DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY

Department of Drug Technology and Biopharmaceutics

APPROVED
Temporary acting vice-rector on
educational and pedagogical work,
assoc.prof. I.I. Solonynko
_____
« 05 » 07 2022

EDUCATIONAL PROGRAM
on discipline

TECHNOLOGY OF MEDICINAL PRODUCTS

for training specialists of the second (master's) degree of higher education
of the branch of study 22 "Health care"
of the specialty 226 "Pharmacy, industrial pharmacy"
for the 3rd-4th years students of Faculty of Pharmacy
of the full-time and part-time forms of education

Approved
at the meeting of Department of
Drug Technology and Biopharmaceutics
Minutes No.12
« 8 » June 2022
Head of the Department
_____ assoc.prof. S.B. Bilous

Approved
by the Methodological Committee on
Chemical and Pharmaceutical Disciplines
Minutes No.3
« 21 » June 2022
Head of Committee
_____ assoc.prof. S.B. Bilous

2022

DEVELOPERS OF THE PROGRAM:

Bilous S.B. – head of the Department, DSc, associate professor
Kalynyuk T.H. – DSc, professor
Vashchenko K.F. – PhD, associate professor
Vashchenko O.O. – PhD, associate professor
Yakymiv O.V. – PhD, associate professor

REVIEWER:

Yackova H.Yu. – PhD, associate professor of the Department of Management and Economy of Pharmacy, Drug Technology and Pharmacoeconomics FPGE of Danylo Halytsky Lviv National Medical University

INTRODUCTION

Educational program of the discipline

«Technology of medicinal products»

according to Standard of higher education of *second (master's) level*
branch of knowledge *22 "Healthcare"*
specialty *226 "Pharmacy"*
educational program of *master of pharmacy*

Description of the educational discipline (annotation)

«**Technology of medicinal products**» belongs to the cycle of basic disciplines for professionally-oriented training of specialists on specialty "Pharmacy, industrial pharmacy" and includes two **content modules**: «Technology of medicinal products in pharmacy» and « Industrial technology of medicinal products».

Program of the discipline "Technology of medicinal products" is organized in accordance with Standard of Higher Education in Ukraine for specialty "Pharmacy, industrial pharmacy".

Program of the discipline "Technology of medicinal products" is intended for applicants of higher education, provides theoretical knowledge and practical skills on on the basic stages of the formation and development of pharmaceutical technology in Ukraine, current development trends of the pharmaceutical branch and professional activity in Ukraine and abroad, general requirement for the production of medicines of various pharmaceutical types in the pharmacy and industrial conditions.

Structure of the academic discipline

Structure of educational discipline	**Number of credits, hours, including**				**Year of study / semester**	**Types of control**
	Total	**Class hours**		**Independent study**		
		Lectures	**Laboratory classes**			
Technology of drugs 10 chapters	13 credits ECTS/ 390 hours	36	160	194	3-4 year courses, semesters V-VI	**credit, exam**
By semesters						
Content module 1. Technology of medicinal products in pharmacy						
Semester V Chapters1-2	2.6 credits ECTS/ 78 hours	6	32	40	semester V	**(credit)**
Semester VI Chapters 3-5	4.4 credits ECTS/ 132 hours	10	58	64	semester VI	**(credit)**
Content module 2. Industrial technology of medicinal products						
VII Semester Chapters 1-3	3 credits ECTS/ 90 hours	10	32	48	semester VII	**(credit)**
Semester VIII Chapters 4-5	3 credits ECTS/ 90 hours	10	38	42	semester VIII	**exam**

Object of the academic discipline is basic statements and progress trends of pharmaceutical technology in Ukraine and other countries of the world; to acquire knowledge on the current principles of normative documents and production of medicinal products in various dosage forms using new types of excipients and modern equipment in pharmacy and industrial conditions.

Interdisciplinary links:

- the discipline is based on studying physics, general and neorganic chemistry, physical and colloidal chemistry, physiology, pharmacognosy, pharmacology;

- the discipline is a basis for studying of medicinal and pharmaceutical commodities, good practices in pharmacy, pharmaceutical chemistry, management and marketing in pharmacy, biopharmaceuticals, standardization of medicines, technology of medicinal cosmetics, and involves the integration with the mentioned disciplines to train skills of applying knowledge in the process of further education and in the professional activity;

- the discipline is a foundation for professional training and promotes the formation of pharmaceutical and technical thinking necessary for the professional activities.

1. Purpose and objectives of discipline

1.1. Purpose of the academic discipline "Technology of medicinal products" is learning by higher education applicants of theoretical foundations and practical skills and abilities to produce medicines in the conditions of pharmacies and pharmaceutical companies with consideration of the requirements of good practice in pharmacy and good manufacturing practice; rules of development and completing the production documents for the manufacture of medicinal products, rules for their storage and packaging; getting knowledge on the characteristics, classification and assortment of dosage forms; studying the influence of excipients on the quality of medicines that will enable the realization of scientific and creative potential of future specialists.

1.2. Primary objectives of the educational discipline "Technology of medicinal products" are:

- learning the requirements of current normative documents (Pharmacopoei, GPP, guidelines and orders of the Ministry of Health) for the organization of production activities of pharmacies to compound medicinal products in various dosage forms;
- familiarization with organization of pharmaceutical production in the conditions of pharmaceutical companies in accordance with the requirements of Good Manufacturing Practice (GMP);
- use of normative and legal acts, requirements of good pharmacy practice (GPP) and good manufacturing practice (GMP) for the production of medicinal products in conditions of pharmacies and industrial enterprises in the professional activity;
- getting the knowledge on theoretical foundations for the production of various types of dosage forms, conducting step-by-step quality control, ways of improving the technology of dosage forms in the pharmacy and industrial conditions;
- studying of the influence of storage conditions and type of packaging on the stability of medicinal products;
- studying of industrial equipment, apparatus and automatic lines.

1.3 Competencies and learning outcomes, which are contributed by learning the discipline (correlation with normative content of the training of higher education applicants formulated in terms of learning outcomes in Standard of Higher Education).

According to the Standard of Higher Education, the discipline provides gaining the following ***competencies*** – ***general and professional***.

General:

CG 2. The ability to use knowledge in practical situations.

CG 3. Desire of saving the environment.

CG 4. The ability for abstract thinking, analysis and synthesis; ability to study and to be modernly trained.

CG 6. The knowing and understanding of subject field and the understanding of profession.

CG 7. Ability to adapt and act in a new situation.

CG 10. The ability to choose communication strategy, ability to work in team and with experts from other fields of knowledge/types of economic activity.

CG 11. The ability to evaluate and ensure quality of performed work.

CG 12. The ability to conduct investigations in an appropriate level.

Professional:

Cluster 1

Pharmaceutical competencies in the branch of health care

PC 1. Ability to conduct health education among the population with the purpose of the prevention of common diseases, dangerous infectious, viral and parasitic diseases, as well as to facilitate the timely detection and maintenance of adherence to the treatment of these diseases in accordance with their medical and biological characteristics and microbiological features.

PC 2. Ability to provide advice on prescription and over-the-counter drugs and other products of the pharmacy range; pharmaceutical care during the selection and sale of over-the-counter drugs by assessing the risk/benefit, compatibility, indications and contraindications based on the health status of a particular patient, taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical characteristics of medicinal products and other pharmaceutical products.

Cluster 2

Competencies in the field of providing pharmaceutical help to the population

PC 7. Ability to ensure proper storage of medicines and other products of the pharmacy range in accordance with their physicochemical properties and the rules of Good Storage Practice (GSP) in health care facilities.

Cluster 3

Professional and personal competences

PC 12. Ability to use in professional activities knowledge of regulations, legislation of Ukraine, and recommendations of Good Pharmaceutical Practices.

PC 13. Ability to demonstrate and apply in practice communication skills, fundamental principles of pharmaceutical ethics and deontology, based on moral obligations and values, ethical standards of professional conduct and responsibility in accordance with the Code of Ethics for Pharmaceutical Workers of Ukraine and WHO guidelines.

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

PC 15. Ability to organize and participate in the production of medicines in pharmaceutical companies, including the selection and justification of the process, equipment and premises with the appropriate development and design of the necessary documentation in accordance with the requirements of Good Manufacturing Practice (GMP); ability to determine the stability of medicinal products.

Cluster 4

Competencies in the field of quality assurance and management

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

PC 19. Ability to organize and carry out quality control of medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and good pharmaceutical practices, to determine sampling methods for the control of medicinal products and to carry out their standardization in accordance with current requirements, to prevent the distribution of falsified medicinal products.

PC 20. Ability to develop methods of quality control of medicinal products, including active pharmaceutical ingredients, medicinal plant raw materials and excipietns using physical, chemical, physical-chemical, biological, microbiological, pharmaco-technological and pharmaco-organoleptic control methods.

Program learning outcomes (PLO), the formation of which is facilitated by the academic discipline:

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

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

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

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

PLO 5. To position one's professional activity and personal qualities on the pharmaceutical labor market; to formulate the goals of one's own activity taking into account public and industrial interests.

PLO 6. To argue the information for decision-making, to be responsible for the decisions in standard and non-standard professional situations; to adhere to the principles of deontology and ethics in professional activity.

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

PLO 8. To carry out professional communication in the official language, to use oral communication skills in a foreign language, to analyze specialized texts and to translate foreign language information sources.

PLO 9. To carry out professional activities using information technologies, "Information data bases", navigation systems, Internet resources, software and other information and communication technologies.

PLO 10. To adhere to the norms of communication in professional interaction with colleagues, management, consumers, to work effectively in a team.

