

DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY

Department of Drug Technology and Biopharmaceutics

“APPROVED”

Vice-rector on educational
and pedagogical work,
prof. M.R. Gzhegotsky



2021

EDUCATIONAL PROGRAM
of propaedeutic practical training on drug technology in pharmacy
for training specialists of the second (master's) level of higher education
branch of knowledge 22 “Healthcare”
speciality 226 “Pharmacy”
for 1st year students of the Faculty of Pharmacy

Approved
at the meeting of Department of
Drug Technology and Biopharmaceutics
Minutes No. 1

31.08.2021
Head of the Department
[Signature] assoc. prof. S.B. Bilous

Approved
by the Methodological Committee on
Pharmaceutical Disciplines
Minutes No.3

31.08.2021
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2021

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INTRODUCTION

Program of studying of educational discipline

«Propaedeutic practical training on drug technology in pharmacy»

according to Standard of higher education of *second (master's) level*

branch of knowledge 22 "*Healthcare*"

speciality 226 "*Pharmacy*"

educational program of *master of pharmacy*

Description of the educational discipline (annotation)

Propaedeutic practical training on drug technology in pharmacy is an initial stage at forming professional knowledge, skills and abilities of future Master of Pharmacy. Practical training includes familiarization with requirements for sanitary conditions in pharmacy and personal hygiene of personnel, with technological process of preparing drug products, packaging preparations and preparing them for dispensing.

Structure of practical training	Number of weeks	Number of credits, hours	Academic year (semester)	Type of control
Propaedeutic practical training on drug technology in pharmacy	1	1.5 credits, 45 h	I course (2 semester)	Graded credit

Object of propaedeutic practical training is familiarization with basic rules of compounding of drug products in pharmacy conditions.

Interdisciplinary links: propaedeutic practical training on drug technology in pharmacy is an important stage in the preparing Masters of Pharmacy. It integrates with the disciplines, which the first year students study in accordance with educational plan: Latin, ethics and deontology in pharmacy, introductory practical training on management and economics in pharmacy etc.

1. Purpose and objectives of propaedeutic practical training

1.1. Purpose of propaedeutic practical training on drug technology in pharmacy is familiarization with principles of sanitary and anti-epidemic regime in pharmacy and personal hygiene of pharmacy staff, preparatory activities and technological processes of preparing different drug products in pharmacy conditions, packaging of these preparations and preparing for dispensing.

1.2. Primary objectives of propaedeutic practical training on drug technology in pharmacy are familiarization with the statements of current normative documents that regulate conditions and rules for preparing and storage of drug products in pharmacies; learning of technological operations of preparing, packaging and labeling of different dosage forms.

1.3. Competencies and educational outcomes, that discipline provides (correlation with normative content of training of higher education graduates that is formulated in terms of educational results in Standard of Higher Education).

According to the Standard of Higher Education, propaedeutic practical training provides gaining the following competencies:

- *general*:

CG 1. The ability to act in socially and civil responsible manner.

CG 2. The ability to use knowledge in practical situations.

CG 4. The ability for abstract thinking, analysis and synthesis.

CG 6. The knowing and understanding of subject field and the understanding of profession.

CG 8. The ability to communicate in the mother tongue in both spoken and written ways. The ability to communicate in other language.

CG 11. The ability to evaluate and ensure quality of performed work.

- *specific (professional, objective)*:

CS 1. The ability to use knowledge of Ukrainian laws and regulations and the recommendations of good pharmaceutical practices in professional activities.

CS 16. The ability to ensure proper storage of medicinal preparations and medical devices with regard to their physical and chemical properties and Good Storage Practice in healthcare facilities.

Specification of competencies in the form of “Matrix of competencies”.

Matrix of competencies

No.	Competency	Knowledge	Abilities	Communication	Autonomy and responsibility
General competencies					
CG 1.	The 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.	The ability to use knowledge in practical situations	To know techniques for implementation of knowledge to solve practical tasks	To be able to use professional knowledge to solve practical tasks	To establish contacts with subjects of practical activity	To be responsible for immediacy of responses
CG 4.	The ability for abstract thinking, analysis and synthesis	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 the timely acquisition of up-to-date knowledge
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 8.	The ability to communicate in the mother tongue in both spoken and written ways. The ability to communicate	To have advanced knowledge of mother tongue and basic knowledge of foreign knowledge	To be able to use knowledge of mother tongue in both spoken and written ways; to be able to communicate in foreign language	To use mother tongue in professional and business communication, for paperwork. To use foreign language in	To be responsible for fluency in mother tongue and for development of professional knowledge

