SYLLABUS OF THE EDUCATIONAL COMPONENT

Biopharmacy

for students of higher education

educational program "Pharmacy"

(name of educational program)

educational program "226 Pharmacy, industrial pharmacy"

(code, name of the specialty)

fields of knowledge "22 Health care"

(code, name of field of knowledge)

Master's level of higher education

(name of level of higher rducation)

TEACHERS

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1. **Name of institution of higher education and department:** National university of Pharmacy, Department of Pharmaceutical Technology of Drugs.
2. **Address:** Kharkiv, St. Valentinivska, 4, 4th floor, t. 0572-67-91-84 .
3. **Website:** http://atl.nuph.edu.ua/

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", "Biopharmaceutics", "Modeling of scientific research".

Brief information: drug technology.

5. Consultations: take place every Friday from 10:00 a.m. to 3:00 p.m. by the teacher on duty according to the schedule in online mode.

6. **Abstract of educational components:** «Biopharmaceutics» is to acquire higher education students theoretical and practical bases of biopharmacy for the scientific substantiation of the composition and technology of new drugs and improve existing using modern up-to-date substances, new technologies, by improving their effectiveness and efficiency.

7. The purpose of teaching of the educational component: the educational discipline "Biopharmaceutics" is an optional discipline for the second (master's) level in the specialty 226

Pharmacy, industrial pharmacy, educational program “Pharmacy”. The form of control is a semester assessment.

8. Competences in accordance with educational programs

GC 2. Ability to apply knowledge in practical situations, make informed decisions.

GC 4. Ability to think abstractly, analyze and synthesize, learn and be modernly trained.

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

GC 9. Skills in using information and communication technologies.

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

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

PC 2. The ability to consult on prescription and non-prescription drugs and other products of the pharmacy range; pharmaceutical care during the selection and sale of an over-the-counter medicinal product by evaluating the risk/benefit ratio, compatibility, indications and contraindications guided by data on the health status of a specific patient, taking into account the biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical features of the medicinal product and other products of the pharmacy assortment .

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).

PC 15. The ability to organize and participate in the production of medicinal products in the conditions of pharmaceutical enterprises, including the selection and justification of the technological process, equipment in accordance with the requirements of Good Manufacturing Practice (GMP) with the appropriate development and preparation of the necessary documentation. Determine the stability of medicines.

9. Program learning outcomes (PLO):

To comply with the standards of sanitary and hygienic regime and requirements of safety equipment when 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.

PLO 5. To position your professional activities and personal qualities in the pharmaceutical labor market; to formulate the purposes of own activity taking into account public and industrial interests.

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

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.

PLO 27. To justify 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.

10. Status of the educational component: *selective*

11. Prerequisites of the educational component: the discipline is based on the study of biophysics with physical methods of analysis, drug technology of pharmacy production, factory drug technology, pharmacology, pharmacotherapy.

12. Scope of the educational component:

for full-time higher education, 3 ECTS credits: 90 hours of classroom classes, of which 6 hours of lectures, 24 hours of practical classes, 60 hours of independent work

13. Organization of training:

Teaching format of the educational component: conducting lectures, practical classes, consultations for better assimilation of educational material

Content of the educational component: Content module 1. Biopharmaceutics as the theoretical basis of drug technology

Topic 1. Basic concepts and terms of biopharmaceutics. The current state and prospects of the development of biopharmaceutics. The influence of the nature of excipients on the therapeutic effectiveness of drugs

Basic concepts and terms of biopharmaceutics. The current state of biopharmaceutical development abroad and in Ukraine. Biopharmaceutics as a scientific direction and its importance in the development of the composition and technology of dosage forms. The main tasks and directions of biopharmaceutical research at the current stage and their significance for practical health care. Modern requirements for the evaluation of the quality of medicinal products. The works of foreign and domestic scientists that contributed to the emergence and further development of biopharmaceutics.

The nature of excipients and their quantity – ointment and suppository bases, the presence of absorption accelerators (various surfactants), melting point or ability to dissolve, adhesive substances, loosening agents, etc. The interaction of medicinal and excipients, the principle of selection of excipients. Types of chemical bonds that occur between active substances and excipients. The duality of the role of excipients. Factors affecting the rate of absorption of substances.

Topic 2. Influence of pharmaceutical factors on the therapeutic effectiveness of drugs. The influence of the degree of API grinding on the therapeutic efficacy of drugs

Characteristics of pharmaceutical factors – type of dosage form and route of its administration, physico-chemical properties of drugs and auxiliary substances, technological process and used equipment.

The physical state of medicinal substances in medicinal preparations (dispersity, aggregate state, crystallinity, solubility, viscosity, pH value, surface tension, degree of purity) and their influence on the release and absorption of medicinal substances. The use of different degrees of grinding in the development of drugs with different bioavailability. Dispersity, crystal structure and polymorphic forms of medicinal substances. Dependence of the therapeutic activity of drugs on the use of anhydrous forms or crystal hydrates of medicinal substances.

