DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY

Department of Drug Technology and Biopharmaceutics

APPROVED
Temporary acting vice-rector on
educational and pedagogical work,
assoc.prof. I.I. Solonynko
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«_05_» _07_____ 2022

EDUCATIONAL PROGRAM
on elective discipline

PRODUCTION PRACTICAL TRAINING ON TECHNOLOGY OF MEDICINAL PRODUCTS

for training specialists of the second (master's) degree of higher education
of the branch of study 22 "Health care"
of the specialty 226 "Pharmacy, industrial pharmacy"
for the 4th year students of Faculty of Pharmacy
of the full-time and part-time forms of education

Approved
at the meeting of Department of
Drug Technology and Biopharmaceutics
Minutes No.12
«_8_» __June_____ 2022
Head of the Department
_____ assoc.prof. S.B. Bilous

Approved
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Chemical and Pharmaceutical Disciplines
Minutes No.3
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2022

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INTRODUCTION

Educational program of the discipline
«Production practical training on technology of medicinal products»
according to Standard of higher education of *second (master's) level*
branch of knowledge *22 "Healthcare"*
specialty *226 "Pharmacy"*
educational program of *master of pharmacy*

Description of the selective discipline (annotation)

Production practical training on technology of medicinal products is one of the stages in the formation of professional knowledge, skills and abilities of the future master of pharmacy. The practical training involves familiarizing students with the technological process of medicines in pharmacies and in industrial conditions, packaging and labeling of the medicines; getting and improving practical skills and abilities necessary for making independent decisions during specific work in production conditions.

Structure of the practical training

Structure of the practical training		**Number of weeks**	**Number of credits, hours**	**Year of study / semester**	**Type of control**
Production practical training on technology of medicinal products	Production practical training on technology of medicinal products in pharmacy	3	4,5 credits, 135 hours	4th year courses / semester VIII	Graded credit
	Production practical training on industrial technology of medicinal products	1	1,5 credits, 45 hours	4th year courses / semester VIII	

The subject of the production practical training on technology of medicinal products is improvement of knowledge and skills in manufacturing of medicines in the conditions of pharmacies and pharmaceutical factories.

Interdisciplinary connections include:

- the practical training is based on learning physics, general and neorganic chemistry, physical and colloidal chemistry, physiology, pharmacognosy, pharmacology;
- the practical training is a basis for studying of good pharmaceutical practices, pharmaceutical chemistry, management and marketing in pharmacy, biopharmaceutics, standardization of medicines, technology of medicinal cosmetics, that involves the integration of the practical training with mentioned above disciplines to train skills of applying knowledge in the process of further studying and the professional activity;
- the discipline is a foundation for professional training and promotes the formation of pharmaceutical and technical thinking necessary for professional activities.

1. Purpose and objectives of production practical training on technology of medicinal products

1.1. The purpose of the production practical training is:

- to deepen knowledge gained during studying the discipline "Technology of medicinal products", to improve the practical skills and abilities in making independent decisions during specific work in production conditions;

- to create the motivation in the future specialists to refresh systematically the knowledge base, to be familiarized with the latest achievements in the pharmaceutical industry, to review scientific literature, and to apply the knowledge and skills into practice.

1.2. Objectives of the production practical training
<u>on "Technology of medicinal products in pharmacy":</u>

- generalization of the rules of safety and pharmaceutical order in the pharmacy;
- learning the features of work with toxic, strong active and narcotic substances; control of single and daily doses and dispensing norms;
- learning of the operation principles of the most common labor-saving tools;
- generalization of the rules of compounding powders with ingredients which possess different physical and chemical properties, packaging the powders and preparing for dispensing;
- generalization of the rules of preparing liquid preparations by weight to volume method;
- generalization of the principles for selecting ointment bases and rules for compounding semi-solid preparations of different types of disperse systems;
- generalization of the rules of compounding suppositories, calculating the base amounts;
- generalization of the rules of preparing solutions for injections and infusions, calculating the isotonic concentrations; selection and preparation of containers;
- learning of the features of filtration, methods of stabilization and sterilization of solutions for injections and infusions in the conditions of pharmacy;
- learning of the production features of eye preparations, preparations with antibiotics and preparations for newborns;
- generalization of rules for preparing compounded preparations for dispensing.

<u>On "Industrial technology of medicinal products":</u>

- familiarization with the organization of production process at pharmaceutical enterprises;
- generalization of knowledge gained from studying the normative documents, general pharmacopoeia articles, and use them in drug manufacturing;
- familiarization with production of preparations in different dosage forms in industrial conditions;
- familiarization with technological equipment of pharmaceutical enterprises, scientific management of labor and prospects of the pharmaceutical manufacturing.

1.3 Competencies and learning outcomes, which are contributed by learning the discipline (correlation with normative content of the training of higher education applicants formulated in terms of learning outcomes in Standard of Higher Education).

The practical training provides gaining the following ***competencies*** – ***general and professional***.

General:

CG 1. Ability to act in socially and civil responsible manner.

CG 2. Ability to use knowledge in practical situations.

CG 3. Striving to preserve the environment.

CG 4. Ability for abstract thinking, analysis and synthesis; ability to study and to be modernly trained.

CG 5. Ability to show initiative and entrepreneurship.

CG 6. Knowing and understanding of subject field and the understanding of profession.

CG 7. Ability to adapt and act in a new situation.

GC 8. Ability to communicate in the official language, both verbally and in writing, the ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity

GC 9. Skills of using information and communication technologies.

GC 10. Ability to choose communication strategy, ability to work in a team and with experts in other fields of knowledge / types of economic activity.
GC 11. Ability to evaluate and ensure the quality of work performed.
GC 13. Ability to exercise the rights and responsibilities as a member of society, to realize the values of civil (free democratic) society and the need for its sustainable development, the rule of law, rights and freedoms of man and citizen in Ukraine.
GC 14. Ability to preserve and multiply moral, cultural, scientific values and achievements of the society on the basis of understanding of history and patterns of development of the subject area, its place in the general system of knowledge about nature and society and in the development of society, technology and technology, use different types and forms motor activity for active rest and leading a healthy lifestyle.

