



**MINISTRY OF HEALTH OF UKRAINE
NATIONAL PHARMACEUTICAL UNIVERSITY
Department pharmaceutical technology of drugs**

WORK PLACEMENT IN PHARMACY BASED TECHNOLOGY OF DRUGS
(name of educational component)

**EDUCATIONAL WORK PROGRAM
of educational component**

training for second master's level
(name of higher education level)

in specialty 226 Pharmacy, industrial pharmacy
(code and specialty name)

field of knowledge 22 Public Health
(code and name of field of knowledge)

of educational program Pharmacy (for foreign students)
(name of educational program)

in specialization(s) _____
(name of specialization, if available)

2023 year
year of creation

CONSIDERED AND APPROVED: NATIONAL UNIVERSITY OF
PHARMACY

Developers:

Lilia VYSHNEVSKA, head of the department of pharmaceutical technology
of drugs, Doctor of Pharmacy, professor

Maryna BURYAK, Ph.D., associate professor of a higher education
institution of the pharmaceutical technology of drugs department, Ph.D.,

Svitlana OLIINYK, Ph.D., associate professor of a higher education
institution of the pharmaceutical technology of drugs department, Ph.D.

(indicate SURNAME, name of authors, their positions, scientific degrees and scientific titles)

Work program has been considered and approved at the Department meeting
Pharmaceutical Technology of Drugs

Minutes dated "_ 1_" of September 2023 No. 1

Head of the department

Pharmaceutical Technology of Drugs _____  prof. Lilia VYSHNEVSKA

Work program has been approved at the meeting of the Methodical Commission of
technological disciplines

Record from of September 1, 2023 No. 1

Head of the specialized commission



prof. Olena RUBAN

INTRODUCTION

The educational component study program "Work placement in Pharmacy based Technology of Drugs" is compiled in accordance with the Standard of Higher Education of Ukraine (hereinafter - the Standard) / Educational (educational-professional, educational-scientific) program second (master's) level fields of knowledge 22 Public Health

In specialty 226 Pharmacy, industrial pharmacy

educational program "Pharmacy"

Description of the educational component (abstract) Educational component program "Work placement in Pharmacy based Technology of Drugs" was compiled for specialty 226 Pharmacy in accordance with the Standard of Higher Education of Ukraine and the working curriculum of Master of Pharmacy training. The educational component " Work placement in Pharmacy based Technology of Drugs " deepens and consolidates the knowledge of higher education students regarding the principles of regulatory documentation and production technologies of pharmacy drugs in the form of various dosage forms in accordance with the requirements of proper pharmacy and production practices.

The subject of educational component study of compulsory educational component «Work placement in Pharmacy based Technology of Drugs» is the main provisions and trends in the development of pharmaceutical technology in the countries of the world and in Ukraine; assimilation of modern principles of regulatory documentation and technologies for the production of medicinal products in various dosage forms with the use of new groups of excipients and modern types of equipment in pharmacy conditions.

Interdisciplinary connections. The educational component is based on the study of biophysics, general and inorganic chemistry, organic chemistry, physical and colloidal chemistry, biology with the basics of genetics, pharmaceutical botany, pharmaceutical drug technology, industrial drugs technology.

1. Purpose and tasks educational component

1.1. The purpose of the educational component «Work placement in Pharmacy based Technology of Drugs» is to consolidate, deepen and expand theoretical knowledge of the pharmaceutical technology of drugs and practical skills in the preparation of solid, liquid, soft, injection, extraction extemporaneous drugs and in-pharmacy preparations , their packaging, labeling and storage taking into account the requirements of good pharmacy practice (GMP); and also acquire skills in performing technological stages (dissolving, grinding, mixing, suspending, emulsifying, dosing, packaging, etc.); implementation of continuous in-pharmacy control; procedure for maintaining production documentation, drawing up technological instructions; use of means of small mechanization, which are necessary to solve specific tasks in the future practical activity of a pharmacist.

1.2. The main tasks of the educational component «Work placement in Pharmacy based Technology of Drugs» are: deepening of knowledge regarding the technology of various medicinal forms (solid, liquid, soft) based on the theoretical provisions of the technology of medicinal preparations, knowledge of properties, medicinal and auxiliary substances; study of the modern range and physical and chemical properties of medicinal products; assimilation of the requirements of current regulatory documents (GPP and current orders) for the organization of production activities of pharmacies for the manufacture of medicinal products in various dosage forms; use in professional activity of regulatory and legislative acts, requirements of good pharmacy practice (GPP) for the manufacture of medicinal products in pharmacies; formation of higher education candidates' knowledge of the theoretical foundations of technology and practical skills necessary for the manufacture of various types of dosage forms, conducting step-by-step control, ways of improving the technology of dosage forms in the conditions of pharmacies; studying the influence of storage conditions and the type of packaging on the stability of dosage forms.