The influence of packaging and storage conditions on the stability of medicinal products. Methods of determining the stability of medicinal products.

Graphical method of calculating the area under the pharmacokinetic curve. Determination of the maximum concentration of medicinal substances, absorption constant and elimination constant.

Using the “in vitro” method of direct diffusion through a semipermeable membrane to establish the bioavailability of ointments.

Topic 3. Pharmaco-technological methods of assessing the release of API from drugs. The influence of the type of dosage form and the route of administration on the therapeutic efficacy of drugs.

Ways of introducing medicinal substances into the body. Characteristics of enteral and parenteral routes of drug administration, advantages and disadvantages. Rational selection of the type of dosage form (tablets, ointments, suppositories, injection solutions, etc.). The effect of the type of dosage form on the process of absorption of medicinal substances into the blood.

Topic 4. Influence of exo- and endogenous factors on the bioavailability of drugs. The effect of a simple chemical modification of API on the therapeutic efficacy of drugs.

Microbiological, acanthous and radioisotope methods of biopharmaceutical research. Simple chemical modification - salts, ethers, acids and bases ("in vivo" methods). Interaction of food and medicines, time of taking medicines (before meals, during or after meals, etc.). Factors of the internal environment of the human body affecting the bioavailability of active pharmaceutical ingredients. The effect of body temperature on the bioavailability of drugs. The influence of magnetic field and meteorological conditions on the bioavailability of medicinal products.

Topic 5. Bioequivalence, its role in the evaluation of the quality of medicinal products. Bioavailability and methods of its determination. The influence of technological factors on the speed of API release and on the stability of drugs.

The concept of bioequivalence, pharmacodynamics and pharmacokinetics of drugs and their relationship with variable pharmaceutical factors. Calculations of pharmacokinetic parameters. Modern nomenclature of brands and generics on the domestic pharmaceutical market. Replacement of drugs

with analogues.

Bioavailability, its types and definitions. Study of bioavailability during the development of new drugs, for control of existing and comparative evaluation of drugs manufactured by different enterprises. Modern modified types of dosage forms.

14. Types and forms of control:

Current control: oral survey, control of practical skills, preparation of test tasks, solution of situational (calculation) problems.

Control of content modules: test tasks of a theoretical focus, 1 theoretical question and a situational task.

Semester control form: semester assessment

Conditions for admission to the control of content modules: For admission to the control of content module 1, it is necessary to have a minimum number of points for the topics (lessons) of content module 1.

Conditions for admission to the semester control: current rating of more than 60 points, availability of the minimum number of points for the control of content module 1, absence of unworked passes of 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, non-differentiated scale (“passed”, “failed”) and on the ECTS scale.

Points from the educational component are calculated according to the following ratio:

Types of assessment	The maximum number of points (% of the number of points for the module - for content modules)
Module 1	
Content module 1: ... - assessment of topics 1-5 (work in classes 1-8): work in classes (oral survey, writing test tasks, solving situational (calculation) problems); - - control of content module 1 (writing test tasks, solving situational (calculation) problems)	*100 (100 %)*
Semester control from module 1	*100 (100 %)*

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

The independent work 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 classes, control of content modules and semester credit (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.

Class attendance policy. 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/rozklad-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 timetable 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:

