## Syllabus of the educational component Pharmaceutical Drug Technology

for applicants for higher education of \_2023-2024\_\_\_\_year of study \_\_\_\_\_ form of education second (master's level) of higher education of educational program «\_Pharmacy\_» (Educational Program Name) in specialty «<u>226 Pharmacy, industrial pharmacy</u>» (Code and Specialty Name) field of knowledge «<u>22 Healthcare</u>\_\_\_» (Code and Knowledge Field Name)

training for <u>second (master's level) of higher education</u> (Higher Educational Level Name)

# TEACHERS



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**1. Name of higher education institution and department:** National University of Pharmacy, Department of Pharmaceutical Technology of Medicines.

2. Address department : Kharkiv, street Valentynyvska, 4, 4th floor, tel. 0572-67-91-84.

- 3. Website of the department: <u>http://atl.nuph.edu.ua/</u>
- 4. Information about teachers:

## Levachkova Yulia Valentynivna

Doctor of Pharmaceutical Sciences, Professor of the Drug Technology Department of the National University of Pharmacy. Experience of scientific activity –15 years, experience of scientific and pedagogical activity – 14 years. Reads courses: "Pharmaceutical Drug Technology", "Biopharmacy", "Modeling of scientific research". Research interests: drug technology.

## Semczenko Kateryna Valentynivna

Doctor of Pharmaceutical Sciences, Associate Professor, 10 years of teaching experience.

She teaches the disciplines "Technology of pharmaceutical drugs", "Biopharmacy", "Homeopathy".

Research interests: conducting research in the field of "Development of composition, technology and biopharmaceutical research of drugs based on natural and synthetic raw materials".

Buryak Maryna Valeriivna

PhD (Pharmaceutical Sciences), Associate Professor of the Drug Technology Department of the National University of Pharmacy. Experience of scientific and pedagogical activity – 14 years. Reads courses: "Pharmaceutical Drug Technology", "Pharmacy-based Technology of Drugs", "Biopharmacy", "Modeling of scientific research". Research interests: drug technology.

#### Kovalov Volodymyr Viktorovich

PhD (Pharmaceutical Sciences), Associate Professor of a higher education institution of the Drug Technology Department of the National University of Pharmacy. Experience of scientific activity – 15 years, experience of scientific and pedagogical activity – 11 years. Reads courses: "Pharmacy-based Technology of Drugs",

"Biopharmacy", "Methodology and methods of scientific research", "Methodology and methods of scientific analysis", "Modeling of scientific research". Research interests: drug technology.

## Konovalenko Ilona Sergiivna

Candidate of Pharmaceutical Sciences (PhD), assistant.

Experience of scientific and pedagogical work 6 years.

Conducts classes in the following disciplines: "Pharmacy drug technology", "Pharmacy drug technology", "Fundamentals of pharmaceutical homeopathy", "Biopharmacy".

Scientific interests: development of composition and technology of extemporaneous drugs for non-

hormonal therapy of climacteric syndrome, development and research of homeopathic medicines.

**5.** Consultations take place every day from 10:00 a.m. to 5:00 p.m. by the teacher on duty according to the schedule in online mode..

**6. Annotation of the educational component:** the educational component "Pharmaceutical drug technology" is compulsory for the second (master's) level in the specialty "226 Pharmacy, industrial pharmacy". Final control - semester exam.

7. **The purpose of the educational component:** assimilation by students of higher education of the theoretical foundations and practical abilities and skills of the manufacture of medicinal products in the conditions of pharmacies.

## 8. Competencies according to the educational program:

## Soft-skills / General competences:

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

GC 11. Ability to evaluate and ensure the quality of performed works.

## Hard-skills / Professional (special) competences (PC):

PC 14. The ability to organize and carry out the production activities of pharmacies regarding 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).

#### 9. Program learning outcomes :

PLO2. Apply knowledge of general and professional disciplines in professional activities

PLO3. To comply with the standards of sanitary and hygienic regime and requirements of safety equipment when carrying out professional activities.

PLO4. 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.

PLO26. Choose a rational technology, manufacture medicinal products in different dosage forms according to the prescriptions of doctors and orders of medical institutions, issue them to vacation Perform technological operations: weigh, measure, dose various medicinal products by weight, volume, etc. Develop and draw up technological documentation for the production of medicinal products in pharmacies.