Professional:

PC 1. Ability to conduct health education among the population with the purpose of the prevention of common diseases, dangerous infectious, viral and parasitic diseases, as well as to facilitate the timely detection and maintenance of adherence to the treatment of these diseases in accordance with their medical and biological characteristics and microbiological features.
PC 2. Ability to provide advice on prescription and over-the-counter drugs and other products of the pharmacy range; pharmaceutical care during the selection and sale of over-the-counter drugs by assessing the risk/benefit, compatibility, indications and contraindications based on the health status of a particular patient, taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical characteristics of medicinal products and other pharmaceutical products.
PC 7. Ability to ensure proper storage of medicines and other products of the pharmacy range in accordance with their physicochemical properties and the rules of Good Storage Practice (GSP) in health care facilities.
PC 12. Ability to use in professional activities knowledge of regulations, legislation of Ukraine, and recommendations of Good Pharmaceutical Practices.
PC 14. Ability to organize and carry out the production activities of pharmacies for the preparation of medicinal products in various dosage forms on prescriptions and orders of medical institutions, including justification of technology and selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).
PC 15. Ability to organize and participate in the production of medicines in pharmaceutical companies, including the selection and justification of the process, equipment and premises with the appropriate development and design of the necessary documentation in accordance with the requirements of Good Manufacturing Practice (GMP); ability to determine the stability of medicinal products.
PC 18. Ability to develop and implement a quality management system for pharmaceutical companies in accordance with the requirements of current Standards, to conduct quality audits and risk management for the quality of pharmaceutical products
PC 19. Ability to organize and carry out quality control of medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and good pharmaceutical practices, to determine sampling methods for the control of medicinal products and to carry out their standardization in accordance with current requirements, to prevent the distribution of falsified medicinal products.
PC 20. Ability to develop methods of quality control of medicinal products, including active pharmaceutical ingredients, medicinal plant raw materials and excipietns using physical, chemical,

physical-chemical, biological, microbiological, pharmaco-technological and pharmaco-organoleptic control methods.

Program learning outcomes (PLO), the formation of which is facilitated by the practical training:

PLO 1. To conduct professional activities in social interaction based on humanistic and ethical principles; to identify future professional activity as socially significant for the human health.

PLO 2. To apply knowledge of general and professional disciplines in professional activities.

PLO 3. To adhere to the norms of the sanitary and hygienic regime and the requirements of safety precautions when carrying out professional activities.

PLO 4. To demonstrate the ability to independently search, analyze and synthesize information from various sources and to use these results for solving typical and complex specialized tasks of professional activity.

PLO 5. To position one's professional activity and personal qualities on the pharmaceutical labor market; to formulate the goals of one's own activity taking into account public and industrial interests.

PLO 6. To argue the information for decision-making, to be responsible for the decisions in standard and non-standard professional situations; to adhere to the principles of deontology and ethics in professional activity.

PLO 7. To perform professional activities using creative methods and approaches.

PLO 8. To carry out professional communication in the official language, to use oral communication skills in a foreign language, to analyze specialized texts and to translate foreign language information sources.

PLO 9. To carry out professional activities using information technologies, "Information data bases", navigation systems, Internet resources, software and other information and communication technologies.

PLO 10. To adhere to the norms of communication in professional interaction with colleagues, management, consumers, to work effectively in a team.

PLO 11. To use methods of evaluating performance quality indicators; to identify reserves for increasing labor efficiency.

PLO 12. To analyze information obtained as a result of scientific research, to generalize, systematize and use it in professional activities.

PLO 13. To carry out sanitary and educational work in professional activities in the event of outbreaks of infectious, viral and parasitic diseases.

PLO 14. To determine the advantages and disadvantages of medicines of various pharmacological groups, taking into account their chemical, physical-chemical, biopharmaceutical, pharmacokinetic and pharmacodynamic characteristics. To recommend to consumers non-prescription drugs and other products of the pharmacy assortment with the provision of advisory assistance and pharmaceutical care

PLO 16. To determine the influence of factors affecting the processes of absorption, distribution, deposition, metabolism, and excretion of the medicinal product and which are determined by the condition, features of the human body, and the physicochemical properties of medicinal products.

PLO 19. To predict and determine the influence of environmental factors on the quality of medicines and consumer characteristics of other products of the pharmacy assortment during their storage.

PLO 24. To plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of good pharmaceutical practices.
PLO 25. To contribute to the preservation of health, in particular the prevention of diseases, the rational prescription and use of medicinal products. To conscientiously fulfill one's professional duties, to comply with the legislation on the promotion and advertising of medicinal products. To possess psychological communication skills to achieve trust and mutual understanding with colleagues, doctors, patients, consumers.
PLO 26. To choose a rational technology, to formulate medicinal products in various dosage forms according to the prescriptions of doctors and orders of medical institutions, to prepare them for dispensing. To perform technological operations: to weigh, to measure, to dose various medicinal products by weight, volume, etc. To develop and draw up technological documentation for the compounding of medicinal products in pharmacies.
PLO 27. To substantiate the technology and organize the production of medicinal products at pharmaceutical enterprises and draw up technological documentation for the production of medicinal products at pharmaceutical enterprises.
PLO 30. To ensure quality control of medicinal products and to document its results. To carry out quality risk management at all stages of the life cycle of medicinal products.
PLO 31. To carry out all types of quality control of medicinal products; to draw up quality certificates of a series of medicinal products and a certificate of analysis, taking into account the requirements of current regulatory documents, the State Pharmacopoeia of Ukraine and the results of quality control. To develop specifications and quality control methods in accordance with the requirements of the current State Pharmacopoeia of Ukraine.
PLO 32. To determine the main organoleptic, physical, chemical, physicochemical and pharmacotechnological indicators of medicinal products, to justify and choose methods of their standardization, to carry out statistical processing of the results in accordance with the requirements of the current State Pharmacopoeia of Ukraine.