1.3. Competencies and planned learning outcomes, the formation of which is facilitated by the educational component (relationship with the normative content of the training of higher education applicants, formulated in terms of learning outcomes in the Standard).

According to the requirements of the standard, the educational component ensures the acquisition of higher education

competencies :

integral:

the ability to solve typical and complex specialized tasks and practical problems in professional pharmaceutical activity with the application of provisions, theories and methods of fundamental, chemical, technological, biomedical and socio-economic sciences; integrate knowledge and solve complex issues, formulate judgments based on insufficient or limited information; clearly and unambiguously convey their conclusions and knowledge, rationally justifying them, to a professional and non-specialist audience.

general:

GC 6. Knowledge and understanding of the subject area and understanding of professional activity.

GC 11. Ability to assess and ensure the quality of performed work.

special (professional):

PC 14. The ability to organize and carry out the production activities of pharmacies for the manufacture of medicinal products in various dosage forms according to the prescriptions of doctors and orders of medical institutions, including the justification of technology and the selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).

Integrative final program learning outcomes (PLO), the formation of which is facilitated by the educational component:

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

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

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

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

PLO12. To analyze the information obtained as a result of scientific research, summarize, systematize and use it in professional activities.

PLO 26. To choose rational technology, to make medicines in various dosage forms according to the prescriptions of doctors and orders of medical institutions, to issue them before release. To perform technological operations: weigh, measure, dose a variety of medications by weight, volume, etc. To develop and draw up technological documentation for the manufacture of medicines in pharmacies.

In result the student of higher education must study the educational component

to know :

- modern requirements of regulatory documentation regulating the technology and quality control of extemporaneous medicinal products in Ukraine and abroad;
- characterization and classification of dosage forms as dispersed systems ;
- theoretical foundations of technology various medicinal forms;
- rules of rational technology of solid, liquid, soft, sterile and aseptic medicinal forms;
- the influence of the physicochemical properties of medicinal substances on the technology of extemporaneous solid, liquid, soft, sterile and aseptic dosage forms,

- assortment and characteristics of excipients used in the technology of extemporaneous medicinal products;
- assortment and principles of using modern means of small mechanization ;
- quality control medicinal forms;
- stability of extemporaneous medicinal products (types, factors influencing the stability of medicinal products);
- types and tasks of documentation when preparing medicines in pharmacies.

be able:

- to work with normative documentation that regulates the prescription, preparation and release of extemporal medicine and intra-pharmacy product, scientific and reference literature;
- to be oriented in the classification of medicinal products by application, aggregate state, dispersal characteristics;
- select auxiliary substances depending on the properties of medicinal substances and justify the need for their introduction;
- calculate the amount of active and auxiliary substances;
- choose equipment for the production of extemporal medicine and intra-pharmacy product;
- choose and substantiate the optimal technology for the preparation of various medicinal forms, taking into account the physicochemical properties of medicinal substances;
- carry out preparation, packaging, labeling of non-sterile and sterile extemporal medicine in various medicinal forms;
- use the means of small mechanization and the equipment available in the pharmacy;
- select taro packaging material taking into account the properties of the ingredients and the purpose of the medicinal product;
- to select labels for labeling extemporal medicine and prepare drugs for release;
- to draw up technological instructions for the preparation of intra-pharmacy product;
- observe the basic rules of safety and pharmaceutical regime in the pharmacy;
- observe the necessary storage conditions of prepared extemporal medicine and intra-pharmacy product.

2. Information content of the educational component

4.5 ECTS credits 135 hours are allocated to the study of the educational component.

Content module 1. Practical implementation of the main provisions of the pharmacy technology of drugs

Topic 1. Getting to know the premises and equipment of the pharmacy. Analysis of requirements of good pharmacy practice for premises and equipment of the pharmacy.

Availability and location of production premises in the pharmacy. Equipping workplaces with the necessary furniture and equipment. Means of small mechanization. Instruction on safety techniques and pharmaceutical procedure in the pharmacy. Normative base regulating the sanitary regime and pharmaceutical order in the pharmacy.

Topic 2. Normative documents regulating the production activity of the pharmacy. Work with prescriptions for extemporaneous medicinal products.

Ensuring the requirements of proper pharmacy practice in the production activity of the pharmacy; regulatory documents regulating the preparation, packaging, labeling and storage of medical devices in the pharmacy. Documentation of the production process of pharmacies (general and technological instructions, production records). Checking the correctness of prescriptions (requirements), compatibility of prescription ingredients.

