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

APPROVED
by First Vice-Rector, Professor
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INDUSTRIAL TECHNOLOGICAL PRACTICE

On-the-job practical training

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

2020

COMPILERS:

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RECOMMENDED FOR APPROVAL:

by the Department of Pharmaceutical Technology of Educational Institution «Belarusian State Medical University»
(protocol №10 of 11.05.2020)

by the Scientific Methodical Council of the Educational Institution «Belarusian State Medical University»
(protocol №1 of 23.12.2020)

EXPLANATORY NOTE

The organization and procedure for conducting industrial practice are established by the resolution of the Council of Ministers of the Republic of Belarus of 03.06.2010, No. 860 "On approval of the regulations on the practice of students, cadets, trainees" (ed. resolutions of the Council of Ministers of 04.08.2011 No. 1049, of 09.12.2011 No. 1663, of 11.09.2012 No. 844, of 08.05.2013 No. 356, of 22.08.2013 No. 736) and The regulation "On the practice of students of the educational institution "Belarusian State Medical University" No. 88 of 29.01.2014.

The purpose of industrial technological practice is to consolidate the knowledge gained and the student's acquisition of skills and abilities that make up the content of the professional activity of a pharmacist.

Tasks of students' industrial technological practice:

familiarization with the structure of the pharmaceutical enterprise and the organization of its premises, equipment and personnel;

formation of the base of social and personal competence by acquiring interpersonal communication skills with pharmacists, technologists and employers of the enterprise;

formation of the foundations of professional competence by acquiring the skills of practical application of knowledge obtained during the study of the discipline "Industrial Technology of Drugs".

During the period of industrial technological practical training, students must follow all the rules of the internal labor regulations of the enterprise for practical training. A student is allowed to enter industrial technological practice if they have a certificate of health and after being instructed on labor protection at the workplace.

At the end of the industrial technological practice, the student should

know:

the organization of industrial production of medicines;

state, industry and local regulatory framework;

The State Pharmacopeia of the Republic of Belarus;

requirements for the quality of pharmaceutical substances and excipients for the industrial production of medicines

be able to:

use The State Pharmacopeia of the Republic of Belarus, Pharmacopeia articles of the manufacturer, technical regulations and other regulatory documentation to search for the necessary information on the composition, production, storage of medicines;

develop technological documentation for finished medicinal products;

possess:

technologies for the production and standardization of various dosage forms in industrial conditions.

In total, 108 academic hours are allocated for industrial technological practice

for 2 weeks in the 10th semester at pharmaceutical enterprises approved by the order of the Ministry of Health of the Republic of Belarus as bases of industrial practice.

The current certification is conducted in accordance with the curriculum in the specialty in the form of a differentiated credit (10 semester).

The current certification is carried out according to the student's diary, report on the implementation of the program of industrial technological practice and characteristics of the direct head of the practice from the enterprise.

CONTENT OF THE TRAINING PROGRAM OF INDUSTRIAL TECHNOLOGICAL PRACTICE

1. State, industry and local regulatory framework:

- European Medicine Agency. Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Public Health. EudraLex - Volume 4 – 2018.
- European Medicine Agency. Guideline on the quality of water for pharmaceutical use, 2018.
- European Medicine Agency. Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container, 2019.
- European Medicine Agency. Guideline on Good Pharmacovigilance Practices (GVP), 2017.
- European Medicine Agency. Guideline on process validation for finished products, 2016.
- Guidelines on packaging for pharmaceutical products, Annex 9 (WHO Technical Report Series, No. 902).
- ICH. Harmonised Tripartite Guideline. Quality Risk Management Q10, 2009.
- Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. Forty-third report. Annex 2 (WHO Technical Report Series, No.953).
- International Council on Harmonisation. ICH Q1A (R2): Stability testing of new drug substances and products.
- International Council on Harmonisation. ICH Q2 (R1): Validation of analytical procedures: text and methodology.
- International Council on Harmonisation. ICH Q3B: Impurities in drug products
- International Council on Harmonisation. ICH Q7: Good Manufacturing Practice: Guide for active pharmaceutical ingredients.
- International Council on Harmonisation. ICH Q8: Pharmaceutical development, 2009.
- Guidelines on good manufacturing practices: validation. In: Quality assurance of pharmaceuticals. WHO guidelines, good practices, related regulatory guidance and GXP training materials, Geneva, World Health Organization, 2016.