PLO 11. To use methods of evaluating performance quality indicators; to identify reserves for increasing labor efficiency.
PLO 12. To analyze information obtained as a result of scientific research, to generalize, systematize and use it in professional activities.
PLO 13. To carry out sanitary and educational work in professional activities in the event of outbreaks of infectious, viral and parasitic diseases.
PLO 14. To determine the advantages and disadvantages of medicines of various pharmacological groups, taking into account their chemical, physical-chemical, biopharmaceutical, pharmacokinetic and pharmacodynamic characteristics. To recommend to consumers non-prescription drugs and other products of the pharmacy assortment with the provision of advisory assistance and pharmaceutical care
PLO 16. To determine the influence of factors affecting the processes of absorption, distribution, deposition, metabolism, and excretion of the medicinal product and which are determined by the condition, features of the human body, and the physicochemical properties of medicinal products.
PLO 19. To predict and determine the influence of environmental factors on the quality of medicines and consumer characteristics of other products of the pharmacy assortment during their storage.
PLO 24. To plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of good pharmaceutical practices.
PLO 25. To contribute to the preservation of health, in particular the prevention of diseases, the rational prescription and use of medicinal products. To conscientiously fulfill one's professional duties, to comply with the legislation on the promotion and advertising of medicinal products. To possess psychological communication skills to achieve trust and mutual understanding with colleagues, doctors, patients, consumers.
PLO 26. To choose a rational technology, to formulate medicinal products in various dosage forms according to the prescriptions of doctors and orders of medical institutions, to prepare them for dispensing. To perform technological operations: to weigh, to measure, to dose various medicinal products by weight, volume, etc. To develop and draw up technological documentation for the compounding of medicinal products in pharmacies.
PLO 27. To substantiate 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.
PLO 30. To ensure quality control of medicinal products and to document its results. To carry out quality risk management at all stages of the life cycle of medicinal products.
PLO 31. To carry out all types of quality control of medicinal products; to draw up quality certificates of a series of medicinal products and a certificate of analysis, taking into account the requirements of current regulatory documents, the State Pharmacopoeia of Ukraine and the results of quality control. To develop specifications and quality control methods in accordance with the requirements of the current State Pharmacopoeia of Ukraine.
PLO 32. To determine the main organoleptic, physical, chemical, physicochemical and pharmacotechnological indicators of medicinal products, to justify and choose methods of their standardization, to carry out statistical processing of the results in accordance with the requirements of the current State Pharmacopoeia of Ukraine.

2. Information volume of the academic discipline

13 credits ECTS 390 hours are given for learning the academic discipline.

Content module 1. Technology of medicinal products in pharmacy. 3rd academic year – 7 credits 210 hours.

Content module 2. Industrial technology of medicinal products. 4th academic year – 6 credits 180 hours.

Content module 1. Technology of medicinal products in pharmacy consists of 5 chapters:

Chapter 1. General principles of compounding drug preparations. Solid preparations.

Chapter 2. Liquid preparations. Aqueous solutions.

Chapter 3. Liquid preparations. Non-aqueous solutions. Heterogeneous liquid preparations. Water extracts from medicinal plant material.

Chapter 4. Semi-solid preparations for cutaneous application. Suppositories.

Chapter 5. Sterile preparations. Pharmaceutical incompatibilities.

Semester V

Chapter 1

General principles of compounding drug preparations. Solid preparations

Topic 1. Basic terms in technology of medicinal products. Legal documents that regulate compounding and manufacture of medicines in Ukraine.

Technology of medicinal products as a science and academic discipline, its objectives at the present stage, the development directions. Basic terms of technology of medicinal products (active pharmaceutical ingredient, excipient, medicinal product, dosage form, etc). Classification of dosage forms by: physical state, method of use, route of administration. The basic principles of good pharmacy practice (GPP). Documents and reference books that regulate the production conditions, storage and dispensing of medicines from pharmacies. Limitation of the range of persons entitled to pharmaceutical activity in accordance with the legislation. Officinal prescriptions and extemporaneous drugs. Writing prescriptions in accordance with normative documents (orders of Ministry of Health of Ukraine). Doses and their classification. Pharmacopoeia, its structure and rules for information searching. Quality control of active ingredients excipients and medicinal products. Standardization of the production conditions and technological process.

Topic 2. Dosing in pharmacy practice. Technology of simple and compound powders.

Types of balances used in pharmacy practice. Structure of prescription and hand (manual) balances. Metrological parameters of balances: precision, accuracy, sensitivity, readability. Calibration of balances. Determination of relative error of weighting. Rules of weighing of solid, liquid and viscous substances using hand and prescription balances. Cleaning and maintaining of balances and standard weights. Measuring devices. Dosing of liquids by volume. Dosing of liquids in drops. Standard dropper. Calibration of nonstandard dropper by weight and volume. Characteristics of powders as a dosage form, classification. Requirements of the Pharmacopoeia to powders. Methods of powders prescribing. Stages of technological process of simple and compound powders.

Topic 3. Technology of compound powders with poisonous, narcotic (psychotropic) and highly potent substances. Triturations.

Rules of prescribing poisonous, narcotic (psychotropic) and highly potent substances, their storage and dispensing from pharmacies in accordance with the requirements of normative documents. Checking of single and daily doses of poisonous and strong active substances in powders. The list of narcotic substances and norms of their one-time dispensing. Features of preparing of compound powders with poisonous, narcotic and highly potent substances prescribed in quantities less than 0.05. Triturations, their characteristics, classification, preparation, storage and use in the preparation of powders. Quality control, rules of design for dispensing and storage of powders with poisonous, narcotic (psychotropic) and highly potent substances in accordance with the requirements of the State Pharmacopoeia of Ukraine and other normative documents.

Topic 4. Technology of simple and compound powders with medicinal substances that differ by the prescribed quantities and physical-chemical properties. Technology of compound powders with dyeing, colored difficult-to-grind substances and liquids.

Rules of preparation of compound powders with substances prescribed in equal and different quantities. Factors affecting an order of the mixing ingredients in the technology of compound powders. Equipment for grinding, mixing and dosing powders. Rules of choosing packaging material with consideration of physical-chemical properties of powder ingredients. Dosing of powders. Biopharmaceutical aspects of powders. Classification of substances on dyeing and colored ones. List of dyeing substances, their storage in pharmacies. Features of preparing powders with dyeing substances and sanitary conditions of their preparation. Features of packing powders with dyeing and colored substances. Characteristics of hard gelatin capsules for packing powders. Characteristics of extracts used in powders, their classification. Preparation of solutions of soft extracts, conditions and shelf life of their storage. Features of technology of compound powders with dry and soft extracts, and solutions of soft extracts. List of difficult-to-grind medicinal substances. Features of technology of powders with difficult-to-grind substances and sanitary conditions of their preparation. Reasons for utilizing auxiliary liquids to improve grinding of difficult-to-grind substances. Rules of the addition of liquids and odorous substances into the powders. Features of packing powders with volatile and odorous substances. Quality control and design for dispensing powders with dyeing, colored, difficult-to-grind substances and liquids in accordance with the requirements of the State Pharmacopoeia of Ukraine and other normative documents.

Chapter 2
Liquid preparations. Aqueous and non-aqueous solutions

Topic 5. Technology of liquid preparations by weight in volume method.

Characteristics of liquid dosage forms as disperse systems, their classification. Methods of prescribing and expressing the concentrations of solutions. Preparation of solutions that contain up to 3% and more than 3% of dry medicinal substances. Addition of syrups, aromatic waters, galenic and neogalenic preparation etc to the solutions. Checking of doses of poisonous and highly potent substances in the liquid mixture. Quality control, design for dispensing and storage of liquid preparations in accordance with the requirements of the State Pharmacopoeia of Ukraine and other normative documents.

Topic 6. Technology of concentrated solutions. Technology of liquid preparations by weight in volume method using concentrated solutions.

Calculation of the quantities of substances and water for preparation of concentrated solutions by

different ways: using the measuring ware; with consideration of the volume increase coefficient; with consideration of the density of solution. Rules for the preparation of concentrated solutions for burette system. Quality control of concentrated solutions, their storage. Structure of the burette system, rules of care and use of it. Rules of preparing liquid preparations using concentrated solutions in accordance with the requirements of normative documents. Addition of syrups, aromatic waters, galenic and neogalenic preparations etc to the solutions. Quality control, design for dispensing and storage of liquid preparations in accordance with the requirements of normative documents.

Topic 7. Individual cases of preparation of aqueous solutions. Technology of aqueous solutions of standard Pharmacopoeial liquids.

The most common types of difficult cases of preparation of aqueous solutions in pharmacies: slow and difficult dissolving or insolubility of substances in prescribed solvent; decomposition of substances that are easily oxidized; decrease of solubility in compatible presence. Special technological techniques that allow preparing solutions of these substances: previous grinding of substances and use of hot solvent; use of freshly prepared purified water and appropriate excipients, use of complexation at preparing of solutions; separate dissolution. Nomenclature of standard pharmacopoeial liquids; their concentrations, chemical and conditional names. The rules of calculating the quantity of water and pharmacopoeial liquids depending on the prescription method. Rules of preparation of solutions with pharmacopoeial liquids. Safety rules for working with acids and alkalis. Quality control, design for dispensing and storage of solutions in accordance with the requirements of the State Pharmacopoeia of Ukraine and other normative documents.

Topic 8. Technology of non-aqueous solutions. Dilution of ethanol. Technology of drops.

Characteristics of non-aqueous solvents (ethanol, vegetable oils, liquid paraffin, glycerol, chloroform, dimexide, macrogol 400 and others), requirements to them. Calculations for diluting ethanol using the dilution formula and alkoholometric tables. Preparation of solutions using volatile and non-volatile solvents. Safety rules for working with flammable and explosive solvents. Characteristics of drops as a dosage form, their classification according to the method of administration. Checking of doses of poisonous and highly potent substances in drops. Rules of preparation of drops using concentrated solutions and by dissolving dry substances. Preparation of drops using non-aqueous solvents. The formation of eutectic mixtures. Quality control, design for dispensing and storage of non-aqueous solutions and drops in accordance with the requirements of normative documents.