Topic 3. Preparation of non-sterile and sterile extemporaneous medicinal products:

- preparation of solid extemporaneous medicines;
- preparation of liquid extemporaneous medicines;
- preparation of mild extemporaneous medicines;
- preparation of extemporaneous medicines in aseptic conditions.

Justification of the method of introduction of medicinal substances with different physicochemical properties into the composition of various forms of extemporal medicine. Nomenclature of solvents and auxiliary substances used in the pharmacy in the preparation of solid, liquid, soft extemporal medicine. Selection of taro-packaging materials. Determination of the sequence of the technological process of various forms of extemporal medicine.

- Preparation of solid extemporal medicine. Calculations of the amount of active and auxiliary substances. Techniques for performing technological operations (shredding, mixing, dosing, packaging, etc.).

- Preparation of liquid extemporal medicine. Performing technological operations (dissolving, filtering, emulsifying, dispersing, mixing, extraction, etc.). Preparation of homogeneous and heterogeneous liquid medicines (aqueous and non-aqueous solutions, drops, solutions of standard pharmacopoeial liquids, high-molecular compounds and protected colloids, suspensions, emulsions, aqueous extracts). Difficult cases of preparation of solutions.

- Preparation of soft extemporal medicine. Performing technological operations (dissolving, emulsifying, dispersing, mixing, dosing, etc.). Preparation of liniments and ointments of various dispersion systems, suppositories by rolling, pouring and pressing methods.

- Preparation of extemporal medicine in aseptic conditions. Ensuring aseptic conditions for the preparation of extemporal medicine. Sequence of technological operations (dissolving, filtering, sterilization, etc.). Selection of auxiliary substances and calculations of their quantity for stabilization and isotonization of solutions. Preparation, filtering and sterilization of solutions for injections, eye drops, preparation of eye ointments and drugs with antibiotics.

Topic 4. Preparation of internal pharmacy preparations, packaging, repackaging. Technological documentation of the production department of the pharmacy.

Normative documents regulating the conditions of preparation of intra-pharmacy products, packaging, repackaging of medicinal products. Rules for cooking intra-pharmacy products, nomenclature, calculations, technology. Conditions and terms of storage of intra-pharmacy products in a pharmacy, the main signs of their instability. Post-stage in-pharmacy quality control of extemporal medicine (written, survey, organoleptic, physical, control upon discharge). General and technological instructions, production records (log of registration of laboratory and packaging works, log of registration of individual stages of production of injection, intravenous infusion and ophthalmic drugs, log of registration of sterilization of drugs, auxiliary materials, dishes, etc.).

Topic 5. Packaging, labeling and storage conditions of medicines. Stability of prepared extemporaneous medicines.

The influence of taro packaging materials on the stability of prepared medicines. Rules of labeling of extemporal medicine. Conditions and terms of storage of extemporal medicine. The main signs of instability of various forms of extemporal medicine.

Semester credit from module 1 - grade credit

Computer testing on practically oriented questions about the technology of drugs according to the prescriptions described by the student of higher education during practice. Checking reporting documentation (practice journal, workbook and report).

3. Form of semester control of success teaching (semester grade credit)

Semester control: in the form of a differentiated semester credit after the completion of Work placement in Pharmacy, during the first week of theoretical training. Completion of computer testing – 40 tests (maximum 40 points).

It is carried out in the amount of educational material determined by the educational program and

in the terms established by the educational plan.

4. Methodological support

1. Educational work program.
2. Algorithm of passing Work placement.
3. Methodical recommendations of Work placement.
4. Video films.
5. Workbook for preparation to the licensed examination “KROK-2” in pharmacy-based technology of drugs: for English-speaking applicants of higher education of specialty “Pharmacy”: Practical aids. For individual work / T. G. Yarnykh, O. A. Rukhmakova, V. V. Kovalyov, M. V. Buryak – Kh.: NUPh, 2017. – 56 p.
6. Tests. Pharmacy-based technology of drugs: A handbook for the out-of-classwork of English applicants/ T. G. Yarnykh, O. I. Tykhonov, O. A. Rukhmakova, G. B. Yuryeva, M. V. Buryak, V.V.; ed. by T.G. Yarnykh. – Kh.: NUPh, 2019. – 156 p.
7. Resource for preparing for the test at the link:
<https://tests.nuph.edu.ua/course/view.php?id=209>.

