SYLLABUS OF THE EDUCATIONAL COMPONENT
Industrial Technology of Drugs
(the name of the educational component)

for applicants for higher education of 4 year of study full-time form of education (term of study 4 years 10 months)
of educational program «_Pharmacy_»
(Educational Program Name)
in specialty «226 Pharmacy, industrial pharmacy»
(Code and Specialty Name)
field of knowledge «22 Public Health»
(Code and Knowledge Field Name)

training for _master
(Higher Educational Level Name)

TEACHERS

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1. **The name of higher education establishment and department: the National University of Pharmacy, Department of Technology of pharmaceutical preparations.**
2. **Address of the department: Kharkiv, st. Valentinovskaya, 4; 2th floor.**
3. **Web site of the department: https://tfp.nuph.edu.ua/**
4. **Information about teachers:**

Antonina SICHKAR Associate Professor of the Department of Technology of Pharmaceutical Preparations. Has experience of teaching work over 23 years At the department she teaches the disciplines "Industrial technology of Drugs", "Industrial technology of pharmaceuticals", "Industrial technology of synthetic substances" and others. Author and co-author of 150 scientific papers including articles and thesis in Ukrainian and foreign editions.

Dmytro SOLDATOV Associate Professor of the Department of Technology of Pharmaceutical Preparations. Has experience of teaching work over 11 years, including reading lectures and conducting practical, laboratorial classes in the disciplines of Industrial technology of Drugs, Theoretical bases of pharmaceutical technology. Author and co-author of 64 scientific papers including articles and thesis in Ukrainian and foreign editions.

Denis PULIAIEV Associate Professor of the Department of Technology of Pharmaceutical Preparations. Scientific research: dedicated to the creation of combined hard and soft dosage forms based on a combination of herbal and synthetic components. Scientific achievements: 79 scientific works (52 scientific publications, 23 of them in specialized publications, 4 - Scopus, 4 - patents, 1 - information sheet), 17 - training manuals, 7 - methodical recommendations.

5. **Consultations:** on Monday at 16.30 up to 17.00 (Dmytro SOLDATOV)
6. **Brief summary of the educational component:** the educational component "Industrial Technology of Drugs" is a compulsory discipline for the second (master's) level in the specialty 226 Pharmacy, educational program "Pharmacy". Final control - credit, exam - grade.
7. **The purpose statement of studying the educational component:** The purpose of teaching the educational component "Industrial Technology of Drugs" is consolidation of theoretical and practical knowledge on industrial technology of drugs production, acquaintance with batch production of medicines; acquisition of practical skills in the manufacture of finished dosage forms with the stages of development and preparation of reference and technical documentation for the production of finished products, Quality Control of drugs, equipment used in dosage forms production.
8. **Competences in accordance with the educational program:**

Soft- skills / General competences (*GC*):

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

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

PC 15. Ability to organize and participate in the production of medications in the context of pharmaceutical companies, 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 design of the necessary documentation. Determine the stability of medications

PC 18. Ability to develop and implement a quality management system for pharmaceutical companies in accordance with the requirements of current Standards, perform quality audits and risk management for the quality of pharmaceutical products.

9. The program learning outcomes: (PLO):

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.

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 27. To substantiate the technology and organize the production of medicines at pharmaceutical enterprises and draw up technological documentation for the production of medicines at pharmaceutical enterprises.

10. Status of the educational component: *compulsory*

11. Prerequisites of the educational component: *"Pharmacognosy", "Pharmacy drug technology", "Physical and colloidal chemistry", "Medical and pharmaceutical commodity science"*

12. The volume of the educational component: 8 ECTS credits correspond to 240 hours of study, including 120 hours of classroom instruction, comprising 26 hours of lectures and 94 hours of laboratory work, as well as 120 hours of independent study

13. Organization of training:

The format of teaching the educational component

Content of the educational component:

Content module 1. Regulatory and technical documentation and production according to GMP. Material balance at the stages of the technological process. Alcoholometry. Production of extraction preparations.

Topic 1. Regulatory and technical documentation in the production of drugs. Packaging and labeling of pharmaceuticals according to GMP. The main activity of the Ministry of Health of Ukraine. Regulatory documents in Ukraine. Basic principles of the registration system. Registration file. Production protocols, validation forms and maps. Pharmaceutical development.

Topic 2. Alcohol measurement. Determination of concentration, dilution and accounting of alcohol use. Methods of ethanol production (from raw materials containing starch, carbohydrates, synthetically). Methods of obtaining absolute ethanol. Basic chemical and physicochemical properties of ethyl alcohol. Determination of concentration, dilution and accounting of alcohol use.

