MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS
EDUCATIONAL INSTITUTION
BELARUSIAN STATE MEDICAL UNIVERSITY

APPROVED
by First Vice-Rector, Professor
_____ I.N.Moroz
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PHARMACY TECHNOLOGICAL PRACTICE

On-the-job practical training

Curriculum for the specialty: 1-79 01 08 «Pharmacy»

2019

COMPILER:

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RECOMMENDED FOR APPROVAL:

by the Department of Pharmaceutical Technology the Educational Institution "Belarusian State Medical University"
(protocol № 9 of 10.04.2019);

by the Methodological Commission of Pharmaceutical Disciplines of the Educational Institution "Belarusian State Medical University"
(protocol № 8 of 23.05.2019)

EXPLANATORY NOTE

The organization and procedure of pharmacy technological practice was established by the Decree of the Council of Ministers of the Republic of Belarus from 03.06.2010 №860 «On the approval of the provisions on the practice of students and cadets» (as amended by the Council of Ministers of 04.08.2011 №1049, 09.12.2011 №1663, 11.09.2012 №844, 08.05.2013 №356, 22.08.201 №736) and the Regulation «The practice of students of the educational institution «Belarusian State Medical University» №88 of 29.01.2014.

The aim of pharmacy technological practice is the consolidation of theoretical and practical skills obtained in the manufacturing of medicines and quality control of medicines manufactured in the chemist's shop. These types of skills form students' abilities that make up the content of the professional activity of a pharmacist.

Objectives of pharmacy technological practice for students:

- acquaintance with the structure and organization of work of personnel for the manufacturing of medicines in chemist's shop, adaptation to the real conditions of the future professional activity;
- the formation of the foundations of social and personal competence through the acquisition by the student of interpersonal skills with the pharmacy staff and patients in the chemist's shop;
- the formation and improvement of professional and practical skills in the manufacturing of medicines in the chemist's shop according to individual prescriptions and the requirements of health care organizations;
- development of students' skills in compliance with the pharmaceutical order and sanitary regime with the manufacturing of medicines;
- deepening and consolidation of theoretical knowledge obtained from the the discipline «Pharmacy technology of drugs».

Pharmacy technological practice for students is carried out at the positions of the pharmacist-technologist of the pharmaceutical institution. During the period of pharmacy technological practice, students obey all the rules of internal labor regulations basic health facilities. A student can be admitted to the pharmacy technological practice if there is a health certificate and after instructing in the workplace on safe working conditions.

At the end of pharmacy technological practice, **the student must know**:

- the content of the general articles of the current State Pharmacopoeia of the Republic of Belarus; main provisions of instructions, orders and regulations of Ministry of Health, which regulates prescription, manufacturing, quality control and dispensing of medicines from the chemist's shop;
- device and principle of operation of the most common means of small mechanization;
- duties of a pharmacist working at various manufacturing sites dosage forms;
- basic principles of compatibility of the ingredients in the prescription;
- measures taken upon prescription in the chemist's shop of prescriptions containing incompatible combinations of ingredients;

– sources of reference and scientific information to search for information necessary in the work of a pharmacist;
– main provisions of safety and pharmaceutical order in the chemist's shop;
– physical and chemical properties of the most frequently used ingredients;
– the shelf life of dosage forms manufactured in the chemist's shop.

The student should be able to:

– use regulatory documents relating to manufacturing activities of pharmaceutical organizations;
– use state pharmacopoeia, pharmacopoeial articles, manufacturer's pharmacopoeial articles, general pharmacopoeial articles, regulations and other regulatory documentation to find the necessary information on composition, manufacturing, storage and dispensing of medicines,
– medicinal plant raw materials and checking doses of substances of List A and B in them;
– manufacture medicines taking into account the compatibility of components in the doctor's prescription;
– find rational ways to overcome incompatibility of ingredients;
– identify frequently repeated prescriptions, conduct intratherapy procurement of medicines and their transfer to industrial production;
– implement stepwise control and standardization of medicines;
– make out manufactured in a pharmacy medicines for sale;
– determine the effect of storage conditions and type of packaging on stability of dosage forms;
– determine physical and physico-chemical constants (temperature boiling point, melting point, specific rotation, specific index absorption, etc.), the concentration of ethyl alcohol density.

The student must determine:

– ways to overcome pharmaceutical incompatibilities;
– skills of pharmaceutical manufacturing of dosage forms, their stepwise control, packaging and clearance for sale.