Matrix of competencies

No.	Competency	Knowledge	Abilities	Communication	Autonomy and responsibility
Integrative competency					
The ability to solve typical and complex specialized tasks and practical issues in the professional pharmaceutical practice using statements, theories and methods of fundamental, chemical, technological, biomedical and social-economic sciences; ability to integrate knowledge and solve complex issues, to formulate judgments in case of insufficient or limited information; to reveal clearly and unambiguously conclusions and knowledge, reasoning them, to the professional and non-professional audience.					
General competencies					
CG 1	Ability to act in socially and civil responsible manner	To know social and civil rights and responsibilities	To form civil consciousness and to act according to it	Ability to prove social and civil position	To be responsible for civil position and activity
CG 2	Ability to use knowledge in practical situations	To know methods of knowledge implementation in solving practical issues	To be able to use professional knowledge for solving practical issues	To establish contacts with entities of practical activities	To be responsible for the timely taken decision
CG 3	Striving to preserve the environment	To know the problems of environmental protection, requirements of the sanitary and hygienic regime and conditions of labor protection	To be able to form the requirements for the preservation of the environment, compliance with the sanitary and hygienic regime and labor protection conditions; interpret the requirements of laws and regulations on labor protection; draw conclusions about the presence of harmful factors during the performance of professional duties; to ensure the safety of pharmaceutical staff	The ability to express their attitude to the environment	To be responsible for the implementation of environmental measures within its competence
CG 4	The ability for abstract thinking, analysis and synthesis, ability to study and to be modernly trained	To know current development trends of the branch and to analyze them	To be able to analyze professional information, make reasoned decisions, acquire up-to-date knowledge	To establish appropriate contacts for achieving the goals	To be responsible for timely acquisition of up-to-date knowledge
CG 5	Ability to show initiative and entrepreneurship	To know the laws and trends of modern economic development	To be able to apply knowledge to the modern development of an enterprise	To use the qualities of a leader to establish	To be responsible for the activity goals

				links with various subjects of professional activity	
CG 6	The knowing and understanding of subject field and the understanding of profession	To know structure and features of professional activities	To be able to carry out professional activities that requires updating and integration of knowledge	To form communication strategy in the professional activities	To be responsible for professional growth with high level of autonomy
CG 7	The ability to adapt and act in a new situation	To know elements of production and social adaptation, factors of successful adaptation to a new environment	To be able to form an effective strategy of personal adaptation for new conditions	To contact with a wide range of the public (colleagues, administration, professionals of other branches) in case of new situations with unpredictable elements	To be responsible for taking decisions
CG 8	Ability to communicate in the state language both orally and in writing, in a foreign language (mostly the English language) at a level that ensures effective professional activity	To have perfect knowledge of the native language and basic knowledge of a foreign language	To be able to apply knowledge of the native language in oral and writing form	To use the language during professional and business communication and preparation of documents in the native language. Use a foreign language in professional activities	To be responsible for fluency in the native language, development of professional knowledge
CG 9	Skills of using information and communication technologies.	To have deep knowledge in the field of information and communication technologies used in professional activities	To be able to use information and communication technologies in the professional field that requires updating and integration of knowledge	To use information and communication technologies in professional activities	To be responsible for professional development knowledge and skills

CG 10	Ability to choose communication strategies, ability to work in a team and with experts in other fields of knowledge / types of economic activity	To know the tactics and strategies of communication, laws, and ways of communicative behavior	To be able to choose ways and strategies of communication to ensure effective teamwork	To use communication strategies and skills of interpersonal interaction	To be responsible for the choice and tactics of communication
CG 11	The ability to evaluate and ensure quality of performed work	To know methods for evaluation of work quality	To be able to ensure competent performance of professional activities	To establish contacts for assurance of competent performance of activities	To be responsible for competent performance of activities
CG 13	Ability to exercise the rights and responsibilities as a member of society, to realize the values of civil (free democratic) society and the need for its sustainable development, the rule of law, human and civil rights and freedoms in Ukraine	To know the rights and responsibilities of members of society and values of civil democratic society	To apply their rights and responsibilities in practice, taking into account the values of civil society	-	To be responsible for their actions in civil society
CG 14	Ability to preserve and multiply moral, cultural, scientific values and achievements of society based on understanding the history and patterns of development of the subject area (pharmacy), its place in the general system of knowledge about nature and society	To know the moral, cultural, scientific values and achievements of society based on understanding the history and patterns of pharmacy, its place in the general system of knowledge about nature and society and in the development of society, technology types and forms of physical activity for active recreation and a healthy lifestyle	To use moral, cultural, scientific values and achievements of society based on understanding the history and regularities of the development of pharmacy in practical activity	The ability to communicate using established norms of Ukrainian language	To be responsible for the observance of moral, cultural and scientific values

	and in the development of society, technique and technology, to use different types and forms of motor activity for active recreation and healthy living lifestyle				
Professional competencies					
PC 1	Ability to conduct health education work among the population in order to prevent common diseases, prevent dangerous infectious, viral and parasitic diseases, as well as to facilitate the timely detection and maintenance of adherence to the treatment of these diseases in accordance with their medical, biological and microbiological features	To know the clinical and pharmaceutical characteristics of dosage forms for the treatment of patients with dangerous infectious and parasitic diseases; principles of compiling pharmaceutical information and creation information products	To organize scientific and practical seminars for medical staff and lectures for the population on the rational administration of medicinal products, medicinal plant raw materials, the harmfulness of drugs and strong active drug abuse, measures for the prevention drug dependence; To compile information messages for doctors and junior pharmacy specialists about new medicinal products and new indications for the use of known medicinal products, data from automated information systems, etc.	To carry out preventive work and take antiepidemic measures to prevent diseases	To be responsible for the quality and timeliness of preventive and anti-epidemic measures
PC 2	Ability to provide advice on prescription and over-the-counter drugs and other products of the pharmacy range; pharmaceutical care during the selection and sale of over-the-counter drugs by assessing the risk/benefit, compatibility,	To know: - symptoms and syndromes, variants of the development of diseases for which the use of over-the-counter drugs is possible; - regulatory documents governing dispensing over-the-counter and prescription drugs; - types of action and routes of drug administration;	To provide information on the regime, periods and requirements for storage of various drug products using knowledge of chemical and physicochemical properties; - to provide information about compatibility, indications and contraindications to the use of drug products taking into account their biopharmaceutical, pharmacokinetic and pharmacodynamic properties;	Provide counseling and pharmaceutical care during dispensing overthe-counter medical products	To be responsible for the implementation of pharmaceutical care during dispensing over-the-counter drug products; for the validity of management of decisions to