Semester VI

Chapter 3

Liquid preparations. Heterogeneous liquid preparations. Aqueous extracts from medicinal plant material

Topic 9. Technology of solutions with macromolecular substances and colloidal solutions.

Characteristic of macromolecular compounds, their classification and use in pharmacy. Influence of the structure of macromolecular compounds on the dissolution process of limited and unlimited swelling substances. Features of preparation of solutions with pepsin, gelatin, starch, methylcellulose, sodium carboxymethylcellulose and plant extracts. Characteristics and properties of colloidal solutions. Technology of solutions of protected colloids (Collargolum, Protargolum, Ichtamolum). Rules of the addition of medicinal substances to the solutions of macromolecular compounds and colloidal solutions.

Quality control and storage of macromolecular substances solutions and colloidal solutions, design for dispensing and storage in accordance with the requirements of normative documents.

Topic 10. Technology of suspensions.

Characteristics of suspensions as a dosage form and a disperse system; requirements to suspensions. Cases of formation of suspensions, factors affecting stability of heterogeneous systems. Dispersive method of preparation of suspensions with hydrophilic (swelling and non-swelling) medicinal substances. Characteristic of stabilizers and mechanism of their action. Features of technology of suspensions with hydrophobic substances with sharply and mildly pronounced properties. Condensation method of preparation of suspensions. Opalescent and muddy mixtures. Quality control of suspensions, design for dispensing and storage of suspensions in accordance with the requirements of normative documents.

Topic 11. Technology of emulsions.

Characteristics of emulsion as a dosage form and a disperse systems, their classification. Requirements of the State Pharmacopoeia of Ukraine to oil emulsions. Types of oil emulsions and determination methods. Characteristics of emulsifying agents, classification and mechanism of their action. General rules and methods of preparation of oil emulsions. Calculation of the quantitits of emulsifier, water and oil. Stages of the technological process of emulsions. Introduction of medicinal substances with different physical-chemical properties into the composition of oil emulsions. Quality control, storage and design for dispensing of emulsions in accordance with the requirements of normative documents.

Topic 12. Technology of aqueous extracts from medicinal plant material.

Characteristics of infusions and decoctions as dosage forms and disperse systems. Prescription methods of infusions and decoctions. Theoretical basis of the process of extraction of medicinal plant material. Factors affecting the extraction process (ratio between quantity of raw material and extraction solvent, histological structure and degree of grinding of raw plant material, material of infuser, temperature, duration of infusion and cooling, pH of the medium, chemical composition, etc.). Rules of preparation of infusions and decoctions from medicinal plant material. Apparatus for the preparation of infusions and decoctions. Features of preparation of aqueous extracts from Althea, medicinal plant materials that contain essential oils, tannins, anthracene derivatives, saponins, alkaloids, cardiac glycosides etc. Calculation of excipients for creating an optimal pH. Author's prescriptions of certain aqueous extracts (Deryahin's mixture, Kvater's mixtura, Ravkin's mixture and others). Quality control, storage of aqueous extracts and design for dispensing in accordance with the requirements of normative documents.

Topic 13. Technology of liquid preparations with extracts-concentrates

Characteristics of standardized extracts-concentrates for the preparation of infusions and decoctions, their nomenclature. Advantages of extracts-concentrates use in the technology of aqueous extracts. Rules of preparation of aqueous extracts with standardized extracts-concentrates and addition of other medicinal substances into the composition of aqueous extracts. Quality control, storage of aqueous extracts and design for dispensing in accordance with the requirements of normative documents.

Chapter 4

Semi-solid preparations for cutaneous application. Suppositories

Topic 14. Technology of single-phase semi-solid preparations.

Characteristics of ointments as a dosage form, classification of ointments (according to the medical purposes, place of application, texture and physical-chemical properties of medicinal substances). Requirements of the State Pharmacopoeia of Ukraine to ointments. Requirements to the ointment bases, classification of bases. List of ointment bases recommended by the State Pharmacopoeia of Ukraine, principles of the selection. Characteristics of hydrophobic and hydrophilic bases. Characteristics of gels as a dosage form. Classification of gels and gelling agents. The main technological stages and rules of preparation of gels. Characteristics of liniments as a dosage form. Classification of liniments by the type of disperse system. The main technological stages and rules of the preparation of homogeneous ointments such as ointment-solution, ointment-fusion and extraction ointments; gels and liniments. Quality control, packaging, design for dispensing and storage of single-phase semi-solid preparations in accordance with the requirements of normative documents.

Topic 15. Technology of two-phase semi-solid preparations.

Characteristics of suspension ointments and their technology depending on the quantitative content of medicinal substances. Official prescriptions of suspension ointments. Features of the introduction of resorcinol and zinc sulfate into the dermatological ointments. Pastes, the preparation. Characteristics of emulsion ointments of different types and the preparation depending on the properties of medicinal substances and excipients. Rules of introduction of protargol, tannin and plant extracts of different consistency into the composition of ointments. Characteristics of creams as a dosage form. Classification of creams and rules for the preparation. Characteristics of emulsifiers for preparation of emulsion ointments. Technology of two-phase gels and liniments. Assessment of quality of double-phase ointments, storage and design for dispensing according to regulatory documents. Quality control of two-phase semi-solid preparations, storage and design for dispensing in accordance with the requirements of normative documents.

Topic 16. Technology of multi-phase semi-solid preparations.

Characteristics of combination ointments, creams and liniments, general rules for the preparation. Stages of technological process of multi-phase semi-solid preparations with consideration of physical and chemical properties of medical substances. Methods of quality control of combination ointments, creams and liniments, storage and design for dispensing in accordance with the requirements of normative documents. Ways of improvement of technology of semi-solid preparations in the conditions of pharmacy.

Topic 17. Technology of suppositories by rolling and molding methods.

Characteristics of supppositories as dosage form and dispersive systems. Classification of suppositories. Requirements of the State Pharmacopoeia of Ukraine to rectal and vaginal suppositories. Methods of prescribing suppositories; checking of doses of poisonous and highly potent substances in rectal suppositories. Basics for suppositories, requirements to them. Features of prescribing of sticks and calculations of base. Characteristics of technological stages of preparation of suppositories by rolling method. Rules of introduction of medicinal substances with different physical-chemical properties into the base; features of introduction of protargol, collargol, tannin, dry and soft extracts. Methods of quality control of suppositories prepared by rolling method, packaging and design for dispensing, storage in accordance with the requirements of normative documents.

Composition and properties of officinal suppository bases used for preparing suppositories by the molding method. Calculations of suppository bases for preparing suppositories by molding method. Coefficient of replacement. Characteristics of technological stages of preparation of suppositories by molding method. Rules of introductions of medicinal substances with different physical-chemical properties into the suppository base when using molding method. Comparative evaluation of preparation methods of suppositories (rolling, molding, compressing). Quality control of suppositories prepared by molding method, design for dispensing, storage conditions in accordance with the requirements of normative documents.

Chapter 5
Sterile preparations. Pharmaceutical incompatibilities

Topic 18. Organization of aseptic conditions for preparation of medicines. Technology of solutions for injections without stabilization and with stabilization.

Aseptic conditions for preparation of medicines. Characteristics of injections, requirements of the State Pharmacopoeia of Ukraine and their implementation in pharmacies. Characteristics of solvents for the preparation of injections. Receiving, storage and quality control of water for injections in accordance with requirements of the State Pharmacopoeia of Ukraine and orders of Ministry of Health of Ukraine. Requirements to the solutions for injections and packaging materials for them. Methods of sterilization and required apparatus.

Technological stages of preparation of solutions for injections. Features of preparation of sodium hydrocarbonate solution for injections. Filtration of solutions and testing on the absence of mechanical impurities. Reasons of degradation of medicinal substances in the solutions for injections. Characteristics of stabilizers used for preparation of solutions for injections; their classification. Principles of selection of stabilizers and calculation of their quantity in accordance with regulations. Stabilization of solutions with medicinal substances subjected to hydrolysis. Features of preparation of glucose and procaine solutions. Stabilization of solutions with substances that are easily oxidized. Antioxidants, their classification. Features of preparation of Ascorbic acid solutions for injections. Methods pf sterilization and required apparatus. Quality control of solutions for injection in accordance with the requirements of normative documents, sealing, design dispensing and shelf life.

Topic 19. Technology of isotonic solutions for parenteral administration

Isotonization of solutions for injections. Methods for calculating isotonic concentrations using isotonic equivalent by sodium chloride, the Raoul's law (cryoscopic method), Vant-Hoff law and Mendeleev-Clapeyron equation. Principles of selection of isotonic agents. General technological techniques of preparation of isotonic solutions. Quality control of isotonic solutions in accordance with the requirements of normative documents, sealing, design for dispensing and shelf life.

Topic 20. Technology of infusion solutions.

Classification of infusion solutions in accordance with the medical purpose and composition. Physiological solutions. Nomenclature of plasma substitute and antishock solutions. Features of preparation of infusion solutions depending on the composition of active ingredients. Calculation of isoosmoticity and ion composition of infusion solutions. Quality control of solutions for infusions according to the requirements of the State Pharmacopoeia of Ukraine and other regulatory documents, sealing, design for dispensing and shelf life.

Topic 21. Technology of eye preparations compounded in pharmacy.

Characteristics of preparations used for the treatment of eye diseases (drops, lotions, washes, ointments etc.), requirements of the State Pharmacopoeia of Ukraine. Isotonization of eye drops, lotions and washes. Prolongation of action of eye drops. Features of preparation of eye drops depending on the physical-chemical properties of drugs. Rules of preparation of lotions and washes. Quality control of liquid eye preparations, sealing, design for dispensing and shelf life in accordance with requirements of the State Pharmacopoeia of Ukraine and other normative documents. Characteristics of semi-solid preparations used for the treatment of eye diseases, requirements of the State Pharmacopoeia of Ukraine. Characteristics of bases used for preparations of eye ointments. Technology of eye ointments and features of the addition of zinc sulfate and resorcinol.