In total, pharmacy technological practice is assigned 108 academic hours during 2 weeks after 7th semester.

The current certification is carried out in accordance with the curriculum for the specialty in the form of a credit test (7 semester).

The current certification is carried out according to the diary presented by the student, report on the implementation of the program of pharmacy technological practice and written characterization of the manager of the chemist's shop.

The assessment is determined by the student's performance of test standards for pharmacy technological practice.

Fulfillment of student standards guarantees the acquisition practical training required level. Practical training levels:

– knowledge (level 1) - the presence of a set of information required for performance of official functions in accordance with the qualification requirements for the position of a pharmacist;

– skill (level 2) - the ability to perform professional elementary (simple) actions acquired through its repetition. The scientifically based multiplicity of repetition of the action, which guarantees the acquisition by the student of the required skill, is established by the test standard;

– skill (level 3) - the ability to independently perform professional actions based on acquired knowledge, skills and experience of their implementation under the guidance of an experienced specialist superviser.

CONTENT OF PHARMACY TECHNOLOGICAL PRACTICE

1. State, industry and local regulatory framework
   State documents regulating the work of the pharmacist.
2. Equipment of the chemist's shop
   Safe working conditions, fire safety rules, rules of aseptics and antiseptics, methods of processing and protecting the hands of medical personnel, the sanitary and anti-epidemic regime regulated by the Order of the Ministry of Health of the Republic of Belarus on the approval Sanitary norms and rules «Sanitary-epidemiological requirements for chemist's shops» dated 01.10.2012 №154.
   3. Professional techniques and methods of work
   In accordance with the minimum content of the type of pharmacy technological practice provided for by the educational standard specialty (in the amount of 50% of the qualification requirements for positions of a pharmacist who does not have a qualification category).
   – drawing up a plan for the assistant room, aseptic unit, with indication of the sanitary condition, equipment and location of workplaces, description of the organization of the manufacturing process in the chemist's shop - the base of practice. Assessment of the feasibility of room planning;
   – study of the device and maintenance of equipment for getting water purified and water for injection, monitoring its quality and storage conditions;
   – familiarization with the organization of the workplace of a pharmacist-technologist on manufacturing of medicines;
   – production of dosage forms according to prescriptions (requirements) in accordance with the schedule of practical training:
   – participation in the manufacture and sale of powders for indoor and outdoor use, fees;
   – participation in the manufacture and execution of the release of liquid medicinal forms: aqueous and non-aqueous solutions, mixtures, drops, colloidal solutions, solutions of high-molecular compounds, suspensions, emulsions, aqueous extracts and others;
   – participation in the manufacture of ointments, suppositories, liniments, clearance them for sale;
   – the study of aseptic conditions for the manufacture of dosage forms, equipment for filtering and sterilization, the rules of its operation;
   – participation in the manufacture of solutions for injections and infusions, eye drops, lotions and ointments, dosage forms with antibiotics, dosage forms for newborns and children of the first year old. Making them sterilized and ready to sale;
   – manufacturing of concentrated solutions for the burette system;
   – study of the work of a pharmacist-technologist for receiving prescriptions and requirements to dispense medicines from the chemist's shop;
   – participation in the implementation of quality control of manufactured dosage forms in the chemist's shop.

TEST CURRICULUM STANDARDS OF PHARMACY TECHNOLOGICAL PRACTICE

Type of practical training, name of the technique	Standard	Done		Level of training
		under supervision	unassisted	
Liquid dosage forms for external and internal use	63	42	21	2
1. Requirements for purified water. Water purification. Distillers.	3	2	1	2
2. Solutions. Special cases of manufacturing of solutions. Aqueous solutions.	6	4	2	3
3. Non-aqueous solutions. Features of manufacturing of solutions on glycerin, oils, alcohol, ether and other non-aqueous solvents.	6	4	2	2
4. Solutions of high molecular compounds. Features of manufacturing of solutions from unlimited swelling and limited swelling high molecular compounds.	6	4	2	2
5. Drops. Features of manufacturing.	6	4	2	2
6. Manufacturing of aqueous extracts from medicinal plant raw materials containing alkaloids, cardiac glycosides, essential oils, saponins, tannins, antraglycosides, phenol glycosides, mucus and manufacturing of aqueous extracts from concentrated extracts. Features of the manufacture of aqueous extract from Althea root.	6	4	2	2