	in other language			professional activities	
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
Special (professional, objective) competencies					
CS 1.	The ability to use knowledge of Ukrainian laws and regulations and the recommendations of good pharmaceutical practices in professional activities	To know legal and ethical norms of pharmaceutical activity	To use laws and regulations that regulate pharmaceutical activity in Ukraine and abroad	To formulate conclusions and apply laws and regulations in a professional manner	To be responsible for competent and timely application of laws and regulations in professional activities
CS 16.	The ability to ensure good storage of medicinal preparations and medical devices with regard to their physical and chemical properties and Good Storage Practice in healthcare facilities	To know: - classification of preparations and dosage forms; - properties of medicinal substances; - type of packings, sealing and packaging material used in medicine and pharmacy; - general requirements to storage of medicinal preparations in pharmacies; - storage regulations for substances with different physical and chemical properties	To provide appropriate conditions for storage of toxic, narcotic and equivalent to them preparations	To monitor constantly good storage of medicinal preparations and medical devices on the pharmaceutical enterprises	To be responsible for storage of medicinal preparations and medical devices according to Good Storage Practice in healthcare facilities

Integrative final program results of propaedeutic practical training:

- identification of future job as socially important for human health;
- implementation of professional activities based on the laws and regulations of Ukraine and the recommendations of good pharmaceutical practices;
- reasoned making of decisions in standard professional situations;
- formation of basic knowledge and practical skills for further studying of such disciplines as drug technology in pharmacy, industrial technology of drugs, pharmacology, management and economics in pharmacy, pharmaceutical chemistry etc.

Learning outcomes of discipline:

- acquisition of knowledge on Ukrainian laws and regulations that regulate activities of pharmacies; general issues of sanitary and anti-epidemic regime in pharmacies; general requirements to sterile and non-sterile preparations in pharmacies; requirements of GPP.
- acquisition of skills in dosing and packaging of medicinal preparations in pharmacies.

2. Information volume of educational discipline

1.5 credits ECTS, 45 hours are given for studying propaedeutic practical training on drug technology in pharmacy.

3. Structure of educational discipline

Propaedeutic practical training on drug technology in pharmacy is performed in compounding pharmacies and at the Department of Drug Technology and Biopharmaceutics (final control). Changes in the order of performed activities given in the plan of propaedeutic practical training are permitted with the agreement of supervisor of practical training.

Plan of propaedeutic practical training on drug technology in pharmacy

No.	Description of activities	Number of days
1.	Passing the briefing on safety awareness, sanitary measures and pharmaceutical order. General familiarization with production rooms in pharmacy. Sanitary and anti-epidemic regime, pharmaceutical conditions. Production rooms of pharmacy, normative requirements and cleaning. Personal hygiene of personnel. Methods for receiving purified water, its quality control and storage conditions. Pharmacopoeial requirements to purified water	1
2.	Dosing in pharmacy practice. Weight measuring devices that are used in pharmacy practice. Normative requirements for deviations allowed in dispensing of drug preparations	1
3.	General requirements for preparing non-sterile preparations in pharmacy conditions. Dosing and packaging of solid and liquid preparations, semi-solid preparations for cutaneous application, vaginal and rectal suppositories. Pharmacopoeial requirements to compounded preparations	1
4.	General requirements for preparing sterile preparations in pharmacy. Providing of aseptic conditions. Methods of sterilization. Workplace of pharmacist, who compounds intra-pharmacy half products. Nomenclature of intra-pharmacy half products. Labor saving devices for preparing intra-pharmacy half products	1
5.	Modern types of containers and packaging materials for different dosage forms; requirements to pretreatment, washing and drying of pharmacy utensils. Types of labels (basic, additional, preventive) and their selection for dispensing of compounded preparations in accordance with administration	1
	Final control – graded credit	
Total		5 days

4. List of practical skills and abilities that student should get during the propaedeutic practical training, and the evaluation in point grades

No.	Practical skills and abilities	Mark in points
1.	To use normative, informative and study literature for solving professional problems	«5» – 5 points «4» – 4 points «3» – 3 points «2» – 0 points
2.	To characterize structural subdivisions of pharmacy, its production premises	- «» -
3.	To analyze requirements to sanitary conditions of production premises, pretreatment, washing and drying of pharmacy utensils	- «» -
4.	To analyze measures to personal hygiene of personnel	- «» -
5.	To choose methods for receiving purified water, and conditions for its storage and control	- «» -
6.	To choose suitable prescription and hand scales	- «» -
7.	To weigh dry active ingredients and excipients	- «» -
8.	To weigh viscous substances and thick liquids	- «» -
9.	To use dosing devices and other labor saving devices for preparing solid preparations	- «» -
10.	To dose liquid preparations using measuring devices	- «» -
11.	To calibrate empirical droppers	- «» -
12.	To use labor saving devices (e.g., burettes, apparatus for preparing of water extracts etc) for preparing liquid preparations	- «» -
13.	To perform basic technological operations for preparing solid preparations (grinding, mixing, sieving, packaging)	- «» -
14.	To perform basic technological operations for preparing liquid preparations (dissolution, filtration, packaging)	- «» -
15.	To perform basic technological operations for preparing semi-solid preparations and suppositories (melting of ingredients, mixing, packaging)	- «» -
16.	To choose labor saving devices for preparing semi-solid preparations and suppositories	- «» -
17.	To substantiate production conditions for injections, eye preparations and intra-pharmacy half products	- «» -
18.	To perform basic technological operations for preparing solutions for injection and liquid eye preparations (dissolution, filtration, packaging, sterilization)	- «» -
19.	To choose labor saving devices for preparing solutions for injection, liquid eye preparations and intra-pharmacy half products	- «» -
20.	To calculate deviations allowed in dispensing of solid preparations	- «» -
21.	To substantiate appropriate conditions for storage of drug products in pharmacy	- «» -
22.	To select packaging materials and containers in accordance with dosage form and physical and chemical properties of ingredients	- «» -
23.	To select labels (basic, additional, preventive) for dispensing drug products in accordance with administration	- «» -
24.	To prepare drug products for dispensing	- «» -