Topic 22. Technology of preparations with antibiotics and for newborns.

Characteristics of preparations with antibiotics; requirements to them and factors affecting stability. Features of technology of liquid and solid preparations with antibiotics (lotions, washes, rinses, drops and powders etc.). Technology of ointments and suppositories with antibiotics; characteristics of basis for the preparation. Quality control of semi-solid eye preparations and preparations with antibiotics, design for dispensing and shelf life in accordance with requirements of the State Pharmacopoeia of Ukraine and other normative documents.

Features of technology of preparations for newborns. Preparations for newborns. Nomenclature of preparations for newborns. Quality control of preparations for newborns, design for dispensing and shelf life in accordance with requirements of the State Pharmacopoeia of Ukraine and other normative documents.

Topic 26 Difficult prescriptions. Incompatible combination of ingredients in preparations

Difficult prescriptions and ways to solve problems in preparation (with specific examples in different dosage forms). Cases of incorrect writing of prescriptions received by pharmacies (overdoses, absence of stamps, writing in not-Latin, incorrect medicinal purpose etc.), actions of the pharmacist. Definition of "incompatibility". Classification of incompatible combinations of ingredients in preparations. Reasons of physical and physical-chemical incompatibility (examples). Classification of chemical incompatibility by the type of reactions. Characteristics of pharmacological incompatibilities (examples).

Content module 2. Industrial technology of medicinal products.

Content module 2. Industrial technology of medicinal products consists of 5 chapters:

Chapter 1. Normative and technical documents regulating manufacture of medicinal products. Material balance. Industrial manufacture of solid preparations.

Chapter 2. Industrial manufacture of liquid preparations.

Chapter 3. Industrial manufacture of semi-solid preparations for cutaneous application, rectal and vaginal preparations.

Chapter 4. Industrial manufacture of sterile preparations.

Chapter 5. Industrial manufacture of preparations from plant and animal raw material, extractive preparations, pressurized preparations. Characteristics of new dosage forms.

Semester VII

Chapter 1

Normative and technical documents regulating manufacture of medicinal products. Material balance. Industrial manufacture of solid preparations

Topic 1. Common principles of the organization of pharmaceutical manufacture. Normative and technical documents. Material balance at stages of the manufacturing process.

Common principles of the organization of pharmaceutical manufacture. Main normative and technical documents regulating the composition of medicinal products, quality of starting material and finished products, technology, manufacturing conditions and storage of medicinal products. Pharmaceutical development.

Material balance at stages of the technological process of medicinal products. Registration dossier of the pharmaceutical product. Production records, validation forms.

Topic 2. Powders. Species.

Powders. Species. Characteristics. Classification. Requirements of the State Pharmacopoeia of Ukraine. Stages of the manufacturing process of powders and species. Grinding, basic physical and chemical parameters influencing grinding process of solids. Theory of grinding. Sieving, types of sieves. Mixing of dry substances. Quality control of powders and species.

Topic 3. Tablets.

Tablets, characteristics, requirements of the State Pharmacopoeia of Ukraine, classification. Excipients. Physical-chemical and technological properties of starting material. Compression. Theoretical aspects of tableting. Methods of tablet production. Types of granulation. Manufacturing stages. Apparatus. Quality control of tablets. Packaging and labeling of tablets.

Covering tablets with coatings: compressed, film and sugar coatings. Multilayer, matrix and molded tablets. Controlled release tablets.

***Topic 4. Granules, dragee, capsules, microcapsules*.**

Granules. Dragee. Characteristics. Manufacturing stages. Nomenclature. Quality control.

Capsules. Characteristics. Production methods of soft and solid gelcapsules, filling capsules with medicinal substances. Quality control. Tubatins. Rectal gelcapsules. Microcapsules. Microencapsulation methods. Apparatus. Dosage forms with microcapsules. Quality control.

Topic 5. Solid dosage forms of a new generation.

Characteristics of solid dosage forms of a new generation. Solid therapeutic systems. Classification. Characteristics. Production methods. Nanopreparations in pharmacy. Biopharmaceutical evaluation of solid preparations.

Chapter 2

Industrial manufacture of liquid preparations

Topic 6. Manufacture of aqueous solutions.

Characteristics of liquid preparations as disperse systems, classification. Water purified, requirements of the State Pharmacopoeia of Ukraine. Receiving and storage of water purified at the enterprises.

Production methods of solutions. Stages in the manufacture of solutions by method of chemical interaction. Mixing. Separation of liquid heterogeneous systems. Filtration, classification of filters.

Syrups. Aromatic waters. Characteristics. Classification. Production methods and purification. Apparatus. Quality control.

Topic 7. Non-aqueous solutions produced in industrial conditions.

Characteristics of non-aqueous solvents, requirements. Alcoholometry. Calculations for dilution of ethanol to a specific concentration. Manufacture of alcohol solutions. Apparatus for manufacture and filtration. Nomenclature of alcohol, oil and glycerol solutions.

Topic 8. Manufacture of suspensions and emulsions.

Characteristics of heterogeneous liquid systems, their sedimentation and aggregative stability. Stabilization of heterogeneous liquid preparations.

Characteristics of suspensions. Reasons for formation of suspensions. Stability of suspensions; factors affecting stability. Production methods. Apparatus. Quality control.

Characteristics of emulsions, classification, requirements. Stability of emulsions. Emulsifying agents, classification, characteristics, mechanism of action. Manufacture of emulsions in industrial conditions. Apparatus. Quality control.

Chapter 3
Industrial manufacture of semi-solid preparations for cutaneous application, rectal and vaginal preparations

Topic 9. Manufacture of semi-solid preparations for cutaneous application.

General characteristics and classification of semi-solid preparations for cutaneous application by the State Pharmacopoeia of Ukraine. Excipients in the composition of semi-solid preparations for cutaneous application. Classification and characteristics of bases for semi-solid preparations for cutaneous application, requirements, biopharmaceutical evaluation. General rules of production of semi-solid preparations for cutaneous application. Stages of the manufacture of semi-solid preparations in industrial conditions. Principles of the addition of medicinal ingredients into bases. Technology of ointments, gels, creams. Plasters, characteristics, classification, nomenclature, use. Mustard plasters, characteristics, manufacturing process, packaging. Nomenclature and use.

Topic 10. Rectal and vaginal preparations.

Classification of rectal and vaginal preparations by State Pharmacopoeia of Ukraine, requirements. Basic production methods in industrial conditions. Quality control.

Characteristics of suppositories as a dosage form. Mechanism of drug absorption from the rectal preparations; factors affecting absorption. Production methods of suppositories in industrial conditions. Suppository bases. Quality control.

Chapter 4
Industrial manufacture of sterile preparations

Topic 11. Parenteral preparations. Ampoule glass. Analysis of ampoule glass. Pretreatment of ampoules for filling

Basic principles of good manufacturing practice (GMP), requirements for manufacture of sterile preparations. Classification of clean areas, cleanliness grades. Production methods of solutions for injections and methods for filling ampoules. Filtration of solutions and mechanical impurities testing. Ampoule sealing and leak testing. Sterilization of solutions for injections, control of sterility. Quality control of solutions for injections, manufacturing process flow diagram.

Characteristics of solvents for injections. Requirements for preparations and containers used for injections. Glass for making ampoules and vials, classes and types. Basic requirements and quality parameters. Ampoule production, methods for ampoule washing, testing of ampoule stability.

Topic 12. Manufacture of solutions for injections that require special methods of purification and solutions for injections that require stabilization.

Manufacture of solutions for injections that require special methods of purification: calcium chloride, magnesium sulfate, glucose, gelatin, calcium gluconate. Factors of drug degradation in the solutions for injections. Characteristics of stabilizing agents used for preparation of solutions for injections, classification. Principles for selection of stabilizing agents and calculation of their quantity in accordance with normative documents. Stabilization of solutions with easily hydrolyzed substances. Stabilization of solutions with easily oxidized substances. Antioxidants, classification. Methods of sterilization and apparatus. Quality control of solutions for injections.

Topic 13. Manufacture of solutions for injections with thermolabile substances and oil solutions for injections

Manufacturing features of solutions with thermolabile substances (hexamethylenetetramine, euphilin etc). Basic stages in the manufacturing process. Methods of sterilization.

Characteristics of non-aqueous solvents. Manufacturing features of oil solutions. Leak testing. Quality control.

Topic 14. Intravenous infusions.

Characteristics and classification of intravenous infusions. Requirements for infusions. Differences between injections and infusions. Technology of infusion solutions. Concentrates for injections and intravenous infusions. Development prospects of infusion solutions, assortment of infusion preparations.

Topic 15. Eye preparations.

Peculiarities of the eye. Mechanism of drug absorption from eye preparations. Classification and characteristics of eye preparations. Eye drops, requirements. Manufacture of eye drops, manufacturing process flow diagram. Packaging and quality control of eye drops. Eye lotions. Powders for eye drops and lotions. Eye semi-solid preparations, manufacturing features. Eye inserts, characteristics.

Chapter 5

Industrial manufacture of preparations from plant and animal raw material, extractive preparations, pressurized preparations. Characteristics of new dosage forms

Topic 16. Theory of extraction. Manufacture of tinctures.

Theoretical aspects of extraction process. Process intensification of extraction. Stages of extraction and their characteristics. Factors influencing the completeness and rate of extraction. Requirements for extraction solvents. Characteristic and classification of tinctures. Production methods of tinctures. Ratio between raw material and extraction solvent. Alcohol absorption coefficient. Manufacturing schemes of tinctures by methods of maceration, percolation and extract dissolution. Purification methods of tinctures. Quality control and storage of tinctures. Nomenclature of tinctures and use.

Topic 17. Manufacture of extracts.

Characteristics and classification of extracts. Production methods. Stages in the manufacturing process of liquid, soft, dry and oil extracts. Apparatus for extract production. Purification methods of extracts from concomitant substances. Quality control and storage of extracts. Nomenclature of extracts and use.