– WHO good manufacturing practices: main principles for pharmaceutical products. In: WHO guidelines, good practices, related regulatory guidance and GXP training materials, Geneva, World Health Organization, 2016.

2. Equipment:

Fire safety regulations;

The rules of asepsis and antisepsis, clean areas;

The sanitary and anti-epidemic regime (regulated by the sanitary norms and rules of the Republic of Belarus);

Sanitary norms and rules of the Republic of Belarus 9-108-98. Sanitary rules and regulations for enterprises producing medicines.

3. Professional techniques:

Drawing up a plan of premises for auxiliary and production workshops, equipment and location of workplaces, description of the organization of the production process on the basis of practice. Evaluating the feasibility of space planning;

Study of the devices and work of equipment for the production of medicines in industrial conditions;

Study of devices and maintenance of equipment for obtaining purified water and water for injections, control of its quality and storage conditions;

Study of industrial production flowcharts for various dosage forms;

Participation in the implementation of quality control of medicines.

INFORMATION AND METHODOLOGICAL PART

CALENDAR AND THEMATIC PLAN

№	Name of works	Number of days
1	Study of the requirements of Good Manufacturing Practice for the organization of medicines production in industrial conditions: air and water treatment, preparation of premises depending on the type of cleanliness, requirements for personnel.	1
2	Organization of the production process, technological and equipment flowcharts of production. Study of manufacturing technology of various dosage forms produced on the basis of industrial practice.	6
3	Organization of work with suppliers of pharmaceutical substances, excipients and packaging materials. Procedure for performing entrance control.	1
4	Functioning of the quality assurance system at the enterprise. Procedure for admission to the market of finished products and their storage (warehouse of finished medicines).	1
5	Forming the product portfolio of a pharmaceutical company. Functioning of the sales system, promotion of products to the market (organization of the marketing department). Documentation at the enterprise (SOP, WI, quality certificates, etc.). The procedure for self-inspection. Procedure for organizing staff training.	1

GUIDELINES FOR PRACTICE MANAGERS AND STUDENTS

Educational, methodological and organizational management of industrial technological practice is carried out by teachers of the Department of Pharmaceutical Technology.

Direct management of practice in the workplace guide employers of the company appointed by the head of the company.

The teacher of the Department of Pharmaceutical Technology and the head of the practice from the enterprise are responsible for the quality of the industrial technological practice.

The teacher of the Department of Pharmaceutical Technology is obliged to:

control the organization and provision of practice;

control the implementation of the practice program;

provide students with organizational and methodological assistance during their practice;

check the diaries and reports of students;

take credit on the basis of practice or in the training rooms of the Department;

The head of the practice is obliged to:

instruct students on safety and labor protection;

create the necessary conditions for students to complete the practice program;

certify weekly with signature in the diary the student's stay in practice (Appendix 2) and the nature of the work performed during this day;

give a description at the end of the practice about the work of each student (Appendix 4)

RESPONSIBILITIES OF THE STUDENT DURING THE PRACTICE

During the practice, the student must keep a "Diary of Industrial Technological Practice" (appendix 1-2).

The diary is a document that records the implementation of the program of industrial technological practice, which reflects in detail all the names of works performed during the working day.

The student must keep a daily diary of their work in the following form:

1. Daily report. Every day, the student records the main points of their practical activities in various departments of the enterprise.

2. Final report. It is compiled at the end of the industrial technological practice. It should contain a list of names of works performed during the practice.

At the end of the practice, the diary is signed by the student, the head of the practice and certified with the enterprise's stamp.

