the basis of which medicines are manufactured in a pharmacy. Draw a scheme and describe the workplace of a specialist engaged in the manufacture of medicines in a pharmacy. Bring his job duties. Draw diagrams of devices and devices used in this pharmacy for the manufacture, filtration, sterilization, obtaining purified water, etc., indicating their name, principle of construction and operation.
4. Acquaintance with the organization of the workplace of a specialist who manufactures various dosage forms in a pharmacy. Describe in detail the workplace technologist depending on the nature of the manufactured dosage forms; solid, liquid, soft, aseptically manufactured, etc. Specify the rules for receiving prescriptions, the requirements for their design, the forms of forms used for prescribing various medicinal substances (stick in the diary various forms of prescriptions).

Describe the rules for dispensing finished drugs from pharmacies.

5. Familiarity with the storage of pharmacy products, compliance with the shelf life of drugs. Indicate how the quality control of drugs manufactured in a pharmacy, their packaging and processing is carried out. Bring the layout of the premises in which pharmacy goods are stored, describe the packaging and packaging of medicines and other goods that are available in the pharmacy. Specify the pharmacy supply system with various goods.

Specify the range of medicinal and excipients used in the pharmacy, to give their general characteristics and scope. Give the name and general provisions of the regulatory documentation, on the basis of which goods are received in a pharmacy and stored in a pharmacy.
6. The manufacture of various dosage forms in the pharmacy. Give the classification and characteristics of dosage forms manufactured in this pharmacy (group of pharmacies): solid, liquid, soft, aseptically manufactured, etc. Write in the diary all received recipes in this pharmacy and their detailed technology adopted in this pharmacy, as well as by reference given in Appendices 3, 4, (to analyze for the entire period of practice) Describe the features of working with potent, toxic and narcotic substances (if in the country where the practice is performed, a similar classification of drugs is used means). Bring schemes and describe the work of small-scale mechanization tools used in the pharmacy; the manufacture of concentrates, semi-finished products and intra-pharmaceutical preparation of medicines.
To consolidate the skills of choosing the optimal technology, packaging, finishing the finished dosage form and assessing the quality of various dosage forms, the student daily in the report (diary) according to the approved plan describes one recipe from the individual task offered by the teacher, which each student receives at the department before leaving for practice.
At the end of the practice, the diary must be certified by the signature of the head of the pharmacy and the seal of the institution where the practice was performed.
For students with disabilities and persons with disabilities on the basis of their written application, the organization of practice is implemented taking into account the peculiarities of psychophysical development, individual capabilities and health of students. This ensures compliance with the following General requirements: the use of special technical means of training
collective and individual use, providing the services of an assistant, providing such a student with the necessary technical assistance, providing convenient access to the buildings and premises where practices are held, other conditions without which it is impossible or difficult to pass the practice. The choice of places of practice for the disabled and persons with disabilities is made taking into account the requirements of accessibility for students and recommendations of medical and social expertise reflected in the individual rehabilitation program of the disabled person. At the direction of the disabled person or person with disabilities in the organization, to the enterprise industry internship supervisor negotiates with the company the terms of its passage and activities taking into account the recommendations of the medico-social assessment and individual program of rehabilitation of the disabled. To master the theoretical part of the practice, disabled people and persons with disabilities are given the opportunity to use electronic technologies, remote mastering of the material by providing tasks and their control over the Internet, as well as individual consultations using both e-mail and visual communication using "Skype". When performing the experimental part of the practice, additional means of protection are provided as necessary, individual assistance of educational and support personnel is provided, as well as other measures taking into account the nosologies of the disease of students. The format of the protection of practice reports for persons with disabilities and persons with disabilities is established taking into account their individual psychophysical characteristics (orally, in writing, using electronic or other technical means). In the course of protection of the report on practice the student with HIA has the right to use technical means necessary for it. For the visually impaired, a portable video magnifier can be provided, it is possible to use your own devices. For deaf and hard of hearing students can be presented sound amplifying equipment, it is possible to use equipment for individual use. At the request of a student with HIA in the process of protection of the report on practice, the presence of an assistant can be provided, providing the student with the necessary technical assistance, taking into account his individual characteristics. If necessary, persons with disabilities and persons with disabilities may be given additional time to prepare responses when defending practice reports.

Фонды оценочных средств для проведения промежуточной аттестации

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

ПК.2

Способен к осуществлению технологических процессов при изготовлении лекарственных препаратов в условиях аптечных организаций

Компетенция	Планируемые результаты обучения	Критерии оценивания результатов обучения
ПК.2.1 Готовит лекарственные препараты по рецептам и требованиям в условиях аптечных организаций	Know: technology, theoretical and regulatory framework for the manufacture of medicines according to prescriptions and requirements in the conditions of pharmacy organizations. Be able to: produce all kinds of dosage forms in the pharmacy. Own: skills of manufacturing and control of dosage forms in the pharmacy.	**Неудовлетворительно** Knowledge is unsystematic, fragmentary. The answers made gross, fundamental mistakes. Difficulties in understanding the technology of manufacturing drugs according to prescriptions and requirements in the conditions of pharmacy organizations. Difficulties and mistakes are not eliminated after leading questions of the teacher. **Удовлетворительно** Knowledge of the main provisions of the program. The answer is not complete, without justification and explanation. Poor knowledge of manufacturing technology of medicines according to prescriptions and requirements in the conditions of pharmacy 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. **Отлично** Comprehensive in-depth knowledge of manufacturing technology of medicines according to prescriptions and requirements in the conditions of pharmacy organizations. The answer is justified, reasoned.
ПК.2.3 Осуществляет упаковку и маркировку изготовленных лекарственных	Know the basic rules of packaging, packaging of various types of dosage forms, requirements for the material of packaging and closures; rules of	**Неудовлетворительно** Knowledge is unsystematic, fragmentary. The answers made gross, fundamental mistakes. Difficulties in understanding the methods of packaging, packaging and labeling of