Extracts-concentrates. Polifraction extracts. Characteristics. Production methods.

Topic 18. Manufacture of new galenic preparations.

Characteristics of maximum purified extractive preparations. Production methods of new galenic preparations. Basic stages in the manufacturing process. Methods of purification. Quality control. Nomenclature and use of new galenic preparations.

Topic 19. Manufacture of preparations from fresh plant material and biogenic stimulators.

Manufacturing features of preparations from fresh plant material. Production methods of juices and extracts from fresh plant material. Apparatus and manufacturing scheme of juices and extracts from fresh plant material. Purification methods of preparations from fresh plant material. Quality control, nomenclature and use.

Biostimulators. Definition, classification, production methods and purification. Quality control, nomenclature and use.

Topic 20. Hormonal and enzyme preparations. Biotechnological preparations

Classification of hormonal and enzyme preparations. Manufacture and characteristics. Nomenclature and use of hormonal and enzyme preparations.

Current approaches to manufacture of biotechnological preparations. Microbiological synthesis. Separation of biosynthesis products. Methods of purification and concentration. Crystallization and drying of biosynthesis products. Equipment. Standardization.

Topic 21. Pressurized preparations.

Pressurized preparations, characteristics, classification. Propellants, classification, requirements. Types of aerosol containers. Types of valve spraying systems. Manufacture and quality control of pressurized preparations.

3. Structure of educational discipline

Topic	Lections	Laboratory classes	Independent study	Individual work
Content module 1. Technology of medicinal products in pharmacy				
Chapter 1. **General principles of compounding drug preparations. Solid preparations**				
Topic 1. Basic terms in technology of medicinal products. Legal documents that regulate compounding and manufacture of medicines in Ukraine	0.5	4	5	-
Topic 2. Dosing in pharmacy practice. Technology of simple and compound powders	0.5	4	5	
Topic 3. Technology of compound powders with poisonous, narcotic (psychotropic) and highly potent substances. Triturations	0.5	4	5	
Topic 4. Technology of simple and compound powders with medicinal substances that differ by the prescribed quantities and physical-chemical properties. Technology of compound powders with dyeing, colored difficult-to-grind substances and liquids	0.5	4	5	

***Chapter 2*. Liquid preparations. Aqueous and non-aqueous solutions**				
Topic 5. Technology of liquid preparations by weight in volume method	1.5	4	5	
Topic 6. Technology of concentrated solutions. Technology of liquid preparations by weight in volume method using concentrated solutions	2	4	5	
Topic 7. Individual cases of preparation of aqueous solutions. Technology of aqueous solutions of standard Pharmacopoeial liquids	-	4	5	-
Topic 8. Technology of non-aqueous solutions. Dilution of ethanol. Technology of drops	0.5	4	5	
***Chapter 3.* Liquid preparations. Heterogeneous liquid preparations. Aqueous extracts from medicinal plant material**				
Topic 9. Technology of solutions with macromolecular substances and colloidal solutions	-	4	6	
Topic 10. Technology of suspensions	1	4	3	
Topic 11. Technology of emulsions	1	4	3	
Topic 12. Technology of aqueous extracts from medicinal plant material	1	4	3	
Topic 13. Technology of liquid preparations with extracts-concentrates	1	4	3	
***Chapter 4.* Semi-solid preparations for cutaneous application. Suppositories**				
Topic 14. Technology of single-phase semi-solid preparations	0.5	4	3	
Topic 15. Technology of two-phase semi-solid preparations	1	4	3	
Topic 16. Technology of multi-phase semi-solid preparations	0.5	4	3	-
Topic 17. Technology of suppositories by rolling and molding methods	2	4	3	
***Chapter 5.* Sterile preparations. Pharmaceutical incompatibilities**				
Topic 18. Organization of aseptic conditions for preparation of medicines. Technology of solutions for injections without stabilization and with stabilization	1	4	4	
Topic 19. Technology of isotonic solutions for parenteral administration	0.5	4	4	
Topic 20. Technology of infusion solutions	0.5	4	4	
Topic 21. Technology of eye preparations compounded in pharmacy	-	4	8	
Topic 22. Technology of preparations with antibiotics and for newborns	-	4	8	-
Topic 26 Difficult prescriptions. Incompatible combination of ingredients in preparations	-	2	6	
Totally for content module 1	**16**	**90**	**104**	**-**
Final control				**Credit**
Content module 2. Industrial technology of medicinal products				
***Chapter 1.* Normative and technical documents regulating manufacture of medicinal products. Material balance. Industrial manufacture of solid preparations**				
Topic 1. Common principles of the organization of pharmaceutical manufacture. Normative and technical documents. Material balance at stages of the manufacturing process	1	2	4	

Topic 2. Powders. Species	1	2	4	-
Topic 3. Tablets	2	8	4	
Topic 4. Granules, dragee, capsules, microcapsules	2	4	4	
Topic 5. Solid dosage forms of a new generation	-	-	4	
Chapter 2. **Industrial manufacture of liquid preparations**				
Topic 6. Manufacture of aqueous solutions	1	8	8	
Topic 7. Non-aqueous solutions produced in industrial conditions	-	4	4	-
Topic 8. Manufacture of suspensions and emulsions	1	-	4	
Chapter 3**. Industrial manufacture of semi-solid preparations for cutaneous application, rectal and vaginal preparations**				
Topic 9. Manufacture of homogeneous and heterogeneous semi-solid preparations for cutaneous application	2	4	4	
Topic 10. Rectal and vaginal preparations	-	-	8	-
Chapter 4. **Industrial manufacture of sterile preparations**				
Topic 11. Parenteral preparations. Ampoule glass. Analysis of ampoule glass. Pretreatment of ampoules for filling	1	2	2	
Topic 12. Manufacture of solutions for injections that require special methods of purification and solutions for injections that require stabilization	1	7	4	
Topic 13. Manufacture of solutions for injections with thermolabile substances and oil solutions for injections	1	4	4	-
Topic 14. Intravenous infusions	1	-	4	
Topic 15. Eye preparations	-	4	4	
Chapter 5. **Industrial manufacture of preparations from plant and animal raw material, extractive preparations, pressurized preparations. Characteristics of new dosage forms**				
Topic 16. Theory of extraction. Manufacture of tinctures	1	4	4	
Topic 17. Manufacture of extracts	1	12	4	
Topic 18. Manufacture of new galenic preparations	1	2	4	
Topic 19. Manufacture of preparations from fresh plant material and preparations of biogenic stimulators	1	3	4	
Topic 20. Preparations from animal raw material. Hormonal and enzyme preparations	2	-	4	-
Topic 21. Pressurized preparations	-	-	4	
Totally for content module 2	**20**	**70**	**90**	**-**
Final control				**Credit**
Final control of discipline				**Exam**
Totally for discipline – 390 / 13 кредитів ECTS	**36**	**160**	**194**	

4. Thematic plan of lectures

No.	Topic	Hours

Content module 1. Technology of medicinal products in pharmacy		
Semester V		
Chapter 1. General principles of compounding drug preparations. Solid preparations		
1.	Technology of medicinal products as a science and academic discipline. Compounding and manufacture of medicines in Ukraine. Powders as dosage forms, rules for compounding of powders	2
Chapter 2. Liquid preparations. Aqueous and non-aqueous solutions		
2.	Liquid preparations. Technology of liquid preparations by weight in volume method. Non-aqueous solutions, features of technology	2
3.	Concentrated solutions for burette system. Technology of liquid preparations with using concentrated solutions and by dissolving dry substances	2
Semester VI		
Chapter 3. Liquid preparations. Heterogeneous liquid preparations. Aqueous extracts from medicinal plant material		
1.	Heterogeneous dosage forms and their stabilization. Suspensions and emulsions as dosage forms	2
2.	Aqueous extracts from medicinal plant material. Technology of liquid preparations containing aqueous extracts. Using of extracts-concentrates in the technology of liquid preparations	2
Chapter 4. Semi-solid preparations for cutaneous application. Suppositories		
3.	Semi-solid preparations for cutaneous application. General rules of compounding of semi-solid preparations. Technology of semi-solid preparations of different types of dispersive system	2
4.	Rectal and vaginal preparations	2
Chapter 5. Sterile preparations. Pharmaceutical incompatibilities		
5.	Sterile compounded preparations. Aseptic conditions. Providing of quality of parenteral preparations	2
	Total for content module 11:	**16**
Content module 2. Industrial technology of medicinal products		
Semester VII		
Chapter 1. Normative and technical documents regulating manufacture of medicinal products. Material balance. Industrial manufacture of solid preparations		
1.	Common principles of the organization of pharmaceutical manufacture. Normative and technical documents. Solid dosage forms: powders, species, granules, dragee. Characteristics, production methods, quality control	2
2.	Tablets. Classification, characteristics. Production methods, quality control	2
3.	Capsules, microcapsules. Classification, characteristics. Production methods, quality control	2
Chapter 2. Industrial manufacture of liquid preparations		
4.	Liquid preparations. Classification, characteristics. Features of liquid preparations manufacture in industrial conditions, quality control	2

Chapter 3. Industrial manufacture of semi-solid preparations for cutaneous application, rectal and vaginal preparations		
5.	Semi-solid preparations for cutaneous application. Manufacturing process, apparatus, quality control	2
Semester VIII		
Chapter 4. Industrial manufacture of sterile preparations		
1.	Parenteral preparations. Requirements of good manufacturing practice to manufacture of sterile preparations. Manufacturing process of solutions for injections in ampoules, quality control. Stabilization of solutions for injections	2
2.	Manufacturing process of solutions for injections in ampoules that are not subjected to thermal sterilization. Manufacturing features of oil solutions for injections in ampoules. Lyophilized parenteral preparations, infusion solutions	2
Chapter 5. Industrial manufacture of preparations from plant and animal raw material, extractive preparations, pressurized preparations. Characteristics of new dosage forms		
3.	Extractive preparations. Theoretical aspects for extraction from medicinal plant material. Tinctures. Extracts. Characteristics, production methods, quality control	2
4.	Maximum purified preparations. Preparation from fresh plant material. Characteristics. Manufacturing schemes, purification methods of extracts, nomenclature	2
5.	Drug preparations from animal material. Classification, characteristics, manufacturing schemes, quality control	2
	Totally for content module 2:	**20**
	Totally for discipline:	**36**