# **10. Status of the educational component:** compulsory

11. Prerequisites of the educational component: the educational component is based on the study of biophysics

with physical methods of analysis, general, inorganic and organic chemistry, physical and colloidal chemistry, biology with the basics of genetics, pharmaceutical botany and is integrated with the technology of industrial production drugs.

**12. Volume of the educational component** : 9,0 credits EKTC: 270 hours of classroom classes, include - 16 hours of lectures and 123 hours - laboratory classes, 131 hours of independent work.

# **13. Organization of training:**

**Teaching format of the educational component:** The format of teaching the educational component: conducting lectures, laboratory classes, consultations for better assimilation of the educational material.

Content of the educational component:			
Module 1. General questions of drug technology. Solid and	Materials of the		
liquid dosage forms.	educational and		
	methodological complex		
Content module 1. General questions of drug technology.	http://atl.nuph.edu.ua/		
Powders. Species.	<u>p</u>		
<b>Topic 1.</b> General questions of drug technology. State control over the production of	https://pharmel.kharkiv.e		
drugs.	du/moodle/course/view.p		
Topic 2. Preparation of simple and complex powders with drugs, different in	hp?id=2697		
prescribed quantity, bulk weight and structure of the particles in pharmacy			
conditions.			
Topic. 3. Preparation of complex powders with poisonous and strong-effective			
substances. Triturations.			
Topic 4. Preparation of complex powders with dyeing, aromatic and poorly			
powdered substances.			
<b>Topic 5.</b> Preparation of complex powders with extracts and semi-finished products.			
Topic 6. Preparation of species in pharmacies.			
<b>Topic 7.</b> Module control CM 1 on the topic "General questions of drug technology.			
Powders. Species".			
Content module 2. Liquid dosage forms.			
Topic 8. Preparation of concentrated solutions.			
Topic 9. Preparation of liquid dosage forms by mass-volume method by dissolution			
of dry medicinal substances and use of concentrated solutions.			
Topic 10. Special cases of preparation aqueous solutions. Drops.			
Topic 11. Preparation of liquid dosage forms by diluting of the standard			
pharmacopoeian liquids. Non-aqueous solutions.			
Topic 12. Solutions of HMC. Colloidal solutions.			
Topic 13. Suspensions.			
Topic 14. Emulsions.			
Topic 15. Infusions and decoctions of medicinal plant raw material.			
Topic 16. Infusions and decoctions from extracts concentrates. Mucilages.			
Topic 17. Module control of CM 2 on the topic "Liquid dosage forms".			
Module 2. Soft dosage forms. Suppositories. Medicinal forms requiring aseptic			
preparation conditions			
Content module 3. Soft dosage forms. Suppositories.			
Topic 18. Liniments and homogeneous ointments.			
<b>Topic 19.</b> Ointments suspension and ointment-emulsion.			
Topic 20. Combined ointments. Creams. Gels.			
<b>Topic 21.</b> Preparation of suppositories by rolling method.			
<b>Topic 22.</b> Preparation of suppositories by casting method.			
Topic 23. Module control CM 3 on the topic «Soft dosage forms and			
suppositories».			
Content module 4. Dosage forms required aseptic conditions of preparation.			
Topic 24. Requirements for the preparation of sterile and aseptic medicines in			
pharmacy conditions.			
Topic 25. Solutions for injections.			
<b>Topic 26.</b> Solutions for injections required stabilization.			
Topic 27. Isotonic and infusion solutions. Solutions for injections with			

thermolabile substances. Suspensions for injection.
<b>Topic 28.</b> Ophthalmic dosage forms. Dosage forms with antibiotics.
Topic 29. Medicinal forms for infants and children under 1 year of age.
Radiopharmaceuticals. Geriatric drugs.
Topic 30. Difficult cases of medicines preparation. Incompatibilities.
Topic 31. Module control CM 4 on the topic «Dosage forms required aseptic
conditions of preparation»
Semester credit of module 2.
Semester exam

# 14. Types and forms of control:

*Current control:* oral survey, production of a medicinal product according to an individual prescription, compilation of test tasks, solution of situational (calculation) problems.

*Control of content modules:* compilation of test tasks, production of a medicinal product according to an individual prescription, solution of situational (calculation) problems.

*Semester exam:* 60 test problems of theoretical orientation, 1 situational problem and a calculation problem. *Semester control form:* semester credit, semester exam.

*Conditions for admission to the control of content modules:* for admission to the control of a certain content module, it is necessary to score a minimum number of points for the relevant topics.