	indications and contraindications based on the health status of a particular patient, taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical characteristics of medicinal products and other pharmaceutical products	- pharmacokinetic and biopharmaceutical factors influencing the choice of the dosage form; - methods of using modern transdermal, inhalation, oral, dosage forms; -deontological aspects of the pharmacist-patient relationship; - chemical structure medicines; - new dosage forms of prolonged action; - therapeutic systems of delivery of medicines; - characteristics of types of action and routes of drug administration; - bioequivalence of medicinal products and the principles of their clinical study; - features of innovative medicinal products, generics, and biosimilars; - requirements for the equivalence of generic drug products and biosimilars	- to provide comparative characteristics of original (innovative) drug products (brands) and their copies (generic drug products), guided by the data of clinical and pharmacological research, pharmacoeconomic indicators and information database on drug products to justify the optimal choice of a drug product		improve the quality of pharmaceutical care
PC 7	Ability to ensure proper storage of medicines and other pharmaceutical products in accordance with their physicochemical properties and the rules of Good Storage Practice (GSP) in health care facilities	To know: - classification of medicinal products and dosage forms; - physicochemical properties of medicinal substances; - types of containers, closures, and packaging materials used in medicine and pharmacy; - orders of the Ministry of Health of Ukraine on the organization of storage of various groups of medicinal products and medical devices in pharmacies; - general requirements for the storage of medicines;	To provide conditions of the storage of medicines to prevent adverse effects; to anticipate the possible influence of storage conditions on the quality of pharmaceutical products, medicinal plant raw materials and medical devices; to control the conditions of the storage of raw materials at pharmaceutical enterprises; to determine the stability of medicines and medical devices during storage for the established shelf-life	To carry out constant monitoring of the proper storage of medicines and medical devices	To be responsible for the storage of medicines and medical devices in accordance with Good Storage Practice (GSP) in healthcare facilities

		- rules of the storage of medicinal substances with different physicochemical properties; - stability and shelf life of medicinal products			
PC 12	Ability to use the knowledge of regulations, legislation of Ukraine and pharmaceutical practices in the professional activities	To know basics of the system of law and pharmaceutical legislation; principal mechanisms of the state regulation of pharmaceutical activity; legal and ethical norms of pharmaceutical activity	To use normative-legal acts regulating pharmaceutical activity in Ukraine and abroad; to monitor and determine changes and amendments in the domestic pharmaceutical legislation; to form relations with patients and doctors in order to meet the ethical criteria of the WHO and the principles of Good Pharmacy Practice (GPP) to promote medicinal products on the market, minimize abuse and misuse of medicinal products	To form conclusions and professionally to apply laws and normative documents	To be responsible for high-quality and timely use of normative documents in professional activity
PC 14	Ability to organize and carry out the production activities of pharmacies for the preparation of medicinal products in various dosage forms on prescriptions and orders of medical institutions, including justification of technology and selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP)	To know pharmacy technology of pharmaceutical products; stability and shelf life of medicines; determination of the influence of the nature of excipients on the therapeutic efficacy of pharmaceutical products by "in vitro" and "in vivo" methods; requirements of regulatory documents (orders, guidelines, etc.) on the design and rules of the development of technological documentation	To characterize dosage forms by types of dispersed systems, method of administration, place of action, physical state; to take into account the physicochemical properties of active substances and excipients; to stabilize pharmaceuticals taking into account biological, physicochemical, technological properties of active and excipients and use of necessary reagents; to make technological schemes and instructions for the manufacture of drugs "in stock" in the pharmacy	To organize the production activities of the pharmacy	To be responsible for the extemporaneous preparation of medicinal products

PC 15	Ability to organize and participate in the manufacture of medicines in the context of pharmaceutical companies, including the selection and justification of the technological process, equipment and premises with the appropriate development and design of the necessary documentation in accordance with the requirements of Good Manufacturing Practice (GMP). To determine the stability of medicinal products	To know: industrial technology of medicinal products; requirements of GMP and other Good Practices for the manufacture of medicinal products, including the development and design of documentation (protocols, production formula, reports, technological instructions, etc.)	To choose the optimal technology of dosage forms, appropriate equipment; to develop documentation related to the technological process, consideration of complaints and product recalls, self-inspections, etc.	To choose the optimal technological process of medicinal product of industrial manufacture	To be responsible for the compliance with Good Manufacturing Practice (GMP)
PC 18	Ability to develop and implement quality management system for pharmaceutical companies in accordance with the requirements of current Standards, perform quality audits, and risk management for the quality of pharmaceutical products	To know the principles of quality management system in pharmaceutical companies	To be able to use the principles of quality management in the organization of quality management system, its support and audits	Communication in the team involved in developing quality management system	To be responsible for the organization and support of quality management system

PC 19	Ability to organize and control the quality of medicines in accordance with the requirements of the State Pharmacopoeia of Ukraine and good practices, to determine methods of sampling for control of medicines and to standardize them in accordance with current requirements, to prevent the spread of counterfeit medicines	To know the requirements of normative documents to quality control of medicines in different dosage forms	To choose optimal methods for control of the main quality parameterss of specific medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and good practices in pharmacy	To form conclusions about the compliance of finished medicinal products with the main requirements of the current analytical and regulatory documentation	To be responsible for the organization and conducting of the quality control of finished medicinal products
PC 20	Ability to develop methods for quality control of medicines, including active pharmaceutical ingredients, medicinal plant raw materials and excipients using physical, chemical, physicochemical, biological, microbiological, pharmacotechnologi cal and pharmacoorganolept ic control methods	To know quality control methods for finishes medicinal products, active pharmaceutical ingredients and excipients in medicines	Be able to develop methods for investigating of the main quality parameters of finished medicines, including those made on the basis of extracts from medicinal plant raw materials	To organize the development of methods for determining the pharmaco-technological, physico-chemical and microbiological quality parameters of medicinal products	To be responsible for the organization of the development of methods of quality control of medicinal products

2. Information volume of the selective discipline

Students have the production practical training on technology of medicinal products in the 4th course year. Duration of the practical training is 4 weeks.

The production practical training on technology of medicinal products consists of two parts – practical training on technology of medicinal products in pharmacy (3 weeks) and practical training on industrial technology of medicinal products (1 week).

3. Structure of the practical training

Students undergo the **production practical training on technology of medicinal products in pharmacy** that compounds preparations.

During the production practical training students perform the job duties of a pharmacist who compounds preparations and a pharmacist.

Changes in the order of tasks given in the plan of the production practical training are allowed with the agreement of supervisor of the practical training.