Topic 3. The main indicators of the material balance. Grinding, sifting, mixing. Preparation of powders and collections. The main methods of crushing solid bodies. The degree of crushing of solids. Classification of solid bodies according to the degree of grinding. The influence of the size of particles of solid bodies on the quality of medicinal products. Sifting and mixing of powdered materials.

Topic 4. Industrial production of tinctures. Intensification of extraction processes. Scheme of production, equipment. Description of the technological process. Standardization of tinctures. Theoretical foundations of the extraction process. Recovery of extractants from spent raw materials

Topic 5. Production of extraction preparations. Industrial production of liquid extracts. Methods of intensification of obtaining extracts from plant raw materials. Scheme of production, equipment. Description of the technological process. Standardization of extracts, packaging and storage conditions. Quality control according to SPhU Modern trends in the production of medicines based on biotechnology. . Preparations of biogenic stimulants. Preparations from fresh plants. Medicines from animal raw materials

Topic 6. Production of thick and dry extracts. Methods of purification of thick and dry extracts. Scheme of production, equipment. Description of the technological process. Standardization of extracts, packaging and storage conditions. Problems and tasks of the production of phytochemical preparations and prospects for their development. Concentrated extracts, oil extracts.

Content module 2. Industrial production of dosage forms and sterile drugs for parenteral and ophthalmic use

Topic 7. Basic principles of good manufacturing practice of medicinal products (GMP), requirements for the production of sterile products. Classification of clean rooms, cleanliness classes. The characteristics of injection solutions in ampoules, the requirements of the DFU for them.

Topic 8. Glass for making ampoules and vials, classes, brands. Basic requirements and quality indicators of ampoule glass. Preparation of ampoules for filling.

Topic 9. Industrial production of solutions for injections. Methods of production of injection solutions and methods of filling ampoules. Method of sealing ampoules and determination of tightness. Sterilization of injection solutions, control of their sterility. Quality control of injection solutions, production scheme. The problem of complex mechanization and automation of ampoule production.

Topic 10. Features of the production of solutions for injections that require stabilization. Peculiarities of manufacturing solutions for injections using non-aqueous solvents.

Solutions for injections, which are produced in aseptic conditions. Block diagram of production. Description of the technological process. Equipment. Standardization.

Topic 11. Production of infusion solutions. Eye medicines. Classification and requirements for infusion solutions. Prospects for the development of infusion solutions, an assortment of domestic and foreign medicines. Structure of ophthalmic dosage forms. Physico-chemical and biological features of creation, prolongation. The main characteristics of dosage forms for ophthalmology, production methods, equipment, quality control, production schemes of ophthalmic preparations.

Topic 12. Control of independent work. Industrial production of nasal and ear medicines. Characteristics, classification, features of production and application. Excipients, types of packaging.

Content module 3. Physico-chemical and pharmaco-technological properties of powders, granules. Production of tablets by the method of direct pressing and with preliminary granulation. Production of coated tablets. Production of medical capsules.

Topic 13. Physico-chemical and technological properties of powders and granules. Study of physico-chemical and pharmaco-technological properties of powders and granules. Influence of the properties of excipients on the technology of obtaining solid dosage forms.

Topic 14. Industrial production of tablets. Industrial production of tablets using preliminary granulation and direct pressing. Granulation methods. Excipients in the production of tablets. Block diagram of production, equipment.

Topic 15. Covering tablets with a shell. Types of coating and methods of application. Production of long-acting tablets, excipients. Block diagram of the production of coated tablets, equipment.

Topic 16. Production of medical capsules. Definition of capsules as drugs, SPhU requirements for capsules. Types of capsules and their purpose. Auxiliary substances in the production of capsules. Methods of manufacturing soft and hard gelatin capsules, filling them with medicinal substances. Tubatyn Rectal gelatin capsules.

Topic 17. Quality control of solid dosage forms. Quality control of finished products in accordance with the requirements of the SPhU.

Content module 4. Production of soft medicines. Ointment Gels. Liniments. Industrial production of suppositories. Medicines under pressure.

Topic 18. Production of soft medicines. Ointment Gels. Liniments. Ointments, pastes, creams, liniments as a medicinal form. Requirements for ointments, classification of bases and general requirements. Excipients in the production of soft dosage forms. Quality assessment, packaging and labeling. Advantages and disadvantages gels Block diagrams of the production of soft dosage forms, equipment. Quality control according to SPhU.