QUESTIONS FOR THE DIFFERENTIATED TEST

1. Regulatory documentation (definition, purpose, categories). Production regulations. Types of regulations. Content of the regulations.
2. Profiling of pharmaceutical companies. The principle of the GMP organization of production of medicines.
3. Types and purpose of receiving and transmitting mechanisms.
4. Heat transfer processes in pharmaceutical production.
5. The use of steam and condensation processes on pharmaceutical enterprises.
6. The grinding methods. Features of grinding herbal raw materials.
7. Stage "grinding" in the technological process (purpose, in the production of which drugs are used).
8. Mechanical classification of solid materials and sieve analysis.
9. The types of mechanized screens (sieves). Safety rules when working with sieves.
10. Mixing of solid materials on pharmaceutical enterprises.
11. Methods of mixing liquids on pharmaceutical enterprises.
12. The separation of the liquid and solid phases. The basic methods.
13. Technology of powder production on a pharmaceutical enterprise.
14. Tablets. Excipients used in the production of tablets.
15. The production of tablets (scheme, description of the technological stages).
16. Granulation (definition, methods) in the technological process. Quality control of the obtained granulate.
17. The application of dry and wet granulation.
18. The use of structural granulation.
19. Coating tablets with shells (purpose, requirements for coatings, auxiliary substances used for coatings).
20. Methods of coating the tablets, their comparative analysis.
21. The application of film coating on tablets.
22. Production of multi-layer and frame tablets.
23. Quality assessment of tablets on the production line and in the laboratory.
24. A package of tablets (requirements, types, content).
25. Production of granules (scheme, description of the technological stages).
26. Production of dragee (scheme, description of the technological stages).
27. Water production in an industrial condition. Collection, storage and control of water quality.
28. Primary packaging of solid dosage forms.
29. Primary packaging of semi-solid drugs.
30. Primary packaging of liquid drugs.
31. Primary packaging of drugs for inhalation.
32. Production of injections in ampoules. Technological scheme and production stages.
33. Production of infusion solutions.

34. Sterilization (purpose, methods).
35. Eye medicines (definition, classification, requirements, solvents).
36. Production of patches (scheme, description of the technological stages).
37. Production of mustard plasters (scheme, description of technological stages).
38. Liquid and solid patches.
39. Medical solutions. Methods for obtaining medical solutions.
40. Solvents and auxiliary substances in the production of solutions.
41. Production of flavoring syrups (scheme, description of technological stages).
42. Production of medicinal syrups (scheme, description of the technological stages).
43. Extraction of herbal raw materials. Stages of the extraction process.
44. The methods of extraction. Classification. Choice of method.
45. The tincture. Preparation of herbal raw materials. Production technology. Storage.
46. Extracts. Production technology. Storage.
47. Application of the "drying" stage in pharmaceutical production. Method of drying.
48. Neogalenical drugs. Production technology.
49. Production of individual substances. Classification. Production technology.
50. Industrial production of suspensions (scheme, description of the technological stages).
51. Industrial production of emulsions (scheme, description of the technological stages).
52. Ointment bases (types, requirements, classification).
53. Industrial production of ointments. Standardization of ointments.
54. Rheological properties of ointments. The degree of release of active substances from the ointment.
55. Methods of industrial production of suppositories. Standardization of suppositories.
56. Production of hard gelatin capsules (scheme, description of the technological stages).
57. Production of soft gelatin capsules (scheme, description of the technological stages).
58. Inhalations and aerosols. Rules for transportation and storage of aerosol packages.
59. The use of dosing machines in the pharmaceutical industry.
60. The use of granulators in the pharmaceutical industry.
61. The use of dryers in the pharmaceutical industry.
62. The use of coaters in the pharmaceutical industry.
63. The use of tablet machines in the pharmaceutical industry.
64. The production of water for injection in the pharmaceutical industry.
65. Methods for washing ampoules in the pharmaceutical production.