Thematic plan of the production practical training on technology of medicinal products in pharmacy

No.	Topic	Number of days
1.	Passing the briefing on safety awareness, sanitary measures and pharmaceutical order. Analysis of structural subdivisions and a personnel staff of pharmacy (production areas of pharmacy, layout and equipment of workplaces, storage conditions for drug products and medical devices); requirements for sanitary and anti-epidemic regime of the pharmacy	1
2.	Preparing of combined powders with ingredients in different amounts and with different physical and chemical properties	1
3.	Preparing of combined powders with colour, colored, hard-grounded ingredients and with liquids	1
4.	Preparing of liquid preparations with dry ingredients and concentrated solutions by weight to volume method	1
5.	Preparing of non-aqueous solutions and drops for oral and external use	1
6.	Preparing of solutions with high molecular compounds and heterogeneous liquid preparations	1
7.	Preparing of homogeneous semi-solid preparations for cutaneous application	1
8.	Preparing of heterogeneous semi-solid preparations for cutaneous application	1
9.	Preparing of suppositories by pouring and rolling methods	1
10.	Preparing of solutions for injections without the stabilization and those that require the stabilization	1
11.	Preparing of isotonic solutions for infusions	1
12.	Preparing of eye preparations	1
13.	Preparing of preparations with antibiotics and for newborns	1
14.	Preparing of intrapharmacy products, including concentrated solutions and intermediate products	1
15.	Reception of prescriptions, control of doses and norms of toxic and potent substances, and compatibility of ingredients, processing for dispensing, and control of finished preparations. The rules of the dispensing preparations with toxic, narcotic ingredients and precursors	1
	Total	15 days

Students undergo the **production practical training on industrial technology of medicinal products** at the Department of Drug Technology and Biopharmaceutics and in pharmaceutical enterprises.

The goals of production practical training on industrial technology of drugs are to deepen the knowledge of students on the manufacture of drug products in industrial conditions; to know the basic stages of the manufacture of drug products in industrial conditions; to create manufacturing and apparatus schemes; to know the basic criteria and methods for quality control of intermediate and finished products.

Thematic plan of the production practical training on industrial technology of medicinal products

No.	Topic	Number of days
1	Safety training. General familiarization with manufacture organization at the pharmaceutical enterprises. Manufacture of solid preparations (production methods, equipment, quality control). Packaging of tablets; tablet packaging machines	1
2	Manufacture of liquid preparations (production methods, equipment, quality control). Manufacturing stages of liquid preparations; nomenclature of aqueous and alcoholic solutions, syrups, aromatic waters, suspensions and emulsions that are produced in industrial conditions	1
3	Manufacture of semi-solid preparations and suppositories (production methods, equipment, quality control). Stages of the manufacturing process, equipment for manufacture of homogeneous and heterogeneous semi-solid preparations. Manufacture of suppositories in industrial conditions.	1
4	Manufacture of parenteral preparations (manufacturing features, requirements of Pharmacopoeia). Construction and operation mechanism of ampoule making machines; pretreatment of ampoules for filling; preparing and filtration of solutions; ampoules filling; sterilization	1
5	Manufacture of extraction preparations (production methods, equipment, quality control). Stages of the manufacturing process, equipment. Rectification and recuperation of ethanol.	1
	Final control of the production practical training	
	Total	5 days

Thematic plan of independent work on the production practical training on technology of medicinal products

No.	Type of work	Number of hours
Technology of medicinal products in pharmacy		
1.	Writing the repots – work with prescriptions	45 hours (3 h for 15 days)
Self-study of topics that are not included in the schedule:		
1.	The main provisions of current regulatory documents (orders of the Ministry of Health, SPhU) regulating the prescription, compounding and dispensing of non-sterile medicinal products in pharmacies	3
2.	Nomenclature of medicinal substances and excipients used for the compounding of medicinal products, their characteristics and scope of application	3

3.	Provision of aseptic conditions in pharmacies; conditions of distillation, collection and storage of purified water and water for injections; rules for working with distillers, filtering equipment	3
4.	Basic provisions of normative documents regulating the quality of medicinal products; various types of internal pharmacy control; terms, conditions and rules of storage of medicinal products	3
5.	Difficult prescriptions and ways to eliminate technological problems. Incompatible combinations of medicinal substances in dosage forms and ways to overcome them	3
	Total	60
Industrial technology of medicinal products		
1.	Writing of reports – solving of individual tasks on the working prescription for manufacture of medicines in different dosage forms	15 hours (3 h for 5 days)
Self-study of topics that are not included in the schedule:		
1.	Guideline "Medicinal products. Technological process. Documentation"	3
2.	Guideline for the production of finished medicinal products	3
3.	Methods of intensification of extraction processes	3
4.	Basic concepts of containers and packaging. Types of consumer containers for different dosage forms	3
5.	New types of packaging and sealing materials for sterile, solid, liquid medicines	3
	Total	30
	Total hours for practical training	**90**

4. List of skills and abilities that student must acquire in the result of the practical training and the assessment in points

List of skills and abilities that student must acquire in the result of production practical training on technology of medicinal products in pharmacy and the assessment in points

No.	Practical skills and abilities	No.
1.	To use normative, informative and study literature to solve the professional problems	«5» – 5 points «4» – 4 points «3» – 3 points «2» – 0 points
2.	To check the appropriateness of prescriptions and determine the compatibility of ingredients. To make the necessary calculations for control of single and daily doses of toxic and potent substances and their dispensing norms	- «» -
3.	To work with prescription and hand balances; to weigh dry, viscous substances, and liquids. To dose liquids by measuring devices and calibrate the empirical dropper	- «» -
4.	To compound powders with ingredients that have different physical and chemical properties; to use dosing and the other labor-saving tools	- «» -
5.	To prepare aqueous solutions by weight to volume method. To use special technological operations for improvement of active ingredients solubility	- «» -
6.	To prepare solutions with non-aqueous solvents; drops, solutions with high molecular compounds, and colloids	- «» -
7.	To select appropriate stabilizing agents for heterogeneous systems and to prepare suspensions and emulsions	- «» -

8.	To prepare aqueous extracts from medicinal plant material and with concentrated extracts	- «» -
9.	To prepare semi-solid preparations; rectal, vaginal and urethral suppositories by pouring and rolling methods	- «» -
10.	To provide and follow aseptic conditions for preparing sterile products. To prepare concentrated solutions for burette system	- «» -
11.	To prepare solutions for injection, eye preparations, preparations with antibiotics and for newborns	- «» -
12.	To select packaging material in accordance with type of dosage form, physical and chemical properties of ingredients. To prepare drug products for dispensing. To perform organoleptical, question, and writing control of preparations compounded in pharmacy	- «» -
	Total sum of points	**36-60**

List of skills and abilities that student must acquire in the result of production practical training on industrial technology of medicinal products and the assessment in points