5. Studying methods. Explanation and illustrative examples, analytical and deductive methods, summarizing, formation of skills and abilities, revision and testing of knowledge are used in the process of propaedeutic practical training.

6. Control methods.

- Control measures include control of *current educational activities* and *final control*.
- According to the educational plan, form of final control is *graded credit*.
- **Mark for propaedeutic practical training on drug technology in pharmacy** consists of sum of points for current educational activity (maximum – 120 points, minimum – 72 points) and sum of points for final control (maximum – 80 points, minimum – 50 points).

Evaluation criteria for practical skills and abilities:

Excellent ("5") – student solved given task in a correct, logical and full manner. Student connects theory with practice, can generalize material, and demonstrates correct performance of practical skills.

Good ("4") – student completed given task correctly, demonstrates practical skills with slight mistakes. Student puts theoretical knowledge to good use for solving the practical tasks, can solve low and medium level tasks, has practical skills and abilities in a scope that does not exceed a required minimum.

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

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

7. Current control of propaedeutic practical training is conducted every day by the immediate supervisor of practical training from pharmacy. It includes evaluation of skills and practical abilities provided by the program.

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

8. Form of final control is graded credit.

Final control is conducted in a written form. The form is standardized and includes tests and situation tasks. 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 current educational activity is 120 points (24x5).

Minimum score that student can gain for current educational activity to be allowed to pass graded credit is 72 points (24x3).

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 propaedeutic practical training on drug technology in pharmacy is calculated as sum of points for current educational activity (not less than 72) and for final control (not less than 50).

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 of students, who study in the same speciality, with consideration of points gained for propaedeutic practical training on drug technology in pharmacy are ranked according to the ECTS scale by the following way:

ECTS mark	Статистичний показник
A	The best 10% of students
B	The following 25% of students
C	The following 30% of students
D	The following 25% of students
E	The last 10% of students

«A», «B», «C», «D», «E» ranking are awarded to students of the same speciality and the same course year, who have successfully completed the study of discipline. Students who have received grades FX, F («2») are not included into the list of ranked students. Students, who have received FX mark, would automatically get “E” mark after repassing.

Points for practical training on drug technology in pharmacy are then converted into the traditional 4-graded scale using absolute criteria shown in Table:

Points for propaedeutic practical training	Mark according to 4-graded scale
170 - 200	5
140 - 169	4
122 - 139	3
less than 122	2

ECTS mark is not converted into the traditional mark, since these scales are independent.

Objectivity of evaluation of students' educational activity is controlled by statistical methods (correlation coefficient between ECTS and traditional-graded marks).

10. Methodical support

Methodical guide for tutors and students – methodical guide for propaedeutic practical training on drug technology in pharmacy that contains general information on the organization of practical training, plan of practical training, list of practical skills and abilities, which student should get in the result of practical training, information on the reporting documents. The example of title page of the report on propaedeutic practical training on drug technology in pharmacy is also given in the methodical guide.

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 all performed types of work, determined by the program of practical training, in the report. Immediate supervisor of practical training from pharmacy should check records in the report every day, and evaluate skills and practical abilities.

The following information must be given in the report:

- structure, floor area and layout plan of premises of pharmacy;

- normative requirements to sanitary and anti-epidemic regime, pharmaceutical conditions, personal hygiene of personnel;
- disposition and equipment of work places in assistant room;
- normative requirements to production rooms of pharmacy and their cleaning;
- methods for receiving purified water, its quality control and storage conditions.