5. Thematic plan of laboratory classes

No.	Topic	Hours
Content module 1. Technology of medicinal products in pharmacy		
Semester V		
Chapter 1. General principles of compounding drug preparations. Solid preparations		
1.	Basic terms in technology of medicinal products. Legal documents that regulate compounding and manufacture of medicines in Ukraine	4
2.	Dosing in pharmacy practice. Technology of simple and compound powders	4
3.	Technology of compound powders with poisonous, narcotic (psychotropic) and highly potent substances. Triturations	4
4.	Technology of simple and compound powders with medicinal substances that differ by the prescribed quantities and physical-chemical properties. Technology of compound powders with dyeing, colored difficult-to-grind substances and liquids	4
Chapter 2. Liquid preparations. Aqueous and non-aqueous solutions		
5.	Technology of liquid preparations by weight in volume method	4
6.	Technology of concentrated solutions. Technology of liquid preparations by weight in volume method using concentrated solutions	4
7.	Individual cases of preparation of aqueous solutions. Technology of aqueous solutions of standard Pharmacopoeial liquids	4

8.	Technology of non-aqueous solutions. Dilution of ethanol. Technology of drops	4
Semester VI		
Chapter 3. Liquid preparations. Heterogeneous liquid preparations. Aqueous extracts from medicinal plant material		
1.	Technology of solutions with macromolecular substances and colloidal solutions	4
2.	Technology of suspensions	4
3.	Technology of emulsions	4
4.	Technology of aqueous extracts from medicinal plant material	4
5.	Technology of liquid preparations with extracts-concentrates	4
Chapter 4. Semi-solid preparations for cutaneous application. Suppositories		
6.	Technology of single-phase semi-solid preparations	4
7.	Technology of two-phase semi-solid preparations	4
8.	Technology of multi-phase semi-solid preparations	4
9.	Technology of suppositories by rolling and molding methods	4
Chapter 5. Sterile preparations. Pharmaceutical incompatibilities		
10.	Organization of aseptic conditions for preparation of medicines. Technology of solutions for injections without stabilization and with stabilization	4
11.	Technology of isotonic solutions for parenteral administration	4
12.	Technology of infusion solutions	4
13.	Technology of eye preparations compounded in pharmacy	4
14.	Technology of preparations with antibiotics and for newborns	4
15.	Difficult prescriptions. Incompatible combination of ingredients in preparations	2
	Totally for content module 1:	**90**
Content module 2. Industrial technology of medicinal products		
Semester VII		
Chapter 1. Normative and technical documents regulating manufacture of medicinal products. Material balance. Industrial manufacture of solid preparations		
1.	Comminution, sieving, material balance. Investigation of physical-chemical and technological properties of powders and granular material. Manufacture of powders, quality control	4
2.	Manufacture of tablets by direct compression and compression with previous granulation	4
3.	Manufacture of coated tablets, molded tablets and dragee. Quality control	4
4.	Manufacture of capsules and microcapsules, quality control	4
Chapter 2. Industrial manufacture of liquid preparations		
5.	Manufacture of aqueous solutions in industrial conditions, quality control	4
6.	Manufacture of syrups and aromatic waters, quality control	4
7.	Alcoholometry. Determination of ethanol concentration. Strengthening and dilution of aqueous alcoholic solutions. Recovery and rectification of ethanol. Manufacture of alcoholic solutions, quality control	4

Chapter 3. Industrial manufacture of semi-solid preparations for cutaneous application, rectal and vaginal preparations		
8.	Manufacture of semi-solid preparations for cutaneous application, quality control	4
Semester VIII		
Chapter 4. Industrial manufacture of sterile preparations		
1.	Solutions for injections in ampoules: manufacturing process, quality control of finished products. Manufacture of solutions for injections that require special methods of purification	5
2.	Manufacture of solutions for injections that require stabilization	4
3.	Manufacture of solutions for injections with thermolabile substances and oil solutions for injections	4
4.	Manufacture of eye preparations, quality control	4
Chapter 5. Industrial manufacture of preparations from plant and animal raw material, extractive preparations, pressurized preparations. Characteristics of new dosage forms		
5.	Manufacture of tinctures, quality control	4
6.	Manufacture of liquid extracts, quality control	4
7.	Manufacture of soft and dry extracts, quality control	4
8.	Manufacture of oil extracts and extracts-concentrates, quality control	4
9.	Manufacture of new galenic preparations, quality control. Manufacture of fresh plant juices and preparations of biogenic stimulators	5
	Totally for content module 2:	**70**
	Totally for discipline	**160**

6. Thematic plan of individual work

No.	Topic	Hours	Types of control
Content module 1. Technology of medicinal products in pharmacy			
Semester V			
1.	**Preparation to laboratory classes** – theoretical preparation and working with the recommended prescriptions	16	Current control during laboratory classes or final control
2.	**Independent study of topics which are not included in the plan of laboratory classes:**		
Chapter 1. General principles of compounding drug preparations. Solid preparations			
2.1	Prescription, its value. Structure of prescription	2	– " –
2.2	Structure of prescription or hand balances, care of balances and weights. Devices and apparatus for dosing	3	
2.3	Requirements to sanitary measures and pharmaceutical order in a pharmacy	3	

2.4	Requirement to storage conditions in pharmacies for different groups of medicinal products	4	
2.5	Packaging material in technology of medicinal products and its influence on quality of dosage forms	4	
	Chapter 2. Liquid preparations. Aqueous and non-aqueous solutions		
2.6	Purification of water before the distillation. Aquadistilators, features in the construction. Demineralization of water, apparatus	4	– " –
2.7	Features of technology of certain liquid preparations according to the author's compositions	4	
	Semester VI		
1.	**Preparation to laboratory classes** – theoretical preparation and working with the recommended prescriptions	30	Current control during laboratory classes or final control
2.	**Independent study of topics which are not included in the plan of laboratory classes:**		
	Chapter 3. Liquid preparations. Heterogeneous liquid preparations. Aqueous extracts from medicinal plant material		
2.1	Requirements of State Pharmacopoeia of Ukraine to nasal and ear preparations	2	– " –
2.2	Solubilization and emulsification of medicinal substances. Solubilizers and emulsifiers as excipients in technology of medicines	2	
2.3	Herbal species	2	
	Chapter 4. Semi-solid preparations for cutaneous application. Suppositories		
2.4	Characteristics of ointment bases (hydrocarbons, fats, silicones, gels of proteins, polysaccharides, cellulose derivatives, macrogols and others.), their biopharmaceutical assessment	2	– " –
2.5	Characteristics of emulsifiers. Calculating the quantities of emulsifiers of I and II types for compounding ointments and creams	2	
2.6	Characteristic of suppository bases, their biopharmaceutical assessment and principles of choice depending on the compounding method of suppositories	2	
2.7	Technology of suppositories by compressing method. Suppository press machines	2	
	Chapter 5. Sterile preparations. Pharmaceutical incompatibilities		
2.8	Operation principle of aquadislillators for receiving water for injections, their types. Non-aqueous solvent for parenteral preparations.	2	– " –
2.9	Containers for injections and infusions, requirements to them, and pretreatment	2	
2.10	Apparatus for filtration, sealing, sterilization and control on mechanical impurities	2	
2.11	Routes of administration of parenteral preparations. Types of injections. Rate	2	

	of therapeutic effect depending on the route of administration		
2.12	Methods of testing of parenteral preparations on sterility, pyrogens, toxicity	2	
2.13	Features of medicinal products for children of different age	4	
2.14	Physical, chemical and pharmacological incompatibility of medicinal products	6	
	Totally for content module 1:	**104**	
Content module 2. Industrial technology of medicinal products			
Semester VII			
Chapter 1. Normative and technical documents regulating manufacture of medicinal products. Material balance. Industrial manufacture of solid preparations			
1.	New excipients in the manufacture of solid preparations	5	Current control during laboratory classes or final control
2.	Characteristics of basic manufacturing processes and apparatus for industrial manufacture of pharmaceutical preparations	5	
3.	General concepts on machines and apparatus, automatic lines in the industrial manufacture of medicinal products	5	
4.	Manufacture of prolonged-release solid preparations. Characteristics of prolongation methods	5	
5.	New solid dosage forms. Classification. Characteristics	4	
Chapter 2. Industrial manufacture of liquid preparations			
6.	Nasal preparations. Features of manufacture in industrial conditions	4	– " –
7.	Ear preparations. Features of manufacture in industrial conditions	4	
8.	Volatile oils. Characteristics. Classification. Methods of receiving and purification	4	
Chapter 3. Industrial manufacture of semi-solid preparations for cutaneous application, rectal and vaginal preparations			
9.	Preparations for rectal use. Classification. Characteristics, production methods, quality control.	4	Current control during laboratory classes or final control
10.	Preparations for vaginal use. Classification. Characteristics, production methods, quality control.	4	
11.	Transdermal therapeutic systems. Classification. Characteristics	4	
	Semester VIII		
Chapter 4. Industrial manufacture of sterile preparations			
1.	Sterile emulsions and suspensions. Characteristics, features of manufacture	5	– " –
2.	Filtration of solutions for injections. Classification and characteristics of filters, operation mechanisms of filters with different construction	4	
3.	Sterilization methods in the industrial manufacture of parenteral preparations	4	
4.	Characteristics of containers for solutions for injections	4	

Chapter 5. Industrial manufacture of preparations from plant and animal raw material, extractive preparations, pressurized preparations. Characteristics of new dosage forms			
5.	Hormone and enzyme preparations. Classification, obtaining, quality control,	5	– " –
6.	New inhalation dosage forms. Classification, characteristics	5	
7.	Characteristics of liposomal preparations, production methods	5	
8.	Characteristics of pediatric and geriatric preparations	5	
9.	Approaches for advancing dosage forms	5	
	Totally for content module 2:	**90**	
	Totally for discipline:	**194**	

7. Inidividual tasks

Individual tasks are not determined by the educational plan.