No.	Practical skills and abilities	Mark in points
1.	To use normative documents, informative and scientific literature to solve practical tasks	«5» – 5 points «4» – 4 points «3» – 3 points «2» – 0 points
2.	To write material balance equations, to calculate output, losses and factor of account at different manufacturing stages of drug products in different dosage forms	- «» -
3.	To make working prescriptions for manufacturing of preparations in different dosage forms with consideration of the factor of account	- «» -
4.	To substantiate an optimal technology for solid, liquid, semi-solid preparations and suppositories in accordance with the composition of preparations	- «» -
5.	To calculate mass of medicinal plant material and volume of extraction solvent, to substantiate a production method for extraction preparations	- «» -
6.	To create the process flow diagrams for manufacturing of drug products in different dosage forms	- «» -
7.	To choose apparatus for manufacturing of preparations	- «» -
8.	To control quality of finished products in accordance with normative standards	- «» -
9.	To choose equipment for testing pharmaco-technological quality parameters of preparations	- «» -
10.	To normalize the concentration of solutions	- «» -
11.	To comply with current GMP requirements for production of sterile and aseptically manufactured drug products	- «» -
12.	To choose packaging materials and containers for preparations in accordance with physical-chemical properties of ingredients and type of dosage form	- «» -
	Total sum of points	**36-60**

5. Teaching methods

There are used the following teaching methods: explanatory-illustrated, analytical, deductive methods, the method of generalization, formation of skills.

6. Methods of control

Methods of control include *current and final control*.

Evaluation criteria for practical skills and abilities.

Excellent ("5") – student solved given tasks in a correct, logical and full manner. Student connects theory with practice, can generalize material, and demonstrates correct performance of practical skills; substantiate composition and technology of preparations, can prepare control the quality of preparation and to prepare it for dispensing.

Good ("4") – student completed given tasks correctly, demonstrates practical skills with slight mistakes. Student puts theoretical knowledge to good use for solving the practical tasks, can solve low and medium complexity tasks. Student has practical skills and abilities in a scope that exceeds a required minimum.

Satisfactory ("3") – student performed given tasks incompletely and not clearly, student solved only the easiest tasks. Student make significant mistakes in demonstrating the practical skills and acquired only a minimum of technological knowledge.

Fail ("2") – student completed less than 50% of a given tasks of practical training. Student is not able to give logical answers and does not understand content of material. Student makes essential mistakes in demonstrating practical skills.

7. Current control of practical training on technology of medicinal products in pharmacy is conducted every day by supervisor from pharmacy by evaluating skills and practical abilities determined by the program of practical training.

Absences from practical training are not allowed.

Evaluation of current educational activity of student is performed using 4-graded (traditional) scale, which is then converted into the points.

Current control of practical training on industrial technology of medicinal products is conducted by supervisor from the Department of Drug Technology and Biopharmaceutics by evaluating the performing of individual practical tasks in the reports, assessing skills and abilities, oral questioning.

Absences from practical training are not allowed.

Evaluation of current educational activity of student is performed using 4-graded (traditional) scale, which is then converted into the points.

8. Form of the **final control** is a graded credit.

Final control is conducted in a written form. The form is standardized and includes performing of situation tasks and control of practical skills. To write final control are allowed students, who have acquired required practical abilities, provided reported documents and scored for current educational activity not less than minimum (72 points).

9. Scheme of evaluation and distribution of points which students gain:

Maximum score that student can get for final control is 80 points.

Minimum score that student can gain for final control to pass credit is 50 points.

Mark for production practical training on technology of medicinal products is calculated as sum of points for current educational activity that student gain for both parts of practical training

–technology of medicinal products in pharmacy and industrial technology of medicinal products (maximal score is 120 points (60 points for each part), minimum – 72 points (36 points for each part)) and for final control (maximal score is 80 points, minimum – 50 points).

Maximum score that student can get for production practical training is 200 points, **minimum score** - 122 points.

Points for practical training are then converted into both ECTS scale and traditional 4-graded (national) scale. ECTS points into 4-graded points are not converted and vice versa.

Points for production practical training on drug technology are converted in 4-graded scale using absolute criteria:

Points for practical training	Mark by 4-point scale
170-200 points	5
140- 169 points	4
122-138 points	3
Less than 122 points	2

10. Methodical support

Methodical guide for production practical training on technology of drugs that contains general information on the organization of practical training, plan and content of practical training, list of practical skills and abilities, which student should get in the result of practical training, information on the reporting documents.

Report on practical training is a main document of student's performance during the practical training, acquisition of practical skills and abilities, implementation of practical training plan. Student should clearly document and describe in the report all performed types of work, determined by the program of practical training. Immediate supervisor of practical training from pharmacy should check records in the report on practical training on technology of medicinal products in pharmacy every day, and evaluate skills and practical abilities. The record on the practical training on industrial technology of drugs, as well as skills and abilities gained during that part of practical training, are controlled by supervisor form the Department.

In the report of production training on technology of medicinal products in pharmacy student must document:

1. disposition and equipment of work places in assistant room;
2. methods for receiving purified water and water for injections, quality control and storage conditions for water;
3. technology of compounded drugs (2 preparation each day).

Prescription is given in the following way:

1. No. of prescription.
2. Ingredients in Latin.
3. Control of doses. Calculation of amounts of the ingredients.
4. Characteristics of the dosage form. Description of technology of the preparation.
5. Quality control of preparation.
6. Packing and labeling in accordance with GPP.

In the report of production training on industrial technology of medicinal products student must document:

1. organization of manufacturing at pharmaceutical enterprise;
4. methods for receiving purified water, its quality control and storage conditions;
2. working prescriptions and technology of medicines with consideration of factor of account for: tablets, liquid preparations, semi-solid preparations, solutions for injections, tinctures, extracts (in accordance with individual task given by the supervisor);
3. process flow diagram for production of drug products.

Lists with points for practical skills and abilities is given together with reports. Supervisor from the Department is responsible for final control and puts the mark for graded credit on production practical training on technology of drugs.