Manufacturing of infusions and decoctions of liquid and dry extracts-concentrates.				
7. Fluid heterogeneous systems. Colloids. Manufacturing of solutions of collargol, protargol, ichthyol.	6	4	2	2
8. Suspensions. Suspension technology of hydrophilic and hydrophobic substances.	6	4	2	2
9. Emulsions. Emulsion technology from oils.	6	4	2	2
10. Concentrated solutions for burette systems. Calculations.	6	4	2	3
11. Mass-volume method of manufacturing of liquid dosage forms. Manufacturing of mixtures.	6	4	2	3
Solid dosage forms for external and internal use	9	6	3	2
1. Powders. Special cases of manufacturing of powders.	6	4	2	3
2. Rules of storage and prescription of substances of the list A and B, medicines in chemist's shop.	3	2	1	1
Soft dosage forms for external and internal use	24	16	8	2
1. Liniments. Special cases of manufacturing. Quality control.	6	4	2	2
2. Ointments. Special cases of manufacturing. Quality control.	6	4	2	3
3. Pastes. Special cases of manufacturing.	6	4	2	2

Quality control.				
4. Suppositories. Special cases of manufacturing. Quality control.	6	4	2	2
Medicines for parenteral use	12	8	4	2
1. Organization of aseptic conditions for the manufacturing of injectable medicines in chemist's shop.	6	4	2	1
2. Injection solutions. Private cases of manufacturing. Quality control	6	4	2	3
Total done	108	72	36	

Notes.

1. Implementation of the test standard for each type and method of practical work of the student:
   - fully and 55-70% of the norm independently meets skill (3rd level of practical training);
   - fully and 35-54% of the norm independently - skill (2nd level of practical training);
   - fully and 25-34% of the norm independently - knowledge (1st level);

2. Fulfillment of test standard less than 25% in the absence of independent performance of the reception (manipulation) as a practical manufacturing of the student is not subjected to assessment.

3. For the calculation of credit standards, it is recommended to use the methodology described in the guidelines of the BSMU.

INFORMATION AND METHODOLOGICAL PART

Regulatory legal documents and literature:

1. Tikhonov A.I., Yarnykh T.G., Yuryeva A.B., Garkavtseva O.A. Chemist's Technology of Drugs: The manual for students of higher schools / Edited by A.I. Tikhonov and T.G. Yarnykh. — Kharkiv: NUPh; Original, 2011. — 424 p.
2. Lectures of Department of Pharmaceutical Technology (etest.bsmu.by).

CALENDAR-THEMATIC PLAN OF PRACTICE

№	Name of works	Number of days
1.	Acquaintance with the production premises of the pharmacy and organization of the workplace of a pharmacist-technologist, his functional responsibilities. Technical Instructions safety, hygienic regime and pharmaceutical order.	1
2.	Manufacturing of prescription medicines and the requirements of health care organizations, including: liquid dosage forms for internal use: - solutions, suspensions, emulsions, solutions of high molecular compounds, drops, water extracts from medicinal plant raw materials; liquid dosage forms for external use: - solutions, colloidal solutions, emulsions, suspensions, water extracts from medicinal plant raw materials; solid dosage forms - powders and extracts; soft medicinal forms of liniments and ointments, representing various types of disperse systems - homogeneous, emulsion, suspension, combined, pastes. rectal and vaginal dosage forms - rectal and vaginal suppositories, sticks; medicines for parenteral use: injection medicines, infusions, ophthalmic drops, lotions, soft eye medicines (ointments, creams, gels).	6
3.	The manufacture of concentrated solutions for burette system, the conditions of their manufacture and quality control. Preparation of mixtures of concentrated solutions.	1
4.	Storage of medical products, compliance and consideration of the shelf life of medicines in the departments of the chemist's shop. Replenishing missing medicines of the assistant room. The organization of work on the reception of the goods and its distribution by storage.	1
5.	Providing practice diary, individual assignment and report.	1
	Total days:	10

Supplement 1. A sample design of the title page of the diary

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Health facility
(number of chemist's shop)