Mandatory literature	1. Біофармація : підруч. для студ. вищ. фармац. навч. закл. і фармац. ф-тів вищ. медич. навч. закл. IV рівня акредитації / О. І. Тихонов, Т. Г. Ярних, І. А. Зупанець, Л. І. Вишневська, О. С. Шпичак, Н. П. Половко, О. С. Данькевич, О. Є. Богуцька, Н. В. Бездітко, Ю. М. Азаренко, Ю. В. Левачкова, Т. М. Зубченко; За ред. О. І. Тихонова, 2-ге вид., перероб. і допов. – Х. : НФаУ : Золоті сторінки, 2019. – 256 с. 2. Практикум з біофармації : навчальний посібник для здобувачів вищої освіти / О. І. Тихонов, Т. Г. Ярних, Л. І. Вишневська, О. Є. Богуцька, О. С. Данькевич, О. М. Котенко, Половко Н. П. — 2-ге вид., перероб. та допов. – [Електронний ресурс]. – Харків : НФаУ, 2023. – 104 с. – Назва з екрана.
Additional literature for in-depth study of the educational component	1. Богуцька О. Є., Вишневська Л. І. Вплив їжі на фармакотерапевтичну активність лікарських засобів // Збірник наукових праць співробітників НМАПО ім. П. Л. Шупика. – Київ, 2018. – Вип. 32. – С. 70–80. 2. Богуцька О. Є., Вишневська Л. І. Проблемні питання хрономедицини і хронотерапії та шляхи їх подолання // Сучасні досягнення фармацевтичної технології та біотехнології : зб. наук. пр. – Харків : НФаУ, 2017. – Вип. 3. – С. 38–40. 3. Буткевич, Т. А. Вивчення впливу допоміжних речовин на фармако-технологічні властивості таблеток сухого порошку біомаси Flammulina velutipes / Т. А. Буткевич, М. Л. Сятиня, В. П. Попович // Фармацевтичний часопис. – 2017. – № 3. – С. 11–14. 4. Гуреєва С. М., Альбедхані О. С., Грошовий Т. А. Застосування біофармацевтичної системи класифікації у розробці нових лікарських препаратів // Актуальні питання фармацевтичної та медичної науки та практики. – 2015. – № 3. – С. 38–43. 5. Лікарські засоби. Дослідження біоеквівалентності, що затверджена Наказом МОЗ України від 02 листопада 2018 року № 2014 : настанова СТ-Н МОЗУ 42-7.2:2018 / МОЗ України. – Київ, 2018. – 80 с. 6. Лікарські засоби. Належна виробнича практика : настанова СТ-Н МОЗУ 42-4.0:2016 / МОЗ України; Державна служба України з ЛЗ. – Київ : Моріон, 2016. – 335 с. 7. Промислова технологія лікарських засобів : баз. підруч. для фармац.

	ВНЗ (фармац. ф-тів) IV рівня акредитації / Є. В. Гладух [та ін.] ; НФаУ. – Харків : НФаУ : Оригі- нал, 2016. – 632 с. 8. Про лікарські засоби: Закон України №123/96-ВР від 4.04.1996 (зі змінами та доп.) [Електронний ресурс]. – Режим доступу: http://zakon5.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80. 9. Тихонов, О. І. Аптечна технологія ліків : підруч. для студентів фармац. ф-тів ВМНЗ України III-IV рівнів акредитації / О. І. Тихонов, Т. Г. Ярних ; за ред. О. І. Тихонова. – 4-те вид., випр. та допов. – Вінниця : Нова Книга, 2016. – 536 с. 10.Фармацевтична опіка : посібник / І. А. Зупанець, В. П. Черних, С. Б. Попов та ін. ; під ред. І. А. Зупанця та В. П. Черних. – Х. : ТОВ «Фармацевт Практик» . – 2016. – 208 с. 11.Definition and Classification of Generic Drugs Across the World / R. Alfonso-Cristancho, T. Andia, T. Barbosa, J. H. Watanabe // Applied Health Economics and Health Policy. – 2015. – Vol. 13, Suppl 1. – P. 5–11. 12.European Pharmacopoeia / European Directorate for the Quality of Medicines (EDQM). – Council of Europe. – 9-th ed. – Strasbourg, 2016. – 4016 p. 13.Good pharmacopoeial practices :15th Rep / WHO Expert Committee on specifications for pharmaceutical preparations: Fiftieth report (WHO Technical Report Series; No. 996), Annex 1. – Geneva : World Health Organization, 2016. – P. 67. 14.Skelly, J. P. A History of Biopharmaceutics in the Food and Drug Administration 1968–1993 / J. P. Skelly // AAPS J. – 2010. – Vol. 12, № 3. – P. 44–50. 15.The International Pharmacopoeia. – 7th Edition, 2017 [Electronic resource]. – Access mode: http://apps.who.int/phint/2017/index.html#p/home (Date of access: 28.02.2020). – The name from the screen. 16.USP 41 – NF 36. – The United States Pharmacopeia and National Formulary 2018 / United States Pharmacopoeial Convention, 2017. – 8200 p.
Current electronic information resources (magazines, sites, etc.) for in-depth studying the educational component	1. Офіційний сайт Державного експертного центру Міністерства охорони здоров'я України [Електронний ресурс]. - Режим доступу: https://dec.gov.ua 2. Сайт кафедри аптечної технології ліків НФаУ – http://atl.nuph.edu.ua 3. Бібліотека НФаУ: e-mail library@nuph.edu.ua 4. Сайт дистанційного навчання НФаУ – http://pharmel.kharkiv.edu 5. .Електронний архів НФаУ – http://dspace.nuph.edu.ua
Moodle distance learning system	*https://pharmel.kharkiv.edu/moodle/login/index.php*

18. Technical and software support of the educational component: the 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, scales electronic 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, GP sterilizer -40 – 1 unit, DE-10 distiller, PTS 3E device for determining the solubility of suppositories (PHARMA TEST, Germany), cell PTSW 0 for determining the solubility of suppositories (PHARMA TEST, Germany), colorimeter medical, laboratory and auxiliary utensils, taro-capping 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.