LIST OF QUESTIONS FOR FINAL CONTROL OF PRODUCTION PRACTICAL TRAINING

Technology of medicinal products in pharmacy

1. Normative documents that regulate rules of drugs production in pharmacies.
2. Dosing in formulated drug technology.
3. Control of doses in dosage forms for oral administration.
4. Basic rules of the compounding simple and combined powders with ingredients in different amounts and with different physical and chemical properties.
5. Triturations, their purpose and use.
6. Preparing of liquid preparations by weight to volume method.
7. Concentrated solutions for burette system: nomenclature, technology, quality control.
8. Calculation for dilution or strengthening of concentrated solutions.
9. Special cases in technology of solutions: silver nitrate, potassium permanganate, iodine, mercury diiodide, mercury dichloride, furacilline, ethacridine lactate, phenobarbital.
10. Standard pharmacopoeial liquids, their nomenclature.
11. Preparing of aqueous solutions of standard pharmacopoeial liquids.
12. Features of technology of solutions with non-aqueous solvents (glycerol, vegetable oils, ethanol etc.).
13. Dillution of ethanol.
14. High-molecular compounds, factors affecting stability of solutions with high-molecular substances.
15. Protected colloids, factors affecting stability of colloidal solutions.
16. Technology of solutions with starch, gelatin, pepsin, collargol, protargol and ichthyol.
17. Suspensions, methods of preparing.
18. Stabilization of suspensions, factors affecting sedimentation (kinetic) and aggregate (condensation) stability of suspensions.
19. Preparing of suspensions with hydrophilic and hydrophobic substances.
20. Emulsions for oral administration, their stabilization.
21. Selection of surface-active substances for stabilization of emulsions in accordance with value of hydrophilic-lipophilic balance.
22. Water extracts from medicinal plant raw material, factors affecting quality of water extracts.
23. Technology of infusions and decoctions from medicinal plant material containing essential oils, tanning substances, mucilages.
24. Technology of infusions and decoctions from plant materials containing alkaloids, anthracene derivatives and cardiac glycosides.
25. Use of concentrated extracts for preparing of water extracts.
26. Semi-solid preparations for topical use, classification, requirements.
27. Mechanism of drug absorption through the skin.
28. Bases for ointments.
29. Principles of introduction of drug substances into the ointment bases.
30. Preparing of homogeneous and heterogeneous ointments.
31. Preparations for vaginal and rectal use, classification and characteristics.
32. Characteristics of suppository bases, their influence on drug bioavailability.
33. Methods of preparing of suppositories.
34. Principles of introduction of aactive ingredients into suppository bases.

35. Calculation of bases for preparing the suppositories by different methods.
36. Solutions for parenteral administration, their classification and characteristics.
37. Pharmacopoeial requirements to parenteral preparations and their implementation in the pharmacies.
38. Features of technology of sodium bicarbonate solutions for parenteral use.
39. Features of technology of glucose solutions for parenteral use.
40. Features of technology of procaine solutions for parenteral use.
41. Features of technology of ascorbic acid solutions for parenteral use.
42. Eye preparations, their classification and characteristics.
43. Requirements to eye drops, thier implementation in pharmacies.
44. Prolongation of drug action in eye drops.
45. Eye semi-solid preparations, bases for the preparations.
46. Features of technology of dosage forms for newborns (dusting powders, liquid preparations for oral and topical use etc.).
47. Features of technology of dosage forms with antibiotics (powders, ointments, suppositories, eye drops etc.).
48. Classification of incompatibilities of drugs.
49. Ways to overcoming of incompatible combinations of drug substances in dosage forms.
50. Difficult prescriptions and ways for overcoming the technological problems.

Industrial technology of medicinal products

1. General statements and definitions in pharmaceutical technology.
2. Dosage forms, requirements, classification.
3. Normative legislative documents for composition of drug products, quality of starting materials and finished products, manufacture, storage conditions and dispensing of drug products.
4. Manufacture of drug products in accordance with GMP rules.
5. Material balance.
6. Characteristics of powders, tablets, capsules, classification, pharmacopoeial requirements.
7. Production methods of tablets and capsules. Quality control, packaging and labeling of solid preparations.
8. Dragee. Granules. Characteristics. Production stages. Nomenclature. Quality control.
9. New solid dosage forms. Classification. Characteristics.
10. Characteristics of liquid preparations as disperse systems, classification, requirements.
11. Solvents, classification, requirements.
12. Water purified as a solvent. Pharmacopoeial requirements, receiving by distillation and non-distillation methods. Water purification equipment, operating mechanism. Quality control, storage conditions and shelf life.
13. Stages in the production of aqueous and non-aqueous solutions.
14. Syrups. Classification. Production methods. Quality control. Nomenclature.
15. Dilution of ethanol to the required concentration. Alcoholometric tables.
16. Manufacturing features of alcoholic solutions. Rectification and recovery of ethanol.
17. Characteristics of suspensions and emulsions. Production methods. Manufacturing equipment. Quality control of heterogeneous liquid preparations.
18. Semi-solid preparations for cutaneous application, classification, requirements.
19. Incorporation of active substances into the ointment bases. Manufacturing equipment for semi-solid preparations.
20. Process flow diagrams for manufacturing of semi-solid preparations. Quality control.
21. Rectal and vaginal preparations, classification and characteristics.
22. Production methods of suppositories. Equipment. Quality control.
23. Preparations that require aseptic manufacturing conditions.

24. Parenteral preparations, classification, requirements and characteristics.
25. Solvents for solutions for injection. Water for injection, receiving methods, storage conditions and quality control in accordance with normative documents.
26. Manufacturing stages of solutions for injection in ampoules.
27. Filtrating methods of solutions for injection; filtration materials and equipment.
28. Methods of sterilization of parenteral preparations.
29. Manufacturing features of solutions for injection that require special methods of purification. Manufacture of solutions for injection with thermolabile substances.
30. Stability of solutions for injection; factors affecting the stability. Stabilization methods of solutions for injection.
31. Manufacture of solutions for injection that require addition of stabilizing agents (novocain, glucose, sodium and caffeine benzoate, ascorbic acid etc.).
32. Manufacturing features of oil solutions for injection. Quality control.
33. Characteristics and classification of eye preparations.
34. Eye drops and eye lotions, requirements and manufacture. Quality control.
35. Characteristics, classification of eye semi-solid and solid preparations, requirements, manufacturing features.
36. Extraction preparations from medicinal plant raw material. Extraction methods. Equipment.
37. Tinctures. Characteristics. Classification. Production methods. Process flow diagrams. Quality control. Nomenclature.
38. Extracts. Extracts concentrates. Characteristics. Classification. Production methods. Process flow diagrams. Quality control. Nomenclature.
39. Neogalenic preparations. Characteristics. Manufacturing features. Quality control.
40. Purification of extraction preparations. Apparatus.

Evaluation criteria for final control of practical training

Final control is carried out in written way. The maximum score that student can receive for the final control is 80 points, the minimum score to pass – 50 points.

RESULTS OF PRACTICAL TRAINING

Summing up the results of practical training is carried out if students submitted the reported documents with evaluation lists.

