

Danylo Halytsky Lviv National Medical University
Department of Drug Technology and Biopharmaceutics



METHODICAL GUIDE

*to propaedeutic practical training on drug technology in pharmacy
for 1st year students of Faculty of Pharmacy
of second (master's) degree of higher education
field of study 22 "Health care"
speciality 226 "Pharmacy"*

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SCOPE OF PROPAEDEUTIC PRACTICAL TRAINING ON DRUG TECHNOLOGY IN PHARMACY

Propaedeutic practical training on drug technology in pharmacy is initial stage of forming professional knowledge, skills and abilities of future Master of Pharmacy.

According to the curriculum of academic program, students conduct propaedeutic practical training on drug technology in pharmacy on the first academic year, semester 2.

Duration of propaedeutic practical training is 1 week (5 work days, 6 hours per day).

Structure of practical training on drug technology in pharmacy

Number of weeks	Number of credits, hours	Academic year (semester)	Type of control
1	1.5 credits, 45 h	I course (semester 2)	Graded credit

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

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

Primary objectives of practical training are:

- acquaintance with statements of current normative documents that regulate conditions and rules of preparing and storing drug products in pharmacies;
- learning technological operations of preparing, packaging and labeling different dosage forms.

Students conduct practical training in compounding pharmacies and at the Department of Drug Technology and Biopharmaceutics (final control).

Supervision of practical training is performed by an appropriate pharmacist and tutors from the Department of Drug Technology and Biopharmaceutics.

Responsibilities of supervisors:

- to ensure that all necessary measures are taken to organize proper conducting practical training;
- to provide instructions on structure and schedule of practical training;
- to provide supervision and control of practical training and reporting documents, and to evaluate student's performance in practical training.

Responsibilities of student:

- to get referral to pharmacy and other required materials for undergoing practical training (schedule, report, guides etc.) before the beginning of practical training;
- to be aware of schedule of practical training, description and scope of activities;
- to act in accordance with the rules of internal code of conduct of pharmacy, and safety rules as well;
- to carry out tasks determined by the plan of practical training in a timely and full manner;
- to prepare a report on practical training;
- to submit practical training reporting documents timely.

During practical training students have to learn the structure of pharmacy, disposition and equipment of work places in the assistant room; statutory requirements to sanitary and anti-epidemic regulations in pharmacy, pharmaceutical conditions, personal hygiene of personnel; methods for receiving purified water; rules and methods of dosing in pharmacy practice; weight measuring devices; general requirements to compounding drug products in pharmacy; types of packaging material and containers for different dosage forms; types of labels for dispensing drug products.

**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 acquaintance 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 drug products	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 aseptic conditions. Methods of sterilization. Workplace of pharmacist, who compounds intra-pharmacy half products. Nomenclature of intra-pharmacy half products. Tools and equipment 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

REPORTING DOCUMENTS ON PROPAEDEUTIC PRACTICAL TRAINING ON DRUG TECHNOLOGY IN PHARMACY

Report on practical training is the 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.

Examples of the title page and the second page of report are given in Appendices 1 and 2.

The following information must be provided in the report:

- structure, floor area and layout plan of premises of pharmacy;
- normative requirements to sanitary and anti-epidemic regulations, 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 of 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 drug products;
- pharmacopoeial requirements to compounded preparations;
- general requirements for preparing non-sterile preparations in pharmacy conditions;
- dosing and packing 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; tools and equipment for preparing intra-pharmacy half products;
- modern types of containers and packaging materials for different dosage forms; requirements for pretreatment, washing and drying pharmacy utensils;
- types of labels (basic, additional, preventive) and their choice for dispensing of compounded preparations in accordance with administration.

Appointed supervisor of practical training from pharmacy should check records in the report every day, and evaluate skills and practical abilities.

List of skills and practical abilities with marks should be filled on a separate sheet of paper in accordance with example given in Appendix 3. This list is given to supervisor from the Department together with report.

In addition, supervisor from pharmacy provides the **reference** and **student's performance evaluation** during the practical training in the end of report.

EVALUATION OF PROPAEDEUTIC PRACTICAL TRAINING ON DRUG TECHNOLOGY IN PHARMACY

The score for propaedeutic practical training on drug technology in pharmacy is calculated as sum of points for current educational activity and for final control. Supervisor from the Department puts this mark into report, student's credit book and credit-and-examination register.

CURRENT CONTROL OF PROPAEDEUTIC PRACTICAL TRAINING ON DRUG TECHNOLOGY IN PHARMACY

Current control of practical training is conducted every day by supervisor from pharmacy by evaluating skills and practical abilities determined by program of practical training.

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

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).

*FINAL CONTROL OF PROPAEDEUTIC PRACTICAL TRAINING
ON DRUG TECHNOLOGY IN PHARMACY*

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.

Final control is conducted in a written standardized form, and it includes tests and situational tasks.

To write final control are allowed students, who acquired required practical abilities, provided reported documents and scored for current educational activity with not less than 72 points.

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.

Points, which student received for final control, are added into report and signed by supervisor from the Department.

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

Points for propaedeutic practical training	Traditional mark
170 - 200	5
140 - 169	4
122 - 139	3
less than 122	2

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.

INFORMATION SOURCES

1. European Pharmacopoeia. 8th edition., 2014.
2. Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services. Available from https://www.fip.org/www/uploads/database_file.php?id=331&table_id=.
3. Langley C.A., Belcher D. Pharmaceutical Compounding and Dispensing. London-Chicago: Pharmaceutical Press, 2008.
4. Shayne Cox Gad. Pharmaceutical Manufacturing Handbook. Production and Processes. Hoboken: John Wiley & Sons, Inc., 2008.
5. Tikhonov A.I., Yarnykh T.G., Yuryeva A.B., Garkavtseva O.A. Chemist's Technology of Drugs: The manual for students of higher schools / Edited by A.I. Tikhonov and T.G. Yarnykh. Kharkiv: NUPh; Original, 2011.

Title page of report

**MINISTRY OF HEALTH OF UKRAINE
Danylo Halytsky Lviv National Medical University**

Department: Drug Technology and Biopharmaceutics

Head of the Department: associate professor S.B. Bilous

REPORT

on propaedeutic practical training on drug technology in pharmacy

Full name of student _____

Faculty: pharmaceutical Course year 1 Group _____

Place of practical training _____

Lviv-20____

Second page of report

Student _____
(full name)

undergoes propaedeutic practical training on drug technology in pharmacy on the
base _____
(name of pharmacy)

in _____
(city, region)

Period of practical training: from _____._____ to _____._____ 20__.

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

Supervisor of practical training from the Pharmacy _____

(post, full name)

Student arrived « __ » _____ 20__ left « __ » _____ 20__

Sign of responsible person _____

Place stamp here

**EVALUATION OF STUDENT'S WORK
DURING THE PRACTICAL TRAINING**

(full name of student)

No.	Practical skills and abilities	Date	Mark	Sign
1.	To use normative, informative and study literature for solving professional problems			
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			
	Total points			