Pharmacopoeial requirements to purified water;

- types and rules of dosing in pharmacy practice; weight measuring devices used in pharmacy practice;
- construction of prescription and hand scales, scale weights;
- allowed deviations in packaging of drug products;
- pharmacopoeial requirements to compounded preparations;
- general requirements for preparing non-sterile preparations in pharmacy conditions;
- dosing and packing of solid and liquid preparations, semi-solid preparations for cutaneous application, vaginal and rectal suppositories;
- general requirements for preparing sterile preparations in pharmacy conditions; providing aseptic conditions, methods of sterilization;
- work place of pharmacist, who compounds intra-pharmacy half products; assortment of intra-pharmacy half products; labor saving tools used for preparing intra-pharmacy half products;
- modern types of containers and packaging materials for different dosage forms; requirements for pretreatment, washing and drying of pharmacy utensils;
- types of labels (basic, additional, preventive) and their choice for dispensing of compounded preparations in accordance with administration.

The report is verified by the sign of supervisor from pharmacy and the pharmacy's stamp.

Student should write the following information on the title page of the report:

DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY

Department of Drug Technology and Biopharmaceutics

REPORT

on propaedeutic practical training on drug technology in pharmacy

Full name of student _____

Faculty: ***pharmaceutical*** Course year 1 Group _____

Base of practical training _____
(name of pharmacy, address)

Period of practical training

from «___» _____ 20 __

to «___» _____ 20 __

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

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

List of skills and practical abilities with marks given by supervisor from pharmacy should be filled on a separate sheet of paper. This list is given to supervisor from the Department together with report.

Supervisor from the Department conducts final control – graded credit, and give mark for practical training.

Questions for final control

1. Requirements to sanitary and anti-epidemic conditions of pharmacy, normative standards.
2. Washing and disinfection products used in pharmacy to provide appropriate sanitary conditions of premises and equipment.
3. Receiving purified water in pharmacy. Equipment.
4. Conditions and time of storage of purified water in pharmacy.
5. Devices for dosing dry, viscous and liquid substances in pharmacy.
6. Types of balances. Prescription and hand scales, construction.
7. Weights. Weighing techniques.
8. Classification of dosage forms.
9. Dosage forms that can be compounded in pharmacy.
10. General technological operations for preparing powders.
11. Packaging material for powders.
12. Types of labels used for drug products compounded by individual prescriptions and for intra-pharmacy half products.
13. General technological operations for preparing liquid preparations.
14. Measuring (volumetric) apparatus and its use for preparing liquid preparations.
15. Materials for filtration of solutions.
16. Labor saving devices for filtering and dosing solutions.
17. Containers and sealing materials for dispensing liquid preparations.
18. Technological operations for preparing semi-solid preparations for cutaneous application.
19. Technological operations for preparing rectal and vaginal suppositories.
20. Production conditions for injections and eye preparations.
21. Aseptics. Aseptic conditions in pharmacy.
22. Sterilization. Methods for sterilization of pharmacy utensils, drug products and other objects.
23. Equipment for sterilization.
24. Containers and sealing materials for eye preparations and solutions for injection.
25. Preparation of compounded drug products for dispensing.

RESULTS OF PRACTICAL TRAINING

Summing up the results of propaedeutic practice on drug technology in pharmacy is carried out if students have submitted the reported documents and written the final control.

Student passes final control on the practical training on drug technology in pharmacy 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 into report, student's credit book and credit-and-examination register.

Report for practical training is 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, Academic Board of the Faculty of Pharmacy.

Points for current educational activity (practical abilities)	Points for final control	Graded credit (sum of points)	Sign of supervisor of practical training from the Department

RECOMMENDED LITERATURE

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», 2016. – Т. 1. - 1128 с., Т. 2. - 724 с., Т. 3. – 732 с.

2. Закон України № 123/96 - ВР від 04.04.96 “Про лікарські засоби”.

3. Наказ МОЗ України № 44 від 16.03.1993 р., “Про затвердження Інструкції по організації зберігання в аптечних установах різних груп лікарських засобів та виробів медичного призначення”.

4. Наказ МОЗ України № 275 від 15.05.2006 р. “Про затвердження Інструкції із санітарно-протиепідемічного режиму аптечних закладів”.

5. Наказ МОЗ України № 812 від 17.10.2012 р. „Про затвердження Правил виробництва (виготовлення) та контролю якості лікарських засобів в аптеках”.

6. Наказ МОЗ України № 500 від 20.07.2006 р. “Про затвердження Переліків назв лікарських форм та упаковок для лікарських засобів”.

7. Постанова КМ України № 906 від 04.10.2010 р. „Про затвердження форми паспорта аптечного закладу (структурного підрозділу)”.

8. Фармацевтичне законодавство (Нормативні акти з організації роботи аптечних підприємств) // Під редакцією проф. Т.А.Грошового. – Тернопіль: Укрмедкнига, 2012. – 569с.

Information sources

Верховна Рада України

www.rada.gov.ua

Міністерство охорони здоров'я України

www.moz.gov.ua

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Фармацевтична енциклопедія

www.pharmencyclopedia.com.ua