

MINISTRY OF HEALTH OF UKRAINE

ODESA NATIONAL MEDICAL UNIVERSITY

Department of Pharmaceutical Chemistry and Drug Technology

APPROVED

Vice-rector for scientific and pedagogical work

Edward BURYACHKIVSKY

September 1st, 2024



**WORKING PROGRAM IN THE DISCIPLINE
«MANUFACTURING PHARMACEUTICAL PRACTICE IN DRUG TECHNOLOGY»**

Level of higher education: second (master's degree)

Field of knowledge: 22 «Health care»

Specialty: 226 «Pharmacy, industrial pharmacy»

Educational and professional program: Pharmacy, industrial pharmacy

The working program is based on the educational and professional program "Pharmacy, Industrial Pharmacy" for the training of specialists of the second (master's) level of higher education in specialty 226 "Pharmacy, Industrial Pharmacy" (protocol no. 10 of June 27, 2024).

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The working program is approved at the meeting of the Department of Pharmaceutical Chemistry and Drug Technology
Protocol No. 1 from "29 " August 2024

Head of the department

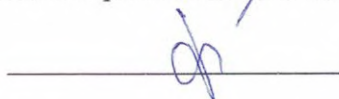
 Volodymyr GELMBOLDT

Approved by the guarantor of
the educational and professional program

 Liana UNHURIAN

Approved by the subject-cycle methodological commission on pharmaceutical disciplines
Protocol No. 1 from "30 " August 2024

Head of the subject-cycle methodological commission on pharmaceutical disciplines

 Natalia FIZOR

Revised and approved at the meeting of the department of pharmaceutical chemistry
Minutes No. ___ dated ___/___/20__.

Head of the department

Revised and approved at the meeting of the department of pharmaceutical chemistry
Minutes No. ___ dated ___/___/20__.

Head of the department

1. description educational disciplines :

Name indicators	Field of knowledge, specialty, specialization, higher level education	Characteristics of the educational disciplines
Total number: Credits: 12 Hours: 360 Content modules: 2	Branch of knowledge 22 "Protection health" Specialty 226 "Pharmacy, industrial pharmacy" Level of higher education second (master's degree)	<i>Full-time education Mandatory discipline</i>
		<i>Year preparation: 3, 4,</i>
		<i>Semesters V - VIII</i>
		<i>Lectures (70 hours)</i>
		<i>Practical (170 hours)</i>
		<i>Independent work (120 hours)</i>
		<i>Form of final control -diff. test exam</i>
		<i>Correspondence form teaching Mandatory discipline</i>
		<i>Year preparation: 4, 5</i>
		<i>Semesters VII – Kh</i>
		<i>Lectures (22 hours)</i>
		<i>Practical (48 hours)</i>
		<i>Independent work (290 hours)</i>
		<i>Form of final control -differentiated test exam</i>

2. Goal and task educational disciplines

Purpose : Mastery acquirer of knowledge and formation elements professional competencies in the field of pharmacy and industrial technology of drugs, acquisition and improvement practical skills, abilities and competences acquired during the study of previous disciplines in narrowly

Task:

1. Assimilation of the requirements of current regulatory documents (SPHU, GPP and current orders) to organizations production activity pharmacy of production medical means in different medical forms

2. Familiarization with organization production medical means in conditions pharmaceutical enterprises, according to with requirements Proper production practice (GMP).

3. Use of regulatory and legislative acts in professional activity of Ukraine, requirements proper pharmacy practice (GPP) and proper production practice (GMR) to production LZ in conditions pharmacy and industrial enterprises.

4. Formation in acquirers higher education of knowledge with: theoretical basics technologies production different species medical forms, carrying out constant control, ways improvement technologies medical forms in pharmacy and industrial conditions

5. Study impact conditions storage and type packaging on stability medical forms

6. Study of industrial equipment, including new, devices and automatic ones lines, modern requirements to production medical forms, including requirements Worldhealth care organization (WHO) to the purity of raw materials, production facilities and staff

Process study disciplines directional on formation elements the following competencies:

- GC01. Ability to abstract thinking, analysis and synthesis, to learn and be modern learned
- GC02. Knowledge and understanding objective region and understanding professional activity
- GC03. Ability communicate state language how orally Yes and in writing
- GC04. Ability communicate foreign language (mainly in English) on levels What provides effective professional activity.
- GC05. Ability evaluate and provide quality performed works
- GC06. Ability work in team
- GC10. Ability act socially responsibly and consciously.
- GC11. Ability apply knowledge in practical situations.
- GC12. Desire to preservation surrounding environment
- GC 13. Ability to show initiative and entrepreneurship
- GC14. Ability to adaptation and actions in new situation.
- GC15. Knowledge and understanding objective industry and understanding professional activity
- GC16. Ability carrying out experimental of research on corresponding levels
- GC17. Ability to approve decision and act, adhering to principle of inadmissibility of corruption and any other manifestations dishonesty

special (professional, substantive):

- PC01. Ability integrate knowledge and to solve complex tasks pharmacy in wide or multidisciplinary contexts.
- PC02. Ability collect, interpret and to apply data, necessary for professional activity, carrying out research and implementation of innovative projects in sphere pharmacy
- PC08. Ability to provide prescription and non-prescription counseling medicines and other products of the pharmacy assortment; pharmaceutical care under the time of selection and implementation of medicinal products of natural and synthetic origin by evaluations correlation risk/benefit, compatibility, from taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physical and chemical and chemical features, indications/contraindications for use based on data about the state of health of a particular patient.
- PC 09 The ability to provide pre-medical assistance to the sick and injured in extreme situations and emergencies.
- PC 12. The ability to ensure proper storage of medicinal products of natural and of synthetic origin and other products of the pharmacy assortment in accordance with them physical and chemical properties and rules Proper practice storage (GSP) in institutions health care.
- PC 16. Ability organize and carry out production activity pharmacy of production of medicinal products in various medicinal forms according to doctors' prescriptions and requirements (orders) curative and preventive institutions, including justification technologies and choice auxiliary materials in accordance to rules Proper pharmacy practice (GPP).
- PC 17. Ability to carry out pharmaceutical development and participate in production medical means natural and synthetic origin in conditions pharmaceutical enterprises according to with requirements Proper production practices (GMP).
- PC 24. Ability use in professional activity knowledge regulatory legal, legislative acts of Ukraine and recommendations of appropriate pharmaceuticals practitioner
- PC 25. Ability to demonstrate and apply in practical activity communication skills, fundamental principles of pharmaceutical ethics and deontology, What based on moral obligations and values, ethical norms professional behavior and responsibility in accordance to Ethical code pharmaceutical workers of Ukraine and WHO leadership.

- PC 26. The ability to organize and participate in the production of medicinal products conditions pharmaceutical enterprises, in particular choice and justification technological process, equipment according to with requirements Proper production practice(GMP) with appropriate development and execution of the necessary documentation. Determine stability of medicines.
- PC 31 Ability to carry out medical evacuation measures.