Conditions for admission to the semester control: current rating of 60 or more points, absence

of missed laboratory and practical classes, fulfillment of all requirements stipulated by the work program of the educational component.

# **15. Evaluation system for the educational component:**

## The evaluation system for the educational component:

The results of the semester control in the form of a semester credit are evaluated on a 100-point, undifferentiated scale ("passed", "failed") and on the ECTS scale. The results of semester control in the form of a semester exam are evaluated according to the ECTS scale, a 100-point scale and a four-point scale ("excellent", "good", "satisfactory", "less than arbitrary"). *Points from education components are calculated according to the following ratio :* 

Kinds assessment	Maximum quantity points			
	(% of quantity points for the module - for			
	content modules )			
Module 1	,			
Content module 1: Solid dosage forms	40 ( 40 %)			
- assessment of topics (1-7) (work in classes 1-6): (oral				
examination, preparation of test tasks, solution of situational				
(calculation) tasks);				
- control of content module 1 (compilation of test tasks, solution of				
situational (calculation) tasks)				
Content module 2: Liquid dosage forms	60 ( 60 %)			
- assessment of topics (8-17) (work in classes 6-16): (oral				
examination, preparation of test tasks, solution of situational				
(calculation) tasks);				
- control of content module 2 (compilation of test tasks, solution of				
situational (calculation) tasks)				
Semester control of the module	100			
Module 2				
Content module 3 Soft dosage forms. Suppositories	50 ( 50 %)			
- assessment of topics (18-23) (work in classes (18-22): (oral				
survey, preparation of test tasks, solution of situational				
(calculation) problems);				
- control of content module 3 (composition of test tasks, solution of				
situational problems) (calculation) problems				

Content module 4 Medicinal forms requiring aseptic	50 ( 50 %)
manufacturing conditions Incompatibilities	
- assessment of topics (24-31) (work in classes (24-30): (oral	
survey, writing test problems, solving situational (calculation)	
problems );	
- control of content module 4 (compilation of test tasks, solution of	
situational (calculation)	
problems	
Semester control of the module	100

Evaluation criteria for each type of control (current, control of content modules, semester, examination) are published at the link http://atl.nuph.edu.ua/

The self-study of students of higher education is evaluated during the current control and during the control of the content module

## **16.** Policies of the educational component:

Academic Integrity Policy. It is based on the principles of academic integrity stated in the POL "On measures to prevent cases of academic plagiarism at the National University of Ukraine". Writing off when evaluating the success of a student of higher education during control measures in practical and seminar classes, control of content modules is prohibited (including using mobile devices ). The detection of signs of academic dishonesty in the student's written work is a reason for the teacher not to enroll it.

*Policy regarding class attendance*. A student of higher education is obliged to attend classes (POL "On the organization of the educational process of the National Academy of Sciences of Ukraine") according to the schedule (https://nuph.edu.ua/roGClad-zanyat/), to observe ethical norms of behavior.

*Policy regarding deadlines , working out, rating increase, liquidation of academic debt.* The completion of missed classes by a student of higher education is carried out in accordance with the POL "Regulations on the completion of missed classes by students and the procedure for eliminating academic differences in the curricula of the National Academy of Sciences" in accordance with the schedule for making up missed classes established by the department . Increasing the rating and liquidating academic debt from the educational component is carried out by the students in accordance with the procedure specified in the POL "On the procedure for evaluating the results of training of students of higher education at the National Academy of Sciences". Applicants of higher education are obliged to comply with all deadlines set by the department for the completion of written works from the educational component. Works that are submitted late without valid reasons are assessed at a lower grade - up to 20% of the maximum number of points for this type of work.

*Policy on appeals of assessment from the educational component (appeals).* Applicants of higher education have the right to contest (appeal) the evaluation of the educational component obtained during control measures. The appeal is carried out in accordance with the POL "Regulations on appealing the results of the semester control of the knowledge of students of higher education at the National Academy of Sciences".

## 17. Information and educational and methodological support of the discipline:

Main	1.	Pharmacy — based technology of drugs : the manual for applicants of higher education /
literature		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.