8. Teaching methods: explanatory-illustrated (multimedia lectures with elements of discussion communication with applicants of higher education), reproductive, research, part-search (independent work of search character, work with literature).

The following teaching methods are used:

- *verbal* – story, explanation, conversation, instruction, lecture, discussion;
- *visual* – demonstration of films, visual equipment (means of small mechanization), illustrations, materials, display of operations and processes of manufacture of medicines in the conditions of pharmacies and industrial enterprises;
- practical methods – laboratory-practical activities;
- objective methods – generalization of the results of observations and experiments.

Active and interactive methods of teaching are preferable (multimedia lections, educational films).

During the laboratory classes students should write protocols and specify the purpose of the class, describe the all work done in accordance with the tasks provided by methodological recommendations, and make conclusions.

Individual work includes chapters of the program necessary for student, which are studied during the educational process on pharmacology, pharmacognosy, pharmaceutical chemistry and other academic disciplines, as well as documents that regulate the composition, quality and safety of extemporal and manufactured medicines.

Plan and organizational structure of laboratory classes on "Technology of medicinal products"

No.	Basic stages of the class, their functions	Methods of control and training	Materials of methodological support (control, visualization etc.)	Time, min
1. Preparatory stage				
1.	Organization of the class			3-5

2.	Determination of educational goals		Relevance of the topic. Purpose of the class	10-15
3.	Control of the initial level of knowledge, skills and abilities	Frontal interview Individual oral interview	Control questions	25-30
2. Main stage				
4.	Formation of professional skills and abilities	Constant practical use of normative documents and internet resources Professional training for performing the practical tasks	Orders of Ministry of health of Ukraine State pharmacopoeia of Ukraine Typical tasks in the form of prescriptions and situational tasks Samples of medicines, containers, labels etc.	80-90
3. Final stage				
5.	Control and correction of the level of knowledge and practical skills	Individual control of the results of solved situational tasks. Control of the results of practical work (checking of prepared medicines and protocols of the class) Test control	Tests for controlling the level of material understanding Typical tasks in the form of situational tasks	25-30
6.	Summary of the class			5-10
7.	Homework: topic, literature		Approximate algorithms for independent work with literature	5-10

9. Methods of control. Control measures include current and final semester control.

According to the academic plan an exam is a form of the final control of the discipline "Technology of medicinal products".

10. Current control is carried out during laboratory classes and is aimed to check an understanding of the educational material by students.

Current control includes: oral examination, test control, control of practical skills, reception of the protocols of practical work. Current control is performed on every laboratory class in accordance with specific objectives.

The form of assessment of current educational activity is standardized and includes control of theoretical and practical preparing.

Control of theoretical preparing is conducted by solving the tests, situational tasks, conducting the practical skills by assessing of quality and completeness of practical tasks and the ability to interpret the results.

On each laboratory class student answers tests on the topic of laboratory class, and standardized questions, the knowing of which is required to understand the current theme; demonstrates knowledge, skills and practical abilities in accordance with topic of laboratory class.

The mark for the laboratory class is determined by the sum of the results of the test control and the performance of practical tasks.

Individual work is assessed by the current control of topic during the laboratory classes. Knowledge of the topics for independent study is controlled at final control.

Student who missed classes is allowed to work out an academic debt by the time determined by the schedule.

11. Final control is carried out to assess the learning results at a certain education qualification level and at the completed stages in accordance with the national scale and the ECTS scale. Final control includes semester control.

Semester control is performed in the form of semester credit **(V-VIII semesters)** and an exam **(semester VIII)** and includes educational material in accordance with working program and in terms determined by educational working plan and by individual educational plan of student.

Semester credit is a form of final control that is aimed to assess the knowledge of educational material on the academic subject studied during the semester based on the results of the current control.

Exam is a form of final control of the knowledge of theoretical and practical material on the academic subject and that is conducted as a control measure.

Those students who attended the all classes provided by the educational program, conducted all kinds of work provided by the working program on the discipline and received an average mark not less "3" are allowed to the exam.

An exam is conducted in written form during the examination session in accordance with schedule. The form of the exam is standardized and includes control of theoretical and practical knowledge. Exam papers include test of different degree of difficulty, situational tasks and tasks for checking the practical skills.

Duration of the exam is 3 academical hours.

The xam consists of the following steps.

Step 1 – a written response on the tests of format A. Evaluation criteria – 1 point for each test.

Student answers on a package of tests. Every package contains 40 tests of format A of each chapter of the discipline.

Step 2 – a written response on the 10 situational tasks of different complexity. Evaluation criteria – 2 points for each situation task.

Student receives a set of questions (situational tasks) and should write answers on them.

Step 3 – evaluation of practical skills. Evaluation criteria – 5 points for each task.

Student conducts calculations, substantiates the technology and writes a passport of written control for 2 dosage forms according to the recommended prescriptions and solves 2 practical tasks on the

manufacture of medicines - compiles the equation of the material balance, calculates output, losses, factor of account, makes working prescriptions with consideration of losses, specifies the production methods and quality parameters for medicines.

Students who did not take the exam without the valid reasons are scored "0" for the final control.

The refusal of the student to perform the examination task is tested as unsatisfactory answer - "0" points for the final control.

LIST OF QUESTIONS FOR FINAL CONTROL

Content module 1. Technology of medicinal products in pharmacy

1. Normative documents regulating rules of medicine compounding in pharmacy conditions.
2. Dosing in technology of medicinal products in pharmacy.
3. Checking of doses in the preparation for use.
4. Basic rules of powder compounding.
5. Triturations, the purpose and use.
6. Characteristics of liquid preparations as disperse systems, classification, requirements.
7. Solvents, classification, requirements, characteristics. Characteristics of water purified as a solvent. Requirements of State pharmacopoeia of Ukraine to water purified. Receiving of water purified by distillation and non-distillation methods. Apparatus for receiving water, operation principles. Quality control, storge and expiration life.
8. Preparation of liquid preparations by weight in volume method.
9. Concentrated solutions for burette system: nomenclature, technology, quality control.
10. Calculations for correcting the concentrated solutions with lower or higher content of active ingredient to the standard.
11. Special cases in technology of solutions: silver nitrate, potassium permanganate, iodine, mercury diiodide, mercury dichloride, furacilline, ethacridine lactate, phenobarbitone.
12. Standard pharmacopoeial liquids, nomenclature.
13. Preparation of aqueous solutions of standard pharmacopoeial liquids.
14. Features of technology of solutions with non-aqueous solvents (glycerol, vegetable oils, ethanol, etc.). Dillution of ethanol.
15. Macromolecular substances, factors affecting stability of the solutions of macromolecular substances.
16. Protected colloids, factors affecting stability of colloidal solutions.
17. Technology of starch, gelatin, pepsin, collargol, protargol and ichthamol solutions.
18. Suspensions, production methods.
19. Stabilization of suspensions, factors affecting sedimentation (kinetic) and aggregate (condensing) stability of suspensions.
20. Formulation of suspensions with hydrophilic and hydrophobic substances.
21. Emulsions for oral use, their stabilization.
22. Selection of surface-active substances for stabilization of emulsions in accordance with value of hydrophilic-lipophilic balance.
23. Aqueous extracts from medicinal plant material, factors affecting quality of aqueous extracts.
24. Technology of infusions and decoctions from medicinal plant material containing essential oils, tanning substances, mucilages, alkaloids, antracene glycosides etc.
25. Use of extracts-concentrates for preraing of aqueous extracts.
26. Semi-solid preparations for cutaneous application, classification, requirements.

27. Mechanism of drug absorption through the skin.
28. Bases for ointments.
29. Principles of introduction of drug substances into ointment bases.
30. Compounding of different ointments in accordance with the type of disperse system (homogeneous, heterogeneous).
31. Preparations for vaginal and rectal use, classification and characteristics.
32. Characteristics of suppository bases, their impact on the drug bioavailability.
33. Production methods of suppositories.
34. Principles of drug introduction into suppository bases.
35. Calculation of the mass of base for compounding suppositories by different methods.
36. Solutions for parenteral administration, classification and characteristics.
37. Requirements of State pharmacopoeia of Ukraine to parenteral preparations and ways of implementation them in pharmacies.
38. Features of technology of sodium bicarbonate solutions for parenteral use.
39. Features of technology of glucose solutions for parenteral use.
40. Features of technology of procaine solutions for parenteral use.
41. Features of technology of ascorbic acid solutions for parenteral use.
42. Eye preparations, classification and characteristics.
43. Requirements to eye drops, ways of their implementation in pharmacies.
44. Prolongation of drug action in eye drops.
45. Eye semi-solid preparations, basis for their compounding.
46. Features of technology of preparations for newborns (dusting powders, liquid preparations for oral and topical use, etc.).
47. Features of technology of dosage forms with antibiotics (powders, ointments, suppositories, eye drops, etc.).
48. Difficult prescriptions and ways to overcome the technological problems.
49. Classification of incompatibilities of drugs.
50. Ways to overcome the incompatible combinations of drug substances in dosage forms.