Software the results teaching (PLO)

- PLO01. Have and apply specialized conceptual knowledge in the field of pharmacy and adjacent industries with taking into account modern scientific achievements
- PLO03. Have specialized knowledge and skills/skills to solve professional problems and tasks, including for the purpose of further development of knowledge and procedures in the field pharmacy
- PLO04. Communicate freely in the national and English languages orally and in writing for discussion professional problems and results activities, presentations scientific of research and innovative projects
- PLO07. Collect the necessary information on the development and production of medicinal products means using professional literature, patents, databases and other sources; to systematize, analyze and evaluate it, in particular, using statistical analysis
- PLO19. Elaborate technological documentation of production medical means, to choose a rational technology, to manufacture medicinal products at various medical facilities forms according to doctors' prescriptions and requirements (orders) of medical and preventive medicine institutions, to issue their before vacation
- PLO20 – Carry out pharmaceutical development of drugs means natural and synthetic origin in conditions industrial production. PLO25. adhere to norms sanitary and hygienic regime and requirements techniques security at implementation professional activity
- PLO25. Observe the norms of the sanitary and hygienic regime and the requirements of safety equipment at carrying out professional activities.
- PLO27. To perform professional activities using creative methods and approaches
- PLO30. Follow norms communion in professional interaction with colleagues, management, by consumers, effectively work in team
- PLO36. Plan and implement professional activity on basis regulatory legal acts of Ukraine and appropriate recommendations pharmaceutical practitioner
- PLO38. Justify technology and organize production medical means at pharmaceutical enterprises and draw up technological documentation regarding production medical funds on pharmaceutical enterprises.
- PLO43. Organize necessary level individual security (own and persons about who are cared for) in the event of typical dangerous situations in an individual poly activity

Expected learning outcomes. As a result of studying the academic discipline the student must:

Know: GMP, GRP, other good pharmaceutical practices and regulatory requirements documents (orders, instructions, etc.) regarding the development and manufacture of medicinal products and execution of technological documentation; technology of pharmaceutical drugs; the main ones groups biologically active substances medical vegetable raw materials; stability and terms storage of medicines; biologically active and auxiliary substances of medicinal forms; pharmaceutical incompatibilities (physical, chemical, pharmacological), methods of their elimination; orders Ministry of Health of Ukraine regarding the release of narcotic, poisonous, intoxicating medicinal products and precursors, know the requirements to containers blocking means and packaging materials/

Be able:

- Use methods assessment indicators drug quality.
- Carry out production medical means in solid LF in conditions pharmacy and industry

- Carry out production medical means in soft LF in conditions pharmacy and industry
- Carry out production medical means in liquid LF in conditions pharmacy and industry
- Carry out production sterile not sterile medical means in conditions pharmacy and industry
- Carry out the production of medicinal preparations under pressure in industrial conditions, TTS and nano- and radiopharmaceuticals.
- Elaborate and to issue technological normative documentation of production (production) medical drugs in pharmacies and on pharmaceutical enterprises.
- Choose rational technology, production medical means in different medical forms by recipes doctors and orders medical institutions, to issue their to vacation Perform technological operations: weigh out, to measure dose various medical means by mass, volume etc.
- Justify technology production medical means on pharmaceutical enterprises.
- Conduct constant quality control medical means and packaging.
- Study influence factors surrounding environment on stability medical means
- Be able justified select necessary auxiliary substances to composition medical means, that are being developed.
- Objectively use advanced foreign pharmaceutical experience manufacturers in technologies production medical means in conditions pharmacy and industry
- Follow requirements ethics, bioethics and deontology in production medicines

To master skills:

- Be able to skillfully use pharmacy and industrial equipment with compliance everyone rules safety equipment.
- Be able plan and implement professional activity on basis regulatory legal Acts of Ukraine and recommendations proper pharmaceutical practitioner
- Choose a rational technology for the production of medicinal products from various pharmaceutical companies forms, conduct constant CONTROL medicines on to everyone stages production;
- Evaluate quality and stability semi-finished products and ready products.
- Carry out professional communion state language use skills oral communication in a foreign language, Latin, analyzing specialized texts and translate foreign languages information sources.
- Carry out professional activity using informative technology, "Information databases", navigation systems, Internet resources, software and others information and communication technologies.
- Adhere to the norms of communication in professional interaction with colleagues, management, consumers, effectively work in team

3. Content educational disciplines

Unit 1. Pharmacy technology medicines

Topic 1. State normalization production medicines in conditions pharmacy general question drug technology.

The main ones pharmaceutical and technological terms: medicine, pharmacy, technology medicine, medicinal product, medicinal raw material, medicinal form, medicinal substance, medicinal drug, etc. The main tasks of drug technology at the current stage and directions development Types of regulatory documents (pharmacopoeia, orders, instructions, etc.). Position Good pharmacy practice (GPP) and good manufacturing practice practice (NVP) (Good manufacturing practice (GMP)) of production medical drugs in pharmacy conditions. The requirements of the general article of the SPHU 5.N.1 "Extemporaneous medical means", SPHU 2.0 T.3 "Non-sterile medicinal products manufactured in pharmacies", Standard of the Ministry of Health of Ukraine "Requirements for the manufacture of non-sterile medicinal products in pharmacies" ST-N MOZ 42 – 4.5 : 2015, Standard Ministry of Health of Ukraine "Requirements to production sterile and aseptic medical means in conditions pharmacy" ST-N MOZ 42 – 4.6 : 2015. Requirements Pharmacopoeias USA and international convention PIC/S to production medicines in conditions pharmacy: conditions manufacturing, equipment, drug stability, primary packaging. Requirements of the National Academy

of Sciences regarding production of non-sterile dosage forms in pharmacies (requirements⁷ for technological process, documentation; medicinal and auxiliary substances; packaging; internally pharmacy control qualities of extemporaneous medical drugs).

Stability extemporaneous medical means: definition, species factors, What affect on stability medical drugs Classifications medical forms:dispersal, by aggregate state in dependencies from way use and ways introduction.

Recipe, its value. Structure recipe Regulations discharge recipes according to regulatory documents (orders Ministry of Health of Ukraine). rights and responsibilities a pharmacist on relation to incorrectly written out recipes according to requirements order Ministry of Health of Ukraine.

Topic 2. Solid dosage forms. Production in the conditions of simple and complex pharmacies powders with medicinal substances, What are different prescribed quantity bulk by mass and structure particles

Production solid medical means in conditions pharmacy in accordance requirements NAP, ordersMinistry of Health of Ukraine and other regulatory documents. Characteristics of powders as medicinal shapes, their classification. Requirements SPHU to powders Methods prescription powders generalrules and stages of the technological process of manufacturing solid dosage forms in the conditions pharmacy Grinding; the main ones physical and chemical patterns, which affect on process grinding of powder ingredients. The degree of grinding of medicinal substances depends on medical appointment medicinal drug factors, which affect on order mix components at manufacturing complex powders Regulations production complex powders with medicinal substances prescribed in equal and different quantities. Rules for the introduction of medicinal substances with different physicochemical properties into the composition powders Technology powders with ingredients, What are different density, bulk mass, structure of particles (amorphous, fine-crystalline, coarse-crystalline) in the conditions of pharmacies. Rules for the selection of packaging material in accordance with physical and chemical properties powder components. Permissible deviations in the mass of individual doses of powders. Quality assessment powders in accordance with the requirements of DF and other ND. Packaging, processing before release,storage. Kinds incompatibilities in powders

Topic 3. Production in conditions pharmacy complex powders with poisonous narcotic and potent substances.