Topic 19. Industrial production of suppositories. Mustard seeds. Plasters. Skin adhesives. The influence of excipients on the quality of soft drugs. Transdermal therapeutic systems. Suppositories, types and requirements for them. Characteristics of bases and auxiliary substances. Manufacturing methods. Block diagram of production, equipment, product quality control in accordance with the SPhU.

Topic 20. Production of medicinal products under pressure. Classification of aerosols, advantages and disadvantages. The main components of aerosol packages, types of valve-spraying system, classification of propellants. Production of aerosols, equipment, quality control according to the SPhU.

Topic 21. Industrial production of non-sterile dosage forms. Pharmaceutical solutions. Syrups. Aromatic waters. Characteristic. Classification. Methods of their preparation and cleaning. Apparatus. Radiopharmaceuticals. The main directions of development of the technology of medicinal forms.

Semester credit from the module

Semester exam

14. Forms and types of academic achievements supervision:

Forms and types of academic achievements supervision

Progress supervision: is monitored in laboratory and seminar classes in accordance with specific goals and during individual work of the teacher with students. The following means of determining the assimilation of educational material by students are used: test tasks, control works, solving situational problems, conducting educational research with interpretation and evaluation of their results, control of practical skills, drawing up a technological scheme for obtaining a given drug, etc. At each class, tasks are checked and logs of practical work are received.

Supervision of content modules: The following means of determining the assimilation of educational material by students are used: test tasks, control works, solving situational problems, drawing up a technological scheme for obtaining a given drug.

Semester exam: types of tests are listed answers to theoretical questions, writing test tasks, solving situational (calculation) problems.

Semester control form: semester credit, semester exam.

Conditions for admission to the supervision of content modules: For example, for admission to the supervision of content modules, it is necessary to have a minimum number of points for the topics (classes) – 30.

Conditions for admission to semester supervision: a current rating of more than 60 points, absence of missed laboratory, practical and seminar classes, fulfillment of all requirements stipulated in the work program of the educational component.

15. Evaluation system of the educational component:

Evaluation system of the educational component: *the results of the semester supervision in the form of a semester credit are evaluated on a 100-point, non-differentiated scale ("passed", "failed") and on the ECTS scale.*

The results of semester supervision 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", "unsatisfactory")

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

Types of evaluation	Maximum number of points (% of the number of points per module - for content modules)
Module 1	
Content module 1: Regulatory and technical documentation and production according to GMP. Material balance at the stages of the technological process. Alcoholometry. Production of extraction preparations. *- evaluation of topics (1-6) (work in classes 1-6): work in classes (oral survey, writing test tasks, solving situational (calculation) problems);* *- supervision of content module 1 (writing test tasks, solving situational (calculation) tasks)*	*50 (50 %)*
Content module 2: Industrial production of dosage forms and sterile drugs for parenteral and ophthalmic use *- evaluation of topics (7-12) (work in classes 7-12): work in classes (oral survey, writing test tasks, solving situational (calculation) problems);* *- supervision of content module 2 (writing test tasks, solving situational (calculation) tasks)*	*50 (50 %)*
Module 2	
Content module 3: Physico-chemical and pharmaco-technological properties of powders, granules. Production of tablets by the method of direct pressing and with preliminary granulation. Production of coated tablets. Production of medical capsules. *- evaluation of topics (13-17) (work in classes 13-17): work in classes (oral survey, writing test tasks, solving situational (calculation) problems);* *- supervision of content module 2 (writing test tasks, solving situational (calculation) tasks)*	*50 (50 %)*
Content module 4: Production of soft medicines. Ointment Gels. Liniments. Industrial production of suppositories. Medicines under pressure. *- evaluation of topics (18-21) (work in classes 18-21): work in classes (oral survey, writing test tasks, solving situational (calculation) problems);* *- supervision of content module 2 (writing test tasks, solving situational (calculation) tasks)*	*50 (50 %)*
Semester Supervision of Module 1,2	100

The individual work of applicants for higher education is evaluated during the progress supervision and during the content module supervision

16. Academic 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 Pharmacy". Cheating during the evaluation of an applicant for higher education during supervision activities in practical (seminar, laboratory) classes, supervision of content modules and the semester exam is prohibited (including the use of mobile devices). Abstracts must have correct text references to the used literature. The detection of signs of academic dishonesty in the student's written work is a reason for the teacher not to credit it.