Content module 2. Industrial technology of medicinal products

1. Manufacture of medicinal products in accordance with GMP guides.
2. Grinding of solids in the pharmaceutical manufacture. Particle size distribution. Mixing.
3. Material balance. Importance of material balance.
4. Characteristics of powders as a dosage form, classification, requirements of State pharmacopoeia of Ukraine. Stages in the manufacture of simple and combination powders. Factors influencing the order of mixing the ingredients in the production of combination powders. Apparatus for grinding, mixing and dosing of powders.
5. Medicinal species, characteristics, classification. Manufacturing process.
6. Tablets. Characteristics. Requirements of State pharmacopoeia of Ukraine. Classification. Excipients. Production methods of tablets. Characteristics. Stages in the manufacture. Compression. Theoretical aspects of tableting.
7. Direct compression. Manufacture of tablets by compression with previous granulation. Process flow diagram for manufacture.
8. Types of granulation. Apparatus. Technological properties of tableting mass.
9. Covering tablets with coatings. Types of coatings. Apparatus for pressed coating.

10. Multilayer, matrix and molded tablets.
11. Quality control, packaging and labelling of tablets.
12. Dragee. Granules. Characteristics. Manufacturing stages. Nomenclature. Quality control.
13. Capsules. Characteristics. Production methods. Quality control. Excipients for capsules. Production methods for soft and solid gelcapsules, filling of capsules with active pharmaceutical ingredients.
14. Microcapsules. Microencapsulation methods. Apparatus. Dosage forms of microcapsules. Quality control.
15. Stages in the manufacture of aqueous solutions by chemical interaction method. Nomenclature of solutions.
16. Syrups. Classification. Production methods. Quality control. Nomenclature.
17. Non-aqueous solvents, classification, requirements, characteristics.
18. Dilution of ethanol to a specific concentration. Alcoholometric tables. Manufacturing features of alcoholic solutions. Rectification and recovery of ethanol.
19. Characteristics of heterogeneous liquid preparations, sedimentation and aggregative stability. Stabilization of heterogeneous liquid preparations.
20. Characteristics of suspensions and emulsion as dosage forms and disperse systems. Production methods. Apparatus for production. Quality control of heterogeneous liquid preparations.
21. Principles of drug incorporation into the ointment bases. Apparatus for manufacture of semi-solid preparations. Process flow diagram for manufacture of semi-solid preparations. Quality control.
22. Plasters, characteristics, classification, nomenclature, use.
23. Mustard plasters, characteristics, manufacturing process, packaging. Nomenclature, use.
24. Preparations for rectal and vaginal application, classification and characteristics. Requirements of State pharmacopoeia of Ukraine.
25. Production methods of suppositories, their comparative characteristics. Apparatus. Quality control.
26. Medicinal products that require aseptic manufacturing conditions. Necessity of aseptic manufacturing conditions.
27. Ampoule glass. Quality parameters. Pretreatment of ampoules for filling.
28. Parenteral route of drug administration, its features. Parenteral preparations, classification, requirements and characteristics.
29. Solvents for solutions for injection. Water for injections, methods of receiving, storage and quality control in accordance with current normative documents.
30. Requirements for active pharmaceutical ingredients and excipients used in the manufacture of injections and infusions.
31. Stages in the manufacture of solutions for injection in ampoules.
32. Filtration methods of solutions for injections; filtration material and apparatus.
33. Features in the manufacture of solutions that require special methods of purification, solutions for injections with thermolabile substances, solutions for injections that require stabilization (novocain, glucose, sodium and caffeine benzoate, ascorbic acid etc.).
34. Non-aqueous solvents for injections. Classification, requirements. Features in the manufacture of oil solutions for injections.

35. Isotonicity of solutions for parenteral administration. Methods of calculating the isotonic drug concentrations. Osmolarity of solutions. Calculation of solution osmolarity.
36. Characteristics and classification of intravenous infusions. Requirements for infusions. Manufacture of intravenous infusions. Quality control, packaging and labelling of solutions for injections and infusions.
37. Characteristics and classification of eye preparations. Necessity of aseptic manufacturing conditions.
38. Manufacture of eye preparations in industrial conditions. Quality control, packaging and labelling of eye preparations.
39. Solid eye dosage forms. Characteristics.
40. Extractive preparations from medicinal plant material. Theoretical aspects of extraction. Convective and molecular diffusion. Factors affecting the extraction process. Methods of extraction. Apparatus.
41. Tinctures. Extracts. Characteristics. Classification. Production methods. Process flow diagram of manufacture. Apparatus. Quality control. Nomenclature.
42. Extracts concentrates. Poliextracts. Oil extracts. Features in the manufacture. Nomenclature.
43. New galenic preparations. Characteristics. Methods of purification. Stages in the manufacture of adonisid, lantosyd, corglicon, ergotal, flaming, plantaglyucyd. Quality control.
44. Preparations from fresh plant material. Features of extraction of fresh plant material. Production methods. Quality control. Nomenclature.
45. Biostimulators. Characteristics. Classification.
46. Classification of hormonal and enzyme preparations. Characteristics. Production methods. Nomenclature, use.
47. Pressurized preparations. Classification. Characteristics. Production methods. Process flow diagram for manufacture of preparations in aerosol containers. Quality control in accordance with requirements of State pharmacopoeia of Ukraine. Propellants, classification, use.
48. Current approaches to manufacture of biotechnological preparations. Microbiological synthesis. Methods of purification and concentration. Crystallization and drying of biosynthesis products. Apparatus. Quality control.
49. Pediatric preparations. Geriatric preparations. Manufacturing features.
50. New dosage forms.

12. The scheme of calculation and distribution of points that students gain

The knowledge of a student is assessed by the marks using a 4-point (traditional) scale and considering the approved criteria. Student must receive a mark for each topic.

The results of the current control are considered to be an indicator of the student's learning level of the discipline program and conducting tasks for independent work. The results of the current control are the basic information to determine the mark for credit and amount to 60% when determining the final mark for the discipline.

A maximum score that student can achieve for current learning activities is 120.

A minimum score – not less than 72.

Scaled score is calculated by finding the arithmetic mean of the traditional marks (AM) for each topic that is rounded to second decimal. The AM is converted into the grade points using formula and a 200-point grading scale given in a table:

$$X = \frac{AM \times 200}{5}$$

Converting the average mark for current learning activities into the grade points

4-point scale	200-point scale	4-point scale	200-point scale	4-point scale	200-point scale	4-point scale	200-point scale
5	120	4.45	107	3.91	94	3.37	81
4.95	119	4.41	106	3.87	93	3.33	80
4.91	118	4.37	105	3.83	92	3.29	79
4.87	117	4.33	104	3.79	91	3.25	78
4.83	116	4.29	103	3.74	90	3.2	77
4.79	115	4.25	102	3.7	89	3.16	76
4.75	114	4.2	101	3.66	88	3.12	75
4.7	113	4.16	100	3.62	87	3.08	74
4.66	112	4.12	99	3.58	86	3.04	73
4.62	111	4.08	98	3.54	85	3	72
4.58	110	4.04	97	3.49	84	less than 3	not enough

A maximum score that student can achieve for the exam is 80.

A minimum score that student can achieve for the exam is not less than 50.

DETERMINATION OF THE NUMBER OF POINTS THAT THE STUDENT HAS RECEIVED FOR THE DISCIPLINE

Student discipline score is calculated by summing the grade points for current learning activities (not less than 72) and the grade points for exam (not less than 50).

A maximum score that student can achieve for the exam is 200.

A minimum score - not less than 122.

Grade points are converted to the corresponding ECTS grade and the mark of 4-point scale. ECTS grade points are not converted into grades of 4-point scale and conversely.

The scores of the students who study on the same specialty with consideration of the discipline scores are ranked into ECTS grades as follows:

ECTS grade	Statistical indicator
A	The best 10 % of students
B	The next 25 % of students
C	The next 30 % of students
D	The following 25 % of students
E	The weakest 10 % of students

Points for discipline for students who successfully completed the program are converted into traditional 4-pointed scale by absolute criteria listed in the table below:

Points for discipline	**Mark according to the 4-point scale**
from 170 till 200 points	5
from 140 till 169 points	4
From 139 points to minimal number of points that student must score	3
Below the minimum number of points that the student must score	2

The ECTS grade is not converted to the traditional scale, as the ECTS scale and the 4-point scale are independent.

The objectivity of the evaluation of students' educational activity is checked by statistical methods (correlation coefficient between the ECTS grade and the grade by the national scale).

13. Methodological support:

- Lecture material (multimedia presentations, lecture texts, schedules of lectures).
- Schedules of laboratory classes.
- Questions for independent work.
- Tests for control work on each topic of the discipline.
- Videofilms.
- Internet resources.
- Methodical guides on technology of medicinal products in pharmacy and industrial technology of medicines.
- Methodical recommendations for self-training of students of the Faculty of Pharmacy for the licensed integrated examination "Step 2. Pharmacy" on the formulated and industrial technology of medicines.
- Text-books on technology of medicinal products in pharmacy and industrial technology of medicinal products.

14. RECOMMENDED LITERATURE

Main (basic)

1. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128 с.

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3. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 3. – 732 с.
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5. Практикум з промислової технології лікарських засобів : навч. посіб. для студ. вищ. навч. закладів зі спеціальності «Фармація» / О.А. Рубан, Д.І. Дмитрієвський, Л.М. Хохлова та ін.; за ред. О.А. Рубан. – Х. : НФаУ ; Оригінал, 2015. – 320 с.
6. Практикум по аптечной технологии лекарств: учеб. пособие для студ. вузов / А.И. Тихонов, С.А. Тихонова, С.М. Мусоев и др.; под ред. А.И. Тихонова и С.А. Тихоновой. – Х.: Оригинал, 2016. – 462 с.
7. Про затвердження Інструкції із санітарно-протиепідемічного режиму аптечних закладів : наказ МОЗ України від 15.05.2006 р. № 275 // Офіційний вісник України від 2006. - № 47.
8. Про затвердження Інструкції по приготуванню в аптеках лікарських форм з рідким дисперсійним середовищем: наказ МОЗ України від 07.09.93 № 197 // Відомості Верховної Ради України, 1993.
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15. Information resources

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