Regulations prescription poisonous, narcotics and powerful medical substances,order storage, vacation and application in compliance with requirements orders Ministry of Health of Ukraine. Audit disposable and per diem dose poisonous and powerful medical substances i powders Narcotic and psychotropic substances, What are used in technologies powdersand norms their disposable vacation Features production complex powders with poisonous, narcotic and potent medicinal substances prescribed for children(Less 0.05) quantities Internal pharmacies blanks (trituration). Characteristic, production, storage, using for production powders Rating qualities, packaging, design to vacation storage powders in compliance with requirements SPHU andothers ND

Topic 4. Production complex powders with colorful, fragrant and hard crushed substances

The list of coloring and odorous substances and their storage conditions according to the requirements of the order of the Ministry of Health of Ukraine. Features technologies powders with colorful substances Regulations introduction fragrant substances (menthol, thymol, camphor) to powders. Features of packing powders with volatile substances, What grind in presence auxiliary liquids; reasons using auxiliary liquids for improvement their dispersion Rating qualities, packaging, design to vacation storage powders with colorful, fragrant substances in accordance requirements SPHU and others ND (orders Ministry of Health of Ukraine).

Topic 5. Production of complex powders with extracts and semi-finished products.

Characteristics of the extracts used in powders, their classification according to the SPHU.Production solutions thick extracts, conditions and term their storage. Features technologies complex powders from dry, thick and solutions thick extracts. Using semi-finished products for production complex powders, their advantages Implementation means small mechanization in process production powders in pharmacies, mechanization of processes of mixing and dosing of powders in industrial conditions. The main ones signs instability solid medical forms

Topic 6. Production meetings in conditions of the pharmacy

Meetings: characteristics, classification and methods of their prescription. Technological stages

of the process of production of fees in the conditions of pharmacies. Rules for introducing various groups into the assembly medical substances (soluble in water, not soluble in water, ethereal oil, substances, soluble in ethanol). Technology dosed meetings Equipment, What is applied in production meetings in conditions pharmacy Rating qualities, packaging, design to vacation storage meetings in accordance with the requirements of the State Pharmacopoeia and other ND (orders Ministry of Health of Ukraine). Medicinal vegetable teas: definition, characteristic, application. Briquettes: definition, characteristic.

Topic 7. liquid medical forms Production concentrated solutions

Characteristics of solutions as dispersed systems, their classification. Getting cleaned water in a pharmacy. Purified water requirements in accordance with established standards State pharmacopoeia, instructions to orders Ministry of Health of Ukraine. Calculations quantity medicinal substances and water for the production of concentrated solutions in various ways: with using measuring utensils; taking into account the volume increase factor; taking into account solution density. Rules for making concentrated solutions for the burette system according to the instructions to the order of the Ministry of Health of Ukraine. Quality control of concentrated solutions, their conditions storage and accounting of prepared solutions in accordance with the orders of the Ministry of Health of Ukraine. Dosage by volume factors, What affect on precision dosage. Building burette systems, regulations care and use by her Types of incompatibilities in liquid medical forms

Topic 8. Production of liquid dosage forms by the mass-volume method dissolution dry medical substances and using concentrated solutions

Characteristics of liquid medicinal forms as dispersed systems, their classification, requirements to them Methods of prescribing and indicating concentrations of solutions. Checking the doses of poisonous and potent substances in mixtures. Rules for the production of liquid medicinal preparations from using concentrated solutions in compliance with instruction on cooking liquid medical forms in pharmacies, approved by order Ministry of Health of Ukraine. Production solutions containing up to 3% and more than 3% of dry medicinal substances, concentrated solutions which are absent. Addition to solutions of syrups, aromatic waters, galena and new galena medical means and in. Rating quality and storage liquid medical drugs in compliance with the requirements of regulatory documents, sealing and registration before release (orders Ministry of Health of Ukraine).

Topic 9. special cases production water solutions Drops.

Kinds difficult cases production water solutions, What most often meet in pharmacies: slow i hard dissolution or insolubility medical substances in prescribed solvent; decomposition substances, What light are oxidized; deterioration solubility at compatible presence Technological techniques, What allow overcome difficulty at cooking solutions: previous grinding substances and using warmed up solvent; using freshly driven water cleaned i appropriate auxiliary materials; addition of auxiliary substances and use of complex formation at cooking solutions; separate dissolution. Characteristic drops as medical forms, their classification by method of application. Verification of poisonous and potent doses substances in drops. Rules for making drops using concentrated solutions and by dissolution dry substances Technology drops on non-aqueous solvents. Eutectic formation mixtures Assessment of water quality and storage solutions and drops, clogging, design to vacation in accordance requirements regulatory documents, (orders Ministry of Health of Ukraine).

Topic 10 . Production of liquid dosage forms by diluting standard dosage forms pharmacopoeia liquids Non-aqueous solutions .

Nomenclature of standard pharmacopoeial liquids; their concentrations, chemical and conventional names Rules for calculating the amount of water and pharmacopoeial liquids depending on the method prescription accordingly instructions to order Ministry of Health of Ukraine. Production solutions pharmacopoeial liquids. Characteristics of non-aqueous solvents (ethyl alcohol, vegetable oils, petroleum jelly, glycerin, chloroform, esilon, dimexide, polyethylene oxide 400), requirements for them. Calculations for diluting ethyl alcohol using the formula dilution and alcoholometric tables Production solutions on volatile i non-volatile solvents. Regulations techniques security at robots with flammable i explosivesolvents. Assessment of the quality and storage of solutions in accordance with the requirements of regulatory documents, clogging and design to vacation (orders of the Ministry of Health of Ukraine).

Topic 11. Solutions Navy Colloidal solutions

Characteristic Navy, their classification and application in pharmacy Influence structures Navy on process dissolution limited i unlimited swelling substances Features production solutions pepsin, gelatin, starch, methyl cellulose, sodium carboxymethyl cellulose, vegetable extracts. Characteristic i properties colloidal solutions Technology of solutions of protected colloids (colargol, protargol, ichthyol). Regulations addition medical substances to solutions Navy i protected colloids Assessment quality i storage of IV solutions and colloids, preparation for release in accordance with the requirements of the orders Ministry of Health of Ukraine.

Topic 12. Suspensions.

Characteristics of suspensions as a dosage form and dispersion system; requirements for them. Factors affecting the stability of heterogeneous systems. Dispersion manufacturing method suspensions with hydrophilic medicinal substances. Characteristics of stabilizers and mechanisms their actions Features technologies suspensions hydrophobic substances Condensation method production of suspensions (chemical dispersion, solvent replacement). Potions are opalescent and muddy. The use of small-scale mechanization in the production of suspensions in the conditions pharmacy Assessment qualities suspensions, regulations blockages, design i storage in agreement with requirements ND

Topic 13. Emulsions.