препаратов	labeling and shelf life of medicines. Be able to carry out packaging and labeling of manufactured drugs. Own methods of packing, packaging and labeling of manufactured drugs	**Неудовлетворительно** manufactured drugs. Difficulties and mistakes are not eliminated after leading questions of the teacher. **Удовлетворительно** Knowledge of the main provisions of the program. The answer is not complete, without justification and explanation. Poor knowledge of the rules and methods of packaging, packaging and labeling of manufactured drugs. 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 rules of packaging, packaging of various types of dosage forms, requirements for the material of packaging and closures; labeling rules and shelf life of medicines. The answer is justified, reasoned.

ПК.8

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

Компетенция	Планируемые результаты обучения	Критерии оценивания результатов обучения
ПК.8.1 Осуществляет и сопровождает процесс при промышленном производстве лекарственных средств	To 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 provision of the population; requirements for labeling,	**Неудовлетворительно** 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. **Удовлетворительно** Knowledge of the main provisions of the program. The answer is not complete, without

	packaging and storage of pharmaceutical products; manufacturing technology of medicines in the pharmacy: powders, aqueous solutions for internal and external use, solutions in viscous and volatile solvents, eye dosage forms, solutions for injections and infusions, suspensions for enteral and parenteral use, aqueous extracts from medicinal plant raw materials, complex combined preparations with a liquid dispersion medium, ointments, suppositories; sanitary requirements for the manufacture of medicines in pharmaceutical organizations; types of drug interaction and types of drug incompatibility; rules of pharmaceutical examination of prescriptions and requirements from medical institutions. Be able to: apply their knowledge to technological processes of pharmaceutical production of medicines; to choose the optimal technology and to produce the dosage form pharmaceutical production; to organize the production of medicines and production of medicines; to make the material balance for individual components of the process; to identify, prevent (where possible) pharmaceutical incompatibilities; dose mass, volume and drops the appropriate dosage forms; to carry out pharmaceutical examination of prescriptions and requirements of medical and preventive institutions; to issue passports of written control; to choose packing material and to carry out marking depending on a type of the dosage form, a way of introduction and physico-chemical properties of	**Удовлетворительно** 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.s. **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.

	medicinal and auxiliary substances. To possess theoretical knowledge about industrial production and manufacture of medicinal products; rules of organization of production and quality control of drugs provided by GMP, GLP, GCP; knowledge to improve the technology of production and manufacture of drugs; technique of creating the necessary sanitation of the pharmacy; skills dosing by weight solid and liquid drugs by means of pharmaceutical weights, liquids by volume; the skills of packaging, design to release dosage forms; methods of production of all types of dosage forms in a pharmacy; skills of drawing up a passport of written control in the manufacture of extemporal dosage forms; the order of the pharmaceutical examination of prescriptions and requirements-invoices, the release of medicines to outpatient and inpatient patients.	

УК.2

Способен управлять проектом, организовывать и руководить работой команды

Компетенция	Планируемые результаты обучения	Критерии оценивания результатов обучения
УК.2.3 Разрабатывает мероприятия по реализации проекта на разных этапах его жизненного цикла, вносит корректировки в ходе реализации проекта	To know: the main methods of project implementation at different stages of its life cycle; modern theoretical and experimental methods for the implementation of own and borrowed results of scientific research. Be able to: implement the project and make adjustments in the course of the project; identify the main patterns of the studied objects, predict new unknown patterns.	**Неудовлетворительно** The student is not able to develop activities for the implementation of the project at different stages of its life cycle, to make adjustments during the implementation of the project. The student is not able to carry out a quick and accurate search and use the necessary information on pharmaceutical activities, regulatory documents. **Удовлетворительно** The student is able to develop measures for the implementation of the project at different stages of its life cycle, but has little knowledge of the methods of its adjustment during

	Own: methods of project implementation at different stages of its life cycle.	**Удовлетворительно** implementation. **Хорошо** The student is able to develop measures for the implementation of the project at different stages of its life cycle, does not fully know the methods of its adjustment in the course of implementation. **Отлично** The student is fully able to develop activities for the implementation of the project at different stages of its life cycle, to make adjustments during the implementation of the project. The student is able to carry out a quick and accurate search and use the necessary information on pharmaceutical activities, regulatory documents.

Оценочные средства

Вид мероприятия промежуточной аттестации : Экзамен
Способ проведения мероприятия промежуточной аттестации : Устное собеседование по вопросам
Продолжительность проведения мероприятия промежуточной аттестации :
время отводимое на подготовку 5

Показатели оценивания

The student did not appear for practice or did not issue a practice diary and did not write a report.	**Неудовлетворительно**
The practice diary and the report on it is not designed in accordance with the criteria; when defending a job, the student does not answer the questions asked or refuses oral protection.	**Удовлетворительно**
The practice diary and the report on it is not designed in accordance with the criteria; when defending a job, the student does not answer the questions asked or refuses oral protection.	**Хорошо**
The practice diary and the report on it is designed in accordance with the criteria; when defending a job, the student answers all the questions asked.	**Отлично**