APPROVED
by manager of chemist's shop
_____Surname
signatura

_____

Place for a stamp

DIARY
of pharmacy technological practice

Name Second Name Surname

Faculty pharmaceutical
4th year students
Academic group №
Practice base_____

Manager
in the workplace _____

Department teacher,
head of practice _____

Minsk BSMU 20__

Supplement 2. Approximate diary form for prescriptions

Date

Prescription	Physical and chemical properties of ingredients	The technology of dosage forms with theoretical justification	Written control passport	Quality assessment of the dosage form

Student Signature (daily)
Date, signature of the manager (daily)

Supplement 3. General requirements for registration diary

The diary is filled in at the end of the working day (1 hour). Diary pages should be numbered. Every practice day, the diary indicates the complete list of prescriptions that they received at the chemist's shop during the working day. Prescriptions are written with prescription numbers. In a diary a student describes only those prescriptions for which medicines are personally manufactured by himself/herself. In addition, in the diary other types of work performed during the day are noted. Manufacturing of three medicines should be described in the diary every day. Not manufactured dosage forms (at the chemist's shop) should not be described.

The description of the manufactured medicines is carried out in the following form:

1. record the medicine in Latin language without abbreviations indicating the patient's age and ways of medicine using;
2. properties of ingredients - a description of the appearance, properties and doses for substances of list A and for strong-effective substances of all excipients;
3. theoretical justification indicating the type of dosage form, its definition, description of features of the manufacturing process. If necessary, the doses and norms of one-time vacation are checked. Specify the type of packaging, design and expiration date of the dosage form;
4. manufacturing - Technological process of manufacturing a medicinal product is described in stages in detail and consistently;
5. written control passport (WCP), prior to the manufacture of the medicinal product, the reverse side of the WCP is filled in, after the manufacture - the front side of the WCP.

Entries should be done in a neat, legible handwriting. Fixes additions after vising the records by the practice manager are not allowed.

Registration of the diary, report, characteristics is carried out in accordance with the requirements of the state standard STB 6-38-2004 to the details, text, document and data in tables. The signature of the head in the practice diary is certified in the prescribed manner.

Diaries, reports, characteristics, other documents for each type of pharmacy technological practices are stored at the department in accordance with the nomenclature of BSMU affairs departments.

Supplement 4. Approximate form of a student time record

Name Second Name Surname

Date	Time of arrival	Signature of student	Time of leaving	Signature of student	Manager's signature

filled in daily

Supplement 5. Form of the practice report

Student report Name Second Name Surname

on completion of pharmacy technological practice at the base of chemist's shop № __

from « » _____ 20__ to « » _____ 20__.

Type of practical training, name of the technique	Standard	Done	
		under supervision	unassisted

Signature
of student _____

Signature
of manager _____

Place for a stamp

« » _____ 20__

Supplement 6. An example of the characteristics

Characteristic

on student-trainee _____
(Name and Surname of the student) passed (a) pharmacy technological practice at the base of _____
from « » _____ 20__ to « » _____ 20__.

The characteristics should reflect qualities of the student-trainee, the demonstrated ability to acquire professional skills as a pharmacist-technologist. Indicate the presence and results of the development of personal qualities necessary for the profession of a pharmacist. Give a general assessment of the results of the curriculum practice and the achieved level of practical training. To characterize the relationship with the team, knowledge and implementation of the norms of pharmaceutical ethics and deontology. In conclusion, it is necessary to give recommendations on the admission of the student to the current assessment of practical training, a proposal to the educational institution to improve the quality of theoretical training, prior to sending the student to practice.

Signature
of manager _____

Place for a stamp

« » _____ 20__

Acquainted with the characteristic. Signature of student _____

Note. The volume of the characteristics is no more than 1 (one) page.

Authors (developers) of the educational program:

Teacher of the Department of Pharmaceutical Technology of Belarusian State Medical University, Master of Pharmaceutical Sciences — O.G. Sechko

Head of the Department of Pharmaceutical Technology of Belarusian State Medical University; associate professor, PhD — N.S. Golyak

Associate professor of the Department of Pharmaceutical Technology of Belarusian State Medical University, PhD — M.E. Parhach

Program content, composition and accompanying documents comply with established requirements.

Dean of the Pharmaceutical Faculty
24.05 2019 — N.S. Gurina

Head of the pharmacy technological practice at Belarusian State Medical University
24.05 2019 — L.I.Zilinskaya

Head of the Foreign Languages Department
24.05 2019 — M.N.Petrova

Methodologist expert at Belarusian State Medical University
24.05.2019 — O.R. Romanovskaya