Student writes final control on the practical training on the last day of practical training at the Department of Drug Technology and Biopharmaceutics.

Supervisor from the Department puts the mark for practical training in credit-and-examination register and student’s credit book.

Reports for practical training are stored for 1 year at the Department.

Results of the practical training are discussed at the meetings of the Department of Drug Technology and Biopharmaceutics, Specialized Methodical Committee of Pharmaceutical Sciences, and Academic Board of the Faculty of Pharmacy.

MARK FOR PRACTICAL SKILLS AND ABILITIES ON THE PRODUCTION PRACTICAL TRAINING ON TECHNOLOGY OF MEDICINAL PRODUCTS IN PHARMACY
of 4th year student of Faculty of Pharmacy

_____

No.	Practical skills and abilities	Mark in points	Sign of supervisor from pharmacy
1.	To use normative, informative and study literature to solve the professional problems		
2.	To check out the appropriateness of prescriptions and determine the compatibility of ingredients. To perform the necessary calculations for checking out single and daily doses of toxic and potent substances and their dispensing norms		
3.	To work with the prescription and hand balances; to weigh dry, viscous substances, and liquids. To dose liquids by measuring devices and calibrate the empirical dropper		
4.	To prepare powders with ingredients with different physical and chemical properties; to use dosing and the other labor-saving tools		
5.	To prepare aqueous solutions by weight to volume method. To use special technological operations for improvement of active ingredients solubility		
6.	To prepare solutions with non-aqueous solvents (ethanol, glycerol, oils), high molecular compounds, and colloids		
7.	To select appropriate stabilizing agents for heterogeneous systems and to prepare suspensions and emulsions		
8.	To prepare aqueous extracts from medicinal plant material and with concentrated extracts		
9.	To prepare semi-solid preparations, rectal, vaginal and urethral suppositories by pouring and rolling methods		
10.	To provide and follow aseptic conditions for preparing sterile products. To prepare concentrated solutions for burette system		
11.	To prepare solutions for injection, eye preparations, preparations with antibiotics and for newborns		
12.	To select packaging material in accordance with type of dosage form and physical and chemical properties of ingredients To prepare drug products for dispensing. To perform organoleptical, question, and writing control of extemporaneous preparations		
	Total sum of points		

MARK FOR PRACTICAL SKILLS AND ABILITIES ON THE PRODUCTION PRACTICAL TRAINING ON INDUSTRIAL TEVCHNOLOGY OF MEDICINAL PRODUCTS
of 4th year student of Faculty of Pharmacy

_____

No.	Practical skills and abilities	Mark in points	Sign of supervisor of practical training
1.	To use normative documents, informative and scientific literature to solve practical tasks		
2.	To make material balance equations, to calculate output, losses and factor of account at different manufacturing stages of drug products in different dosage forms		
3.	To write working prescriptions for manufacturing preparations in different dosage forms with consideration of the factor of account		
4.	To substantiate an optimal technology for solid, liquid, semi-solid preparations and suppositories in accordance with the composition of preparation		
5.	To calculate mass of medicinal plant material and volume of extraction solvent for manufacturing extraction preparations and to substantiate the production method		
6.	To create the process flow diagrams for manufacturing preparations in different dosage forms		
7.	To choose apparatus for manufacturing preparations		
8.	To control quality of finished preparations in accordance with normative standards		
9.	To choose apparatus for testing pharmaco-technological properties of preparations in accordance with pharmacopoeial requirements		
10.	To normalize concentration of solutions		
11.	To be able to use current GMP requirements for production of sterile and aseptically produced drug products		
12.	To select packaging materials and containers for preparations with regard to physical and chemical properties of ingredients and type of dosage form		
	Total sum of points		

SAMPLES OF TITLE PAGES OF THE REPORTS ON PRODUCTION PRACTICAL TRAINING ON TECHNOLOGY OF MEDICINAL PRODUCTS

Title page of the report of production practical training on drug technology in pharmacy

DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY
Department of Drug Technology and Biopharmaceutics

REPORT
on production practical training on technology of medicinal products in pharmacy

Student of _____ group of _____ year of Faculty of Pharmacy
_____
(full name)

Base of practical training
_____
(pharmacy, address)

Period of practical training
from «___» _____ 202 __
to «___» _____ 202 __

Supervisor of practical training from the Pharmacy:
_____
(post, full name)

Supervisor of practical training from the
Department:_____
(post, full name)

Title page of the report of production practical training on industrial technology of drugs

DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY
Department of Drug Technology and Biopharmaceutics

REPORT
on production practical training on industrial technology of medicinal products

Student of _____ group of _____ year of Faculty of Pharmacy
_____
(full name)

Period of practical training
from «___» _____ 202 __
to «___» _____ 202 __

Supervisor of practical training:_____
(post, full name)

RECOMMENDED LITERATURE

REQUIRED

1. Державна Фармакопея України: в 3 т. / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів». – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.; 2015. - Т.1 – 1128; Т.3 – 732 с.
2. Закон України «Про лікарські засоби» № 123/96-ВР від 4.04.96.
3. Наказ МОЗ України №812 від 17.10.2012 р. „Про затвердження Правил виробництва (виготовлення) та контролю якості лікарських засобів в аптеках”.
4. Наказ МОЗ України №44 від 16.03.93 р. «Про організацію зберігання в аптечних установах різних груп лікарських засобів та виробів медичного призначення».
5. Наказ МОЗ України №360 від 19.07.2006 р. “Про затвердження Правил виписування рецептів та вимог-замовлень на лікарські засоби і вироби медичного призначення, порядку відпуску лікарських засобів і виробів медичного призначення з аптек та їх структурних підрозділів, інструкції про порядок зберігання, обліку та знищення рецептурних бланків та вимог замовлень”.
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9. Настанова СТ-Н МОЗУ 42-4.6:2015 «Вимоги до виготовлення стерильних та асептичних лікарських засобів в умовах аптек». – К.: МОЗ України, 2015. – 96 с.
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15. Промислова технологія ліків: базовий підручник/ Є.В. Гладух, О.А.Рубан, І.В.Сайко [та ін.] . – Харків: НФаУ, Оригінал, 2016. - 632 с.
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ADDITIONAL

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Спеціалізоване медичне інтернет-видання для лікарів, провізорів, фармацевтів, студентів медичних та фармацевтичних вузів	www.morion.ua
Фармацевтична енциклопедія	www.pharmencyclopedia.com.ua