Class attendance policy. An applicant for higher education is obliged to attend classes (POL "On the organization of the educational process of the National University of Pharmacy ") 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 debts. The completion of missed classes by an applicant for higher education is carried out in accordance with the POL "Regulations on the completion of missed classes by applicants and the procedure for eliminating academic differences in the curricula of the National University of Pharmacy" in accordance with the schedule for working out missed classes established by the department. Increasing the rating and liquidating academic debts from the educational component is carried out by the applicants in accordance with the procedure specified in the POL "On the procedure for evaluating the results of training of applicants for higher education at the National University of Pharmacy ". 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 evaluation of the educational component (appeals). Applicants for 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 final supervision of knowledge by applicants of higher education at the National University of Pharmacy".

17. Information and educational and methodical support of the discipline:

The main reading suggestions	1. Industrial drug technology: tutorial for control. Laboratory classes for students of specialty Production of liquid extracts. “Pharmacy”/ Yu. V. Yudina, Yu. V. Shmyreva, Stages of technological process. S.V. Stepanenko [et. al]. – Kharkiv: NUPh : Equipment. Technological Original, 2012. – 254 p. 2. Train aid for preparation for the licensed integrated test-based exam «Krok 2. Pharmacy» in specialty «226 Pharmacy, industrial pharmacy» for students of the Faculty for Foreign Citizens’ Education / A. A. Sichkar, S. V. Stepanenko, D. P.

Supplementary reading suggestions for in-depth study of the educational component	Soldatov, O. S. Kukhtenko. – Kharkiv: NUPh, 2021. – 73 p. 1. Industrial drug technology: tutorial for control. Laboratory classes for students of specialty Production of liquid extracts. “Pharmacy”/ Yu. V. Yudina, Yu. V. Shmyreva, Stages of technological process. S.V. Stepanenko [et. al]. – Kharkiv: NUPh : Equipment. Technological Original, 2012. – 254 p. 2. All about hard gelatine capsules.— Basel: Firma extracts. Stages of technological “Capsugel”, 1994.— 47 p. 3. Good manufacturing practices for pharmaccutical products. in; WHO Expert Committee on Specifications for Pharmaceutical Preparalions. Thirly-second report. Geneva, Wor1d Health Organization, 1992, Annex 1 (WHO Technical Report Series, No. 823). 4. Enciclopaedia of Pharmaceutical Technology / Ed. J. Swarbrick, I.C. Boylan.— 2-nd — New-York, Basel: Marcek Dekker, Inc.— 2002.— Vol. 3.— 3032 p.
Current electronic information resources (magazines, websites) for in-depth study of the educational component	EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines. https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en#annexes
Moodle distance learning system	*Module 1* *https://pharmel.kharkiv.edu/moodle/course/view.php?id=3750* *Module 2* *https://pharmel.kharkiv.edu/moodle/course/view.php?id=2690*

18. Technical support and software of the educational component:
Computers for testing, multimedia devices, and screens are used. During laboratory work, laboratory equipment or equipment simulating industrial pharmaceutical production of medicinal products is utilized.
Here is the equipment list:
1. Distilled water generator (Aquadistillator)
2. pH meter pH150MI
3. Mixing and coating machine
4. Rotary vacuum evaporator
5. Water bath BV-20 (20L) and electrically heated bath
6. Metal woven sieve SLM-200.
7. Electronic scales Certus, FR-H Series, Jadever
8. Standard set of sieves

9. Analytical electronic scales AN 100 "AXIS"
10. Tabletop tablet press NTN-01B
11. Laboratory homogenizer
12. Water thermostat TS-80
13. Granulator PT-11
14. Air-circulating thermostat FD 200
15. Automatic dosing pump A-2
16. Household refrigerator
17. Timatic Micro 0.5L extractor
18. Soxhlet circulation apparatus 250 ml
19. Laboratory magnetic stirrer LMM-2
20. Round drying cabinet
21. Capping machine for bottle caps
22. Laboratory stirrer RT-2
23. SV-34/12 buchner funnel (40x60)
24. Laboratory mill
25. Measuring cylinder B-CC27/S
26. WiseStir stirrer
27. Laboratory funnels
28. Luman microscope
29. Graduated glass flasks, measuring, conical, etc.
30. MBS-9 microscope
31. Graduated pipette 1 ml with 0.01 subdivisions
32. Stirrer for solutions
33. Test tube P-1-10-0.2 and others
34. Laboratory grinder RT-1
35. Low and high glass beakers, 100 ml with a scale
36. Tissue grinder RT-2
37. Glass refrigerator HPT-1 400-29/32-29/32
38. Device 545 RAK-8 (friability tester)
39. Device AK-3 for powder research
40. Equipment set for the classroom
41. Device for determining essential oil
42. Motorized screen with mounting kit
43. Compact rheometer Rheolab QC C-LTD80/QC
44. EPSON EB-X05 projector (V11H839040)
45. Extractor hood