66. Methods of filling ampoules.
67. Sealing of ampoules. Choice of the method.
68. Quality control of tablets.
69. Quality control of capsules.
70. Quality control of injections.
71. Quality control of ointments according.
72. Quality control of suppositories.
73. Functioning of the sales system, promotion of products to the market (organization of the marketing department).
74. The formation of the product portfolio of a pharmaceutical company.
75. Procedure for admission to the market of finished products and their storage (warehouse of finished medicines).
76. The procedure of the entrance control. Functioning of the quality assurance system at the enterprise.
77. Air treatment at pharmaceutical enterprises.
78. Classes of purity in the pharmaceutical enterprise.
79. Requirements for personnel of pharmaceutical companies.
80. Rules of safety, sanitary and hygienic regime and pharmaceutical order.
81. Good Manufacturing Practice on pharmaceutical enterprises.
82. The quality of the pharmaceutical substances and auxiliary substances for industrial production of medicines.
83. The technology of obtaining herbal teas.
84. Types of packaging used in the production. Types of material.
85. The use of filtration in the production of drugs.
86. The use of centrifugation in the production of drugs.
87. Material, energy, technical and economic balance.
88. General concepts: raw materials, ingredients, semi-finished product, finished product, by-product, waste.
89. Freeze-drying. Application. Examples of medicinal products obtained by freeze-drying.

LIST OF PRACTICAL SKILLS

Organization of medicines production in industrial conditions: air and water treatment, preparation of premises depending on the type of cleanliness, requirements for personnel.

Organization of work with suppliers of pharmaceutical substances, excipients, and packaging materials. The implementation of the entrance control.

Organization of the production process, technological and equipment schemes of production. Dossier series and evaluation of the quality of products.

Self-inspection: documentation at the enterprise, staff training, organization of work with complaints.

Development of technological documentation, validation of technological equipment and technological process of industrial production of medicines.

Study of the functioning of the quality assurance system at the enterprise.

Study of the procedure for admission to the market of finished products and their storage.

Study of the system of forming the assortment portfolio of a pharmaceutical enterprise. Functioning of the sales system, promotion of products to the market.

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

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D I A R Y

Industrial Technological Practice

_____
(Name Surname)

Faculty _____
Educational year _____
Academic group № _____

Practice base _____
(name of organization)

Head in the workplace _____
(Name Surname)

Department teacher, head of practice _____
(Name Surname)

Minsk BSMU 20__

Appendix 2. An exemplary form of the diary of student

Date	Forms and types of work	Signature of the responsible person
	Only the types of work performed by the student are listed, indicating the degree of participation (observed, performed independently). The student's own assessment of the working day result, analysis of the current result of practical training in comparison with the standards is desirable.	*Student's signature (daily)* *Date, signature of the Manager (per week)*

Notes:

1. Entries are made in a neat, legible handwriting. Corrections and additions are not allowed after the practice manager has reviewed the records.
2. Registration of the diary, report, characteristics is performed on paper in A4 format and is carried out in accordance with the requirements of the state standard 6-38-2004 to the details, text, document design and data in tables.
3. The signature of the head in the practice diary is certified in accordance with the established procedure.
4. Diaries, reports, characteristics, and other documents on industrial technological practice are stored in accordance with the nomenclature of the Department of Pharmaceutical Technology, responsible for the organization of industrial practice.

Appendix 3. Form of the practice report

APPROVED
Head of the practice
(organization name)
Name Surname
___ _____ 20____ .

Student report _____
(Name Second Name Surname)

on completion of industrial technological practice at the base of

_____
(name of practice base)

from _____20___ to _____20___.

Type of practical training, name of the technique	Done

Signature of student _____

Signature
of manager _____

Place for a stamp

____ _____ 20___ .

Appendix 4. An example of the characteristics

CHARACTERISTIC

on student-trainee _____
(Name Surname)

(Name and Surname of the student) passed (a) pharmacy technological practice at the base of from 00.00.20__ to 00.00.20__.

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

Acquainted with the characteristic.

Signature of student _____

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

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

Dean of the Medical Faculty of International Students of Educational Institution «Belarusian State Medical University» O.S.Ishutin
21. 12. 2020

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22. 12 2020

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21. 12. 2020

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