Additional literature for	1. Державна Фармакопея України / ДП «Український науковий	
in- depth study of the	фармакопейний центр якості лікарських засобів». 2-ге вид. Харків :	
educational component	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 :	
	ЛП «Український науковий фармакопейний центр якості лікарських	
	засобів», 2014. Т. 2. 724 с.	
	3. Лержавна Фармакопея України / ЛП «Український науковий	
	фармакопейний центр якості лікарських засобів». 2-ге вил. Харків :	
	ПП «Український науковий фармакопейний центр якості лікарських	
	засобів» 2015 Т 3 732 с	
	4 Про затверлження правил виробництва (виготовлення) лікарських	
	засобів в умовах аптеки · наказ МОЗ України від 17.10.12 р. № 812	
	Офіційний вісник Vкраїни 2012 $\mathbb{N}$ 87 28 с	
	5 Стандарт МОЗ України «Вимоги до виготовлення нестерильних	
	nikanci kiy 3ACOEIB B vonobugy anteky CT_H MO3V 42 - 4.5 no: 2015	
	// За ред проф О I Тихонова и проф Т Г Ярних - Київ 2015 - 109 с	
	(Затверичено наказом MO3 Vknajini № 398 pin 01 07 2015 p.)	
	$(3a_{15}c_{12}d_{15}c_{12}d_{15}c_$	
	о. Стандарт моз экраїни «Вимоги до виготовлення стерильних и	
	$A \in \mathbb{R}^{2}$ 2015 // 20 род проф. О.І. Тихоноро и проф. Т.Г. Прину. Киїр	
	4.0 do. 2015 // Sa ped. npow. O.1. Tuxohosa u npow. 1.1. Aphux Kuis,	
	2013 70 с. (затверджено наказом №ОЗ у країни лº 398 від 01.07.2013	
	p.). 7 John E Marriett Keith A Wilson Christenbar A Landow Deve Beleher	
	7. John F Marriott, Keith A Wilson, Christopher A Langleyv, Dawn Beicher	
	Pharmaceutical Compounding and Dispensing Published by the	
	Pharmaceutical Press. – 2010. – 288 p.	
	8. USP Pharmacists' Pharmacopeia. – II ed. – Rockville. The United State	
	Pharmacopeial, Inc., $2008 1519 \text{ p.}$	
	9. <u>https://pharmel.kharkiv.edu/moodle/course/view.php?id=1094</u>	
Current electronic	1. Ministry of Health of Ukraine [Electronic resource]: official website Access	
information resources	mode: www.moz.gov.ua - (date of application 09/26/18).	
(magazines, websites, etc.	2. National Pharmaceutical University [Electronic resource]: Scientific library of	
) for in-depth study of	the National Pharmaceutical University. – Access mode: http://lib.huph.edu.ua	
the educational	(access date $09/26/18$ ).	
component	5. National Pharmaceutical University. Department of Medicine Technology	
	[Electronic resource]: website of the Department of Medicine Technology. –	
	Access mode: http://inupn.edu.ua (date of application 09/20/18).	
	4. Electronic archive of the library of the National Academy of Sciences of	
	Ukraine. http://iio.nupn.edu.ua; e- mail <u>library@nupn.edu.ua</u>	
	5. Educational portal http://pharmel.kharkiv.edu - the center of distance	
	technologies of the National Academy of Sciences	
Moodle distance learning	https://pharmel.kharkiv.edu/moodle/course/view.php?id=2697	
system		

**18. Technical and software provision of educational components:** laboratories are equipped with pharmacy furniture, equipment and devices for dosing and manufacturing pharmaceuticals (turntables for medicinal and auxiliary liquids, burette units, capsule machines, universal thermal cabinet ED-53 - 3 units, magnetic stirrers (BINDER, Germany) - 2 units, homogenizers Salent Crusher M (Heidolph instruments Gmbh&Co. KG) and Daihan Homogenizer with Direct Controller HG-15A (Daihan Scientific, Korea), laminar cabinet Streamline SCR-2A1, electronic scales AXIS BTU-2100, electronic scales TBE - 3 units, pH meter "pH-305" and pH-150 MI, Granum R40 microscope (R40003) with Granum DCM 310 digital video camera, rotary evaporator, sterile filtration unit, LabAnakyt DM 0412 clinical centrifuge, sterilizer ΓΠ-40 – 1 unit, distiller DE-10, device PTS 3E for determining the solubility of suppositories (PHARMA TEST, Germany), measuring cup PTSW 0 for determining the solubility of suppositories (PHARMA TEST, Germany), colorimeter medical, laboratory and auxiliary dishes, packaging materials, medicinal and auxiliary substances, LRS. Means of communication, Internet access, interactive whiteboard, computers - 57 units, printers - 15 units, scanner - 1 unit, Misubishi EX-10 multimedia projectors - 3 units.