Characteristics of emulsions as a dosage form and dispersion system, their classification. Requirements State pharmacopoeias to oil emulsion Types oil emulsion i methods their definition. Characteristics of emulsifiers, their classification and mechanism of action. General rules and methods production oil emulsion Stages technological process production emulsions Introduction of medicinal substances with different physico-chemical properties into the composition oil emulsions. Peculiarities of introduction of phenyl salicylate and sulfonamides. Quality assessment and storage emulsion, clogging, design to vacation in compliance with requirements SPHU and other ND (orders of the Ministry of Health of Ukraine). Means of small mechanization in the production of emulsions in conditions pharmacy

Topic 14. Infusions and decoctions with medical vegetable raw materials

Characteristics of infusions and decoctions as medicinal forms and dispersion systems. Methods prescription infusions i decoctions Theoretical foundations process extraction from vegetable medical raw materials factors, What affect on process extraction (ratio between quantity of raw materials and extractant, standard, histological structure and degree of detail raw materials, material funnel cakes, temperature, duration infusion i cooling, pH environment, chemical composition, etc.). Rules for making herbal infusions and decoctions raw materials i addition to them medical substances in agreement with requirements DF. Apparatus, What used in the technology of infusions and decoctions. Features of the production of water hoods from herbal medicinal raw materials containing alkaloids, cardioglycosides, essential oils, tannins substances, anthracene derivatives, saponins etc. special cases production infusions i decoctions ("double" infusions, decoctions from senna leaves, etc.). Author's prescriptions for water extracts (mixture Deryagin, Kvatera, Ravkina, etc.). Quality assessment, storage of water extracts, clogging and their registration before release in accordance with the requirements of the State Pharmacopoeia and other regulations documents (orders Ministry of Health of Ukraine). Kinds incompatibilities in water hoods

Topic 15. slime Technology RLF with using extracts-concentrates.

Characteristics of standardized extracts-concentrates for making infusions i decoctions, their nomenclature. The advantages of their use in the technology of water hoods. Regulations production of aqueous extractions using extracts-concentrates and introduction into them various medicines. Features of making extracts from raw materials containing mucus (althea root, flax seeds, etc.) and adding various medicinal substances to them. Assessment quality and storage of water extracts in accordance with the requirements of regulatory documents, sealing and processing before release (orders of the Ministry of Health of Ukraine). Improvement of technology water hoods

Topic 16. soft medical forms Liniments and ointments homogeneous

Characteristics of liniments as a dosage form and dispersion systems; their classification in dependencies from nature dispersive environment, physical and chemical properties ingredients and medical purpose. Rules for manufacturing liniments of various types of dispersed systems: solutions, suspensions, emulsions, combined. Pharmacopoeia prescriptions and difficult cases production

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liniments, their technology. Characteristic ointment as medical forms and dispersed systems, their classification (by medical destination place application, consistency and physical and chemical properties medical substances, What are included to composition ointments), requirements of the State Pharmacopoeia for them. Requirements for ointment bases, their classification. List ointments foundations, which are recommended by the SFU, the principles of their selection. Characteristic hydrophobic and hydrophilic basics The main ones technological stage and regulations production homogeneous ointments such as solutions, alloys. Pharmacopoeia prescriptions of ointments-solutions. Rating quality and storage liniments and ointment in accordance to requirements regulatory documents, packaging and registration before discharge (orders Ministry of Health).

Topic 17. Ointment heterogeneous

Characteristics of diphilic (hydrophilic-lipophilic) ointment bases and emulsifiers for their production. Characteristic suspension ointment and their technology. Official prescriptions suspension ointment Features introduction in dermatological ointments resorcinol and zinc sulfate. paste, their classification. Features production dermatological pastor Characteristic emulsion ointment different types and their production in dependencies from properties of medicinal and auxiliary substances. Rules for introducing protargol, tannin into ointments and plant extracts of various consistencies. Assessment of the quality of two-phase ointments, storage and design to vacation in agreement to requirements State pharmacopoeias, others regulatory documents (orders of the Ministry of Health of Ukraine).

Topic 18. Ointment combined Creams. Gels

Characteristic combined ointment and general regulations their production. Stages technological process of manufacturing multiphase ointments taking into account physico-chemical properties of medicinal substances. Biopharmaceutical aspects of ointments. The principle of selection of bases with taking into account medical appointment ointment The main ones rheological characteristics, as indicators qualities of ointments. Methods of quality control of combined ointments, their storage and design release in accordance with the requirements of the State Pharmacopoeia, other regulatory documents (orders of the Ministry of Health of Ukraine). Directions improvement ointment and liniments extemporaneous production. Characteristics of gels and creams. Modern bases for their production. Technology of creams and gels in conditions pharmacy Kinds incompatibilities in soft medical forms

Topic 19. Suppositories. Production suppositories method rolling out Sticks Pills

Characteristics of suppositories as a dosage form and as a dispersion system. Classification suppositories Requirements of the State Pharmacopoeia for them. Ways of prescribing suppositories; audit dose poisonous and powerful medical substances in them Pharmacopoeia prescriptions and difficult cases Production of liniments, their technology. Bases for suppositories; requirements, presented to them, and a brief description. Peculiarities of prescription of sticks and calculation of the basis for them. Characteristics of the technological stages of manufacturing suppositories by the rolling method. Rules for the introduction of medicinal substances with different physico-chemical properties properties in the basis; peculiarities of introduction of protargol, kolargol, tannin, dry and thick extracts. Methods of assessing the quality of suppositories, packaging, registration before release, rules storage in accordance with the requirements of regulatory documents, relevant instructions (orders of the Ministry of Health of Ukraine). Characteristics of pills as a dosage form. Definition. Characteristic. Requirements to them Excipients used in pill technology, their characteristics (thick and dry extracts, powders, starch-sugar mixture, bentonites, etc.). Their principle selection depending ed chemical nature medical substances Stages production the pill Definition incompatibilities in pills Assessment quality pill: homogeneity, decay, deviation from the average mass, etc. Packaging, storage conditions. Cases of incompatibilities in pills

Topic 20. Production suppositories method outpouring

Composition i properties official suppositories basics, which are used at methods outpouring. Calculations quantity suppositories basics for Production candle, balls and sticks by pouring method. Concept of substitution coefficients. Bases for suppositories; requirements for them and a brief description. Characteristics of technological stages of manufacturing suppositories by pouring method. Rules for administration of medicinal substances with different physico-chemical properties

into bases when using the pouring method. Comparative assessment methods Production¹¹ suppositories (rolling, outpouring, pressing). Biopharmaceutical aspects of suppositories, principles of selection of excipients for their Production. Rating quality suppositories, packaging, design to vacation conditions storage according to requirements regulatory documents (orders of the Ministry of Health of Ukraine).

Topic 21. Requirements for the manufacture of sterile and aseptic medicinal products conditions of pharmacies

Requirements proper pharmacy practice of production sterile and aseptic dosage forms in pharmacies. Aseptic conditions for the manufacture of medicinal products. Order control by compliance sanitary and anti-epidemic regime in pharmacy institutions Requirements

to premises, equipment and sanitary and hygienic requirements at manufacturing medical means in aseptic conditions. Requirements for personal hygiene of the staff of pharmacy establishments, which carry out production medical means in aseptic conditions Characteristic solvents, What are used for Production injectable medical forms Obtaining, storing and quality control of water for injections. Requirements for medicinal products and auxiliary substances used for the production of medicines in aseptic conditions. Non-aquatic solvents. Fatty oils, requirements for them and preparation before use.

Requirements for taro-clogging materials used for production medicines in aseptic conditions Classification methods sterilization Thermal methods sterilization and the equipment used for this. Procedure for controlling temperature modes of operation sterilizers. Modes sterilization individual objects and order registration results of sterilization in relevant journals. Requirements for sterile and aseptic quality control medical forms Kinds documentation, which is being conducted at cooking individual and serially made medical means (general technological instructions, technological instructions for drugs individual and mass production, production records).

Requirements GMP to production sterile products (preparation air environment, staff, clothing, equipment, premises).

Topic 22. Solutions for injections

Characteristic injectable medical forms; requirements, What are put forward to them State pharmacopoeia and their realization. Aseptic conditions Production medical means Characteristic solvents, What are used for Production injectable medical forms Obtaining, storing and quality control of water for injections according to the requirements of the State Pharmacopoeia of Ukraine. Requirements for medicinal products and taro - sealing materials, which are used for production injectable drugs Technological stages Production of solutions for injections. Filtering solutions and checking for their absence mechanical impurities. Sterilization methods and equipment used for this purpose. Assessment qualities solutions for injections, clogging, design to release and storage in compliance with requirements State pharmacopoeias and appropriate instructions (orders Ministry of Health of Ukraine).

Topic 23. Solutions for injections, What need stabilization

Causes of destruction (decomposition) of medicinal substances in solutions for injections. Characteristics of stabilizers used for the manufacture of injectables solutions; their classification. Principles selection stabilizers i calculation their quantity Stabilization solutions medical substances, What surrender hydrolysis and saponification Antioxidants, their classification. Stabilization solutions substances, What light are oxidized Features of production of glucose and sodium bicarbonate solutions for injection. Rating quality solutions for injections, clogging, design their to vacation and storage (orders Ministry of Health of Ukraine).

Topic 24. Isotonic and infusion solutions. Solutions for injections with thermolabile substances Suspensions for injections

Value toning solutions for injections. Methods calculation isotonic concentrations with using equivalents by sodium chloride, laws Raul (cryoscopic method), Van't-Hoff and the Mendeleev-Clapeyron equation. Principles of selection of isotonic substances i general technological techniques Production isotonic solutions Infusion (physiological) solutions; requirements of the State Pharmacopoeia and other regulatory documents to them Classification infusion solutions by their medical destination and composition Nomenclature of the most frequently used plasma-substituting and anti-shock solutions in the form of ready-made medicinal forms. Features of the technology of infusion solutions in dependence from the composition of active substances. Rules for making

solutions for injections with thermolabile ones substances and suspensions for injections. Assessment of the quality of solutions, clogging, their design to vacuum and storage (orders Ministry of Health of Ukraine). Requirements isotonicity, isohydria, isoions, redox potential of solutions. Powders and tablets for sterile solutions Their features technologies, lyophilization.

Topic 25. Eyes medical forms

Characteristic medical forms, What are used for treatment eye diseases (drops, lotions, washes, ointments, suspensions, powders); requirements for them in compliance with State pharmacopoeia. Isotonization eye drops, lotion, washings Prolongation of the effect of eye drops. Features of the technology of eye drops depending on physical and chemical properties medical substances Regulations production lotion and washings Modern species ophthalmological medical forms Requirements SPHU and valid orders to them Eyes medical inserts, characteristic, nomenclature, requirements to them Characteristic basics, which are used for production eye ointment Technology eye ointment, features introduction to composition eye ointment zinc sulfate and resorcinol

Topic 26. Medicinal forms with antibiotics

Characteristics of dosage forms with antibiotics; the demands placed on them and factors What affect on their stability. Features technologies liquid i solid medical forms with antibiotics (lotions, washes, rinses, eye and ear drops, powders and etc.). Technology ointment and suppositories with antibiotics; characteristic basics for their production. Evaluation of the quality of ophthalmic dosage forms and dosage forms with antibiotics, sealing, preparation for release and storage. Characteristics of bases and solvents for medical forms with antibiotics. Thermolabile and thermostable antibiotics.

Topic 27. Children's and geriatric medical forms

Medicinal forms for infants and children up to 1 year. Characteristics of children's medicines forms Requirements to them Conditions production medical forms for babies and children to 1 year in pharmacies. Features of medicines for the treatment of elderly people. Medicinal shapes, that have advantages in geriatrics.

Subsection 2. Industrial technology of medicines. Topic 28. Normative documentation in production GLZ

The main one activity Ministries protection health of Ukraine and State pharmacological center Normative documents in Ukraine. The main ones principles systems registration Registration dossier. Protocols production, validation forms and cards. Categories regulatory documentation in the industrial production of medicinal products according to the rules GMP. Basic terms used in the production of medicinal products. The goal is value material balance sheet; regulations its drafting on to each stage production; calculation its main indicators.

Topic 29. Requirements for sterile products. Determination of the main quality indicators ampoule glass

Requirements for sterile products. Glass for making ampoules and vials, its classes and brands The main ones requirements and indicators quality ampoule glass Preparation fiberglass, methods washing ampoules, study of stability of ampoules.

Topic 30. Industrial production injectable solutions

The main principles of good manufacturing practice of medicinal products (GMP), requirements for production of sterile products. Classification of clean rooms, cleanliness classes. Water for injections, requirements, equipment, CONTROL. Production injectable drugs without and with stabilizers, aseptically made, on non-aqueous solvents and others Methods stabilization, isotonization, purification of solutions, types of filters. Methods of filling ampoules, modern methods fillings ampoules and definition their tightness Sterilization injectable solutions, CONTROL their sterility CONTROL quality injectable solutions Technological scheme production; the equipment used.

Topic 31. Industrial production infusion solutions

Characteristic infusion solutions, using. Classification and requirements to infusion solutions Prospects development infusion solutions, assortment domestic and foreign medicines. Production of infusion solutions. Their quality control. Technological scheme production; equipment, that is used

Topic 32. Industrial production ocular, ear and nasal medical forms

The main ones characteristics ocular, ear and nasal medical forms Methods their manufacturing, equipment used. Physico-chemical and biological features creation, prolongation. Quality control. Technological schemes of eye, ear production and nasal medical drugs

Topic 33. Theoretical foundations extraction

Theoretical foundations of extraction. Stages of extraction and their characteristics. factors, which affect on completeness and extraction rate. Requirements to extractants

Topic 34. Production tincture Spiritometry

Characteristic and classification tincture Methods their production and cleaning. Technological scheme production, equipment, What is used CONTROL quality tincture as a medicinal form, packaging and storage conditions. Methods of ethanol production (from raw materials containing starch, carbohydrates, synthetically). Rules of determination concentration alcohol, dilution and accounting using alcohol The main ones principles recoveryand ethanol rectification.

Topic 35. Production extracts liquid

Characteristic and classification extracts. The main ones stage production liquid extracts. Technological scheme of production, equipment used. CONTROL quality liquid extracts.

Topic 36. Production extracts thick and dry Intensification processes extraction

Production of thick extracts. Theoretical foundations of the evaporation process, equipment and the principle of its operation. Production of dry extracts. Theoretical foundations of the drying process, equipment, What is used Technological schemes production thick and dry extracts. Standardization extracts, packaging and conditions storage. Methods intensification obtaining extracted from vegetable raw materials.

Topic 37. Production drugs under pressure

Classification aerosols, advantages and disadvantages The main ones components aerosol packages, types of valve-spray system, classification of propellants and aerosols concentrates. Production aerosols, CONTROL quality according to SPHU Technological scheme production; the equipment used.

Topic 38. Physico-chemical and technological properties powders and granules.

Study physical and chemical and pharmaco-technological properties powders and granules. Their impact on the technology of obtaining solid dosage forms. Theoretical foundations tableting

Topic 39. Production of tablets by the method of direct pressing and with the previous one granulation

Industrial production tablets from application direct pressing and previous granulation Study equipment for carrying out grinding, screeningand mixing of raw materials, the principle of its operation. Granulation methods; equipment that is used Auxiliary substances in production tablets Technological scheme production

Topic 40. Industrial production tablets covered shell CONTROL qualityCoating tablets shells Kinds coating and methods causing. pressed, teased and film shells Technological scheme production pills, coveredshells; equipment, What is used Production tablets prolonged actions, auxiliary substances for provision of extension. CONTROL the quality of tablets according to requirements
SPHU

Topic 41. Production medical capsules

Definition of capsules, requirements of the SPHU for them. Types of capsules and their purpose. Auxiliary substances in production capsules Methods production soft and solid gelatinous capsules, filling them with medicinal substances. Quality control according to SPHU. Tubatyn Sponsored Rectal gelatinous capsules. Technological aspects production capsules with modified release of active substances. Technological scheme of production of soft and solid gelatinous capsules; equipment that is used

Topic 42. Industrial production of soft medical means

Ointments, gels, paste, creams, liniments as medical shapes, their characteristic and classification. Advantages and disadvantages. Requirements for ointments, classification of bases and general requirements. Auxiliary substances in production soft medical forms Technological schemes productionsoft medical forms; equipment, What is used Structural and mechanical(rheological) characteristics ointment CONTROL quality according to with SPHU Packaging and marking

Topic 43. Industrial production suppositories

Suppositories, types and requirements for them. Characteristics of bases and auxiliary substances. Manufacturing methods. Technological scheme of production; the equipment used.

CONTROL the quality of suppositories according to the SFU.

Topic 44. Production plasters and TTS.

Classification plasters Auxiliary substances, What are used at their production Technological scheme production; equipment, What is used CONTROL quality plasters An alternative method of drug administration is transdermal therapeutic systems (TTS). Types and categories of TTS. Requirements for active substances included in TTS. Building membrane and matrix TTS. Auxiliary substances used in the creation TTS. Quality indicators TTS. Technology improvement of TTS.

Topic 45. Production nano- and radiopharmaceuticals drugs

Production and use of radiopharmaceuticals. Assortment and composition radiopharmaceuticals drugs on pharmaceutical market of Ukraine. Features their technologies and control quality Using nanotechnologies in production medical drugs Basic principles and directions of nanotechnology. Nanopreparations. Their features production Carriers for drug transport (liposomes, nanospheres, nanocapsules, colloidal carriers with monoclonal antibodies, etc.).

4. Structure educational disciplines

Names topics	Number hours daytime form teaching					Number hours extramural form teaching				
	That's all	in ago number of				That's all	in ago number of			
		lectures	seminars	practical	SRS		lectures	seminary	practical	SRS
Contentful module 1. Pharmacy technology medicines										
Topic 1. State normalization production medicines in conditions pharmacy General questions technologies medicines	6	2	0	2	2	9	1	0	1	7
Topic 2. Solids dosage forms. Production in conditions of pharmacies simple ones and complex powders from medicinal substances that are different prescribed amount, bulk mass and structure of particles.	8	2	0	4	2	7.25	0.25	0	1	6
Topic 3. Production in conditions of pharmacies complex powders with poisonous narcotic and powerful substances.	4.5	0	0	2	2	6.75	0.25	0	0.5	6
Topic 4. Production complex powders with colorful, fragrant and difficult crushed substances	4	0	0	2	2	6.75	0.25	0	0.5	6

Topic 5. Production complex powders with extracts and semi-finished products .	4	0	0	2	2	6.75	0.25	0	0.5	6
Topic 6. Production meetings in conditions pharmacies	4	0	0	2	2	4.5	0	0	0.5	4
Topic 7. Liquids dosage forms. Production of concentrated solutions	6	2	0	2	2	7.5	0.25	0	0.25	7
Topic 8. Production liquid medicines forms by mass and volume by method dissolution of dry medicinal substances and using concentrated solutions	6	0	0	2	4	7.5	0.25	0	0.25	7
Topic 9. special cases production water solutions Drops.	2	0	0	2	0	4.75	0.25	0	0.5	4
Topic 10. Production liquid medical forms by dilution standard pharmacopoeia liquids Non-aqueous solutions	4	0	0	2	2	6.75	0.25	0	0.5	6
Topic 11. Solutions Navy Colloidal solutions	7	1	0	4	2	5	0.5	0	0.5	4
Topic 12. Suspensions.	7	1	0	4	2	5.5	0.5	0	1	4
Topic 13. Emulsions.	7	1	0	4	2	5.5	0.5	0	1	4

Topic 14. Infusions and decoctions of medicinal plant raw materials.	4	2	0	2	0	6	1	0	1	4
Topic 15. Mucus. RLF technology using extracts-concentrates.	6	2	0	2	2	7	0	0	1	6
Topic 16. Soft dosage forms. Liniments and ointments homogeneous	8	2	0	4	2	9.5	0.5	0	2	7
Topic 17. Heterogeneous ointments.	7	1	0	4	2	5.25	0.25	0	1	4
Final control #1	2	0	0	2		0	0	0	0	0
Topic 18. Ointments combined Creams. Gels.	7	1	0	4	2	7.25	0.25	0	1	6
Topic 19. Suppositories. Production of suppositories by the rolling method. Sticks Pills	8	2	0	4	2	7.25	0.25	0	1	6
Topic 20. Production of suppositories by pouring method	6	0	0	4	2	7.25	0.25	0	1	6
Topic 21. Requirements for the manufacture of sterile and aseptic medicinal products in pharmacies.	5	2	0	2	1	7.5	0.5	0	1	6
Topic 22. Solutions for injections.	5	1	0	2	2	7.5	0.5	0	1	6

Topic 23. Solutions for injections that require stabilization	7	2	0	4	1	6.5	0.5	0	1	5
Topic 24. Isotonic and infusion solutions. Solutions for injections with thermolabile substances. Suspensions for injections	7	1	0	4	2	3.5	0.5	0	1	2
Topic 25. Eyes dosage forms	8	2	0	4	2	3.5	0.5	0	1	2
Topic 26. Medicinal forms with antibiotics	6	1	0	4	1	8.25	0.25	0	1	7
Topic 27. Children's and geriatric medicine forms	11	1	0	6	4	4.25	0.25	0	2	2
Final CONTROL No. 2	2	0	0	2	0	0	0	0	0	0
Preparation to offset offset	6	0	0	0	6	6	0	0	0	6
In total hours for content module 1:	180	30	0	90	60	180	10	0	24	146
Contentful module 2. Industrial technology medical means										
Topic 28. Normative documentation in production RM	4	0	0	2	2	11	0	0	1	10
Topic 29. Requirements to sterile products Definition basic quality indicators ampoule glass	10	2	0	4	4	11.5	0.5	0	1	10

Topic 30. Industrial production of injectable solutions	10	2	0	6	2	8	1	0	1	6
Topic 31. Industrial production of infusion solutions	8	2	0	4	2	5.5	0.5	0	1	4
Topic 32. Industrial production of eyeglasses, ear and nasal medical forms	11	2	0	4	2	9	1	0	2	6
Topic 33. Theoretical foundations of extraction	6	2	0	0	4	11.5	0.5	0	1	10
Topic 34. Production of tincture. Spiritometry.	10	2	0	4	4	6.5	0.5	0	1	5
Topic 35. Production of extracts liquid	9	1	0	6	2	9.5	0.5	0	1	8
Topic 36. Production of extracts thick and dry Intensification of processes extraction	7	1	0	4	2	9.5	0.5	0	1	8
Topic 37. Production drugs under pressure Characteristics, structure of aerosol packaging. Propellants. Medical sprays. Technology of aerosol systems. Standardization of storage of drugs under pressure.	1	4	0	4	2	5	1	0	0	4
Final control No. 3	2	0	0	2	0	0	0	0	0	0
Topic 38. Physico-chemical and technological properties powders and granules.	11	2	0	4	4	7.5	0.5	0	2	5
Topic 39. Production tablets method direct pressing and with the previous one granulation .	14	4	0	6	4	7.5	0.5	0	2	5
Topic 40. Industrial production tablets covered shell. Control quality.	12	2	0	6	4	11.5	0.5	0	1	10
Topic 41. Production medical capsules	10	2	0	6	2	11.5	0.5	0	1	10
Topic 42. Industrial production of soft medical means	12	4	0	6	2	11	1	0	2	8
Topic 43. Industrial production of suppositories	13	2	0	6	2	7.5	0.5	0	2	5

Topic 44. Production of plasters and TTS.	13	4	0	4	4	9.5	0.5	0	2	7
Topic 45. Production of nano- and radiopharmaceuticals them drugs.	11	2	0	4	4	12	1	0	2	9
Final control No 4/	2	0	0	2	0	0	0	0	0	0
Preparation for the exam	6	0	0	0	6	6	0	0	0	6
In total hours for content module 2:	<i>180</i>	<i>40</i>	<i>0</i>	<i>80</i>	<i>60</i>	<i>168</i>	<i>12</i>	<i>0</i>	<i>24</i>	<i>144</i>
Total hours:	360	70	0	170	120	360	22	0	48	290

5. Topics lectures / seminary / practical / laboratory classes

5.1. Topics lectures classes

No	Name topics	How many hours	
		Daily	Correspondence
1.	State normalization production medicines in conditions pharmacy general question technologies medicines	2	1
2.	Solid medical forms Technology powders with medicinal substances that differ in the prescribed quantity, in bulk by mass and structure particles Technology powders with poisonous and powerful substances. Technology of powders with dyes, fragrant, hard crushed substances and extracts.	2	1
3.	Liquid medical forms Technology concentrated solutions and mixture Technology drops, solutions SFR, non-aqueous solutions special cases production water solutions Technology drops	2	1
4.	Technology solutions Navy Technology colloidal solutions	2	1
5.	Technology suspensions Technology emulsions	2	1
6.	Aqueous extracts from medicinal plant raw materials-infusion Features of production.	2	1
7.	Decoctions from medicinal plant raw materials. liquid LZ with using extracts-concentrates. slime	2	1
8.	Soft dosage forms. Liniments. Homogeneous ointments, production technology, features.	2	1
9.	Heterogeneous ointments - general rules for manufacturing suspension and emulsion ointments; pasta; combined ointments.	2	0
10.	Suppositories method rolling out and outpouring.	2	0.5
11.	Requirements for the manufacture of sterile and aseptic medicinal products in pharmacies. Organization of work in aseptic conditions. Technology of parenteral drugs.	2	
12.	Solutions for in ' ections isotonic and infusion solutions , technology production	2	2
13.	Solutions for injections with thermolabile substances. Suspensions for injections.	2	0
14.	Eyes medical forms: drops, ointments, eye lotions, washes, suspensions, emulsions. Manufacturing technology.	2	0.5
15.	Medicinal forms with antibiotics Children's and geriatric medical forms Incompatibilities.	2	
16.	Medicines for parenteral use. Creation of conditions for sterile production. Preparation of containers and sealing means (ampoules, vials).	2	2

17.	Requirements for raw materials and solvents (production of water for injections in industrial conditions). Preparation of parenteral solutions (isotonization , stabilization).	2	0
18.	Filtration, sterilization of parenteral solutions. Quality control of these tools.	2	0
19.	Industrial production ophthalmic medicinal forms. Production technology of eye drops, lotions, sprays, soft medicines, inserts. Ear dosage forms.	2	1
20.	Extractive preparations. Stages of extraction. Requirements for extractants.	2	2
21.	Extraction methods (maceration, remaceration, percolation, flow extraction, circulation extraction.). Extraction with liquefied gases.	2	0
22.	Tinctures. Production of thick, dry extracts. Extracts-concentrates	2	0
23.	Production drugs under pressure Characteristics, structure of aerosol packaging. Propellants.	2	1
24.	Medical sprays. Technology of aerosol systems. Standardization of storage of drugs under pressure.	2	
25.	Physico-chemical and technological properties powders and granules.	2	1
26.	Tablets, characteristics and classification. Direct pressing.	2	0
27.	Tablets. Granulation. Types of tablet machines	2	0
28.	Covering tablets with shells. Pellets pellets Dragee.	2	2
29.	Production of medical microcapsules. Methods of microencapsulation.	2	0
30.	Soft medicines . Characteristics , classification. Ointment bases, auxiliary substances.	2	1
31.	Technology of homogeneous and heterogeneous ointments. Standardization, packing, packaging.	2	
32 .	Industrial production suppositories	2	0.5
33 .	Production of medical plasters, characteristics, classification, industrial production . Mustard seeds	2	0.5
34.	Transdermal therapeutic systems. General characteristics, classification, systems with controlled release.	2	
35.	Production nano- and radiopharmaceuticals drugs	2	1
	In total hours:	70	22

5.2. Topics practical classes

5.2.1. Full-time education

No	Topic	How many hours
Unit 1. Pharmacy drug technology		
1	State regulation of the manufacture of medicines in pharmacies. General issues of drug technology.	2
2.	Solid dosage forms. Preparation of simple and complex powders with medicinal substances in pharmacies that differ in the prescribed amount, bulk weight and particle structure.	4
3	Production of complex powders with toxic and potent substances. Trituration.	2
4	Production of complex powders with colored, odorous and difficult to grind substances.	2
5	Production of complex powders with colourful, odorous and difficult to	2
6	Preparation of preparations in a pharmacy.	2
7	Liquid dosage forms. Preparation of concentrated solutions.	4
8	Preparation of liquid dosage forms by the bulk method by dissolving dry medicinal substances and using concentrated solutions.	2
9	Special cases of preparation of aqueous solutions. Drops.	2
10	Manufacturing of liquid dosage forms by diluting standard pharmacopoeial liquids. Nonaqueous solutions.	2
11	Intravenous solutions. Colloidal solutions.	4
12	Suspensions.	4
13	Emulsions.	4
14	Infusions and decoctions of medicinal plant materials.	2
15	Mucus. MF technology using extracts-concentrates.	2
16	Soft dosage forms. Liniments and ointments are homogeneous.	4
17	Ointments are heterogeneous.	4
18	Solving situational and test tasks on state regulation of drug production in pharmacies, General issues of drug technology; Special cases of production of aqueous solutions, drops, HMW solutions, colloidal solutions, suspensions, emulsions, infusions and decoctions from medicinal plant raw materials, slimes, soft medicinal forms, liniments and ointments.	2
19	Combined ointments. Creams. Gels.	4
20	Suppositories. Making suppositories by rolling out. Sticks. Pills.	4
21	Manufacturing of suppositories by pouring.	4
22	Requirements for the manufacture of sterile and aseptic medicines in pharmacies. Solutions for injection.	4
23	Solutions for injection that require stabilisation.	4
24	Isotonic and infusion solutions. Solutions for injection with thermolabile substances. Suspensions for injection.	4
25	Eye dosage forms.	4
26	Dosage forms with antibiotics.	4
27	Children's and geriatric dosage forms.	4
28	Solving situational and test tasks for the production of combined ointments, creams, gels, suppositories, pills, sterile and aseptic drugs in the conditions of pharmacies, solutions for injections, suspensions for injections, ophthalmic dosage forms, dosage forms with antibiotics, children's and geriatric medicinal forms.	4
Total hours in the unit Pharmacy technology of drugs		90
Sub-unit 2. Industrial technology of medicines		
29	Regulatory documentation in the production of medicinal products.	2
30	Requirements for sterile products. Determination of the main quality indicators of ampoule glass.	4

31	Industrial production of injectable solutions.	6
32	Industrial production of infusion solutions.	4
33	Industrial production of eye, ear and nasal dosage forms.	4
34	Production of tinctures. Alcoholometry.	4
35	Production of liquid extracts.	6
36	Production of thick and dry extracts. Intensification of extraction processes.	4
37	Production of preparations under pressure.	4
38	Solving situational and test tasks on Industrial production of injection solutions, infusion solutions, ophthalmic dosage forms, ear and nasal dosage forms; Production of tinctures, liquid extracts, thick and dry extracts, preparations under pressure; Alcoholometry.	2
39	Physical, chemical and technological properties of powders and granulates.	4
40	Production of tablets by direct pressing and with preliminary granulation.	6
41	Industrial production of coated tablets. Quality control.	6
42	Production of medical capsules.	6
43	Industrial production of soft medicines.	6
44	Industrial production of suppositories.	4
45	Production of patches and TTS.	4
46	Production of nano- and radiopharmaceuticals.	2
47	Solving situational and test tasks on the Physico-chemical and technological properties of powders, granules; Production of tablets, tablets by direct pressing and pre-granulation, plasters and TTS, nano- and radiopharmaceuticals; Industrial production of coated tablets, medical capsules, soft drugs, suppositories.	2
Total hours in the subdivision Industrial technology of medicines		
Total hours		170.0

5.2.2. Correspondence form teaching

No	Topic	How many hours
1.	Introductory examination on the topics: "Preparation of complex powders. Trituration. Suspensions and emulsions Infusions and decoctions." Dosage medical means by by mass Building and audit trays and manual weight Features dosage medical means by by mass depending from their consistency	2
2.	Powders Preparation complex powders Trituration. Technology powders with powerful and poisonous substances, extracts, semi-finished products, fragrant and colorful substances Rating quality powders .	2
3.	Preparation mixture with using concentrated solutions and by dissolving dry medicinal substances prescribed in different quantities. Rating qualities of mixtures. Non-aqueous solutions (alcohol, glycerin, oil). Preparation of spirit solutions and water solutions standard pharmacopoeia liquids Rating quality Solutions high molecular weight compounds, features their technologies in dependencies from structures macromolecules Solutions protected colloids	2
4.	Suspensions and emulsions for internal application. Preparation suspensions dispersive and condensing methods. Preparation emulsions with using different emulsifiers Rating quality suspensions and emulsions	2

5.	Infusions and decoctions. Preparation of water extracts from plant raw materials, which contains alkaloids, cardiac glycosides, saponins, tannins, mucus Preparation infusions and decoctions from extracts-concentrates. Rating quality infusions and decoctions	2
6.	Entrance control on topics: "Medical shapes, What require asepticcooking conditions Difficult and incompatible combinations of ingredients." Liniments. Preparation homogeneous, suspension, emulsion and combined liniments Rating quality liniments	2
7.	Ointment Preparation of homogeneous, suspension, emulsion, etc combined ointment Rating quality ointment	2
8.	Suppositories. Preparation of suppositories in the pouring method anddeflation. Rating quality suppositories Introduction to their composition different medical substances	2
9.	Solutions for injections Receiving water for injections Preparation solutions for injections without stabilizers and with stabilizers.	2
10.	Preparation isotonic and infusion solutions Rating quality solutions for injections	2
11.	Eyes medical forms Preparation eye drops dissolving drymedical substances and from concentrates. Preparation eye lotionand ointment Rating quality eye medical forms Medicinal forms with antibiotics.	2
12.	Children's and geriatric dosage forms.	2
13.	Entrance control work on topics: "NTD in production RM Production pharmaceutical solutions, tasteful and medical syrups, essential oils and aromatic waters. Production of injection solutions Preparation eye medical forms Extractivedrugs Production tincture and thick, dry, liquid extracts." NTD in RM production.	2
14.	Production injectable solutions Solutions for injections from substances, which need special cleaning Solutions for injections which need stabilization Preparation eye medical forms	4
15.	Production tincture from powerful and non-active medical vegetable raw materials Standardization.	2
16.	Extraction preparations. Production of thick, dry, liquid extracts. Standardization.	2
17.	Entrance control work on topics: "Industrial preparation powders and collections. Production of tablets by direct pressing and prior granulation of the material. Production of soft