6. Recommended Books

The main reading suggestions

1. Pharmacy — based technology of drugs : the manual for applicants of higher education / O. I. Tykhonov , T. G. Yarnykh, O. A. Rukhmakova, G. B. Yuryeva; ed. by O. I. Tykhonov and T. G. Yarnykh. - Kharkiv : NUPh : Golden Pages, 2019. - 488 p.
2. Workbook for Pharmacy-based Technology of Drugs: A tutorial for the 3-rd year English-speaking applicants of higher education of “Pharmacy” specialty / T. G. Yarnykh, O. I. Tykhonov, O. A. Rukhmakova, M. V. Buryak, V. V. Kovalyov, I. V. Herasymova – Kh.: NUPh, 2020. – 149 p.
3. Workbook for preparation to the licensed examination “KROK-2” in pharmacy-based technology of drugs: for English-speaking applicants of higher education of specialty “Pharmacy”: Practical aids. For individual work / T. G. Yarnykh, O. A. Rukhmakova, V. V. Kovalyov, M. V. Buryak – Kh.: NUPh, 2017. – 56 p.
4. Tests. Pharmacy-based technology of drugs: A handbook for the out-of-classwork of English applicants/ T. G. Yarnykh, O. I. Tykhonov, O. A. Rukhmakova, G. B. Yuryeva, M. V. Buryak, V.V.; ed. by T.G. Yarnykh. – Kh.: NUPh, 2019. – 156 p.
5. Handbook to Laboratory Classes in Pharmacy-based Technology of Drugs : for English applicants of higher education of "Pharmacy" speciality / Yarnykh T. G., Rukhmakova O. A., Yuryeva A. B., ed. by T.G. Yarnykh. – Kh.: NUPh, 2021. – 156 p.

Supplementary reading suggestions

1. Державна Фармакопея України / ДП «Український науковий фармакопейний центр якості лікарських засобів». 2-ге вид. Харків : ДП «Український науковий фармакопейний центр якості лікарських засобів», 2015. Т. 1. 1128 с.
2. Державна Фармакопея України / ДП «Український науковий фармакопейний центр якості лікарських засобів». 2-ге вид. Харків : ДП «Український науковий фармакопейний центр якості лікарських засобів», 2014. Т. 2. 724 с.
3. Державна Фармакопея України / ДП «Український науковий фармакопейний центр якості лікарських засобів». 2-ге вид. Харків : ДП «Український науковий фармакопейний центр якості лікарських засобів», 2015. Т. 3. 732 с.
4. Про затвердження правил виробництва (виготовлення) лікарських засобів в умовах аптеки : наказ МОЗ України від 17.10.12 р. № 812. Офіційний вісник України. 2012. № 87. 28 с.
5. Стандарт МОЗ України «Вимоги до виготовлення нестерильних лікарських ЗАСОБІВ в

- умовиях аптек» СТ-Н МОЗУ 42 - 4.5 до: 2015 // За ред. проф. О. І. Тихонова и проф. Т.Г. Ярних. - Київ, 2015. - 109 с. (Затверджено наказом МОЗ України № 398 від 01.07.2015 р.).
6. Стандарт МОЗ України «Вимоги до виготовлення стерильних и асептичних лікарських ЗАСОБІВ в умовах аптек» СТ-Н МОЗУ 42 - 4.6 до: 2015 // За ред. проф. О.І. Тихонова и проф. Т.Г. Ярних. - Київ, 2015. - 76 с. (Затверджено наказом МОЗ України № 398 від 01.07.2015 р.).
7. John F Marriott, Keith A Wilson, Christopher A Langleyv, Dawn Belcher Pharmaceutical Compounding and Dispensing. - Published by the Pharmaceutical Press. – 2010. – 288 p.
8. USP Pharmacists' Pharmacopeia. – II ed. – Rockville. The United State Pharmacopeial, Inc., 2008. – 1519 p.
9. <https://pharmel.kharkiv.edu/moodle/course/view.php?id=1094>

12. Electronic resources, including the Internet

1. Ministry of Health of Ukraine [Electronic resource]: official website. - Access mode: www.moz.gov.ua - (date of application 09/26/18).
2. National Pharmaceutical University [Electronic resource]: Scientific library of the National Pharmaceutical University. – Access mode: <http://lib.nuph.edu.ua> (access date 09/26/18).
3. National Pharmaceutical University. Department of Medicine Technology [Electronic resource]: website of the Department of Medicine Technology. – Access mode: <http://tl.nuph.edu.ua> (date of application 09/26/18).
4. Electronic archive of the library of the National Academy of Sciences of Ukraine. <http://lib.nuph.edu.ua>; e- mail library@nuph.edu.ua
5. Educational portal <http://pharmel.kharkiv.edu> - the center of distance technologies of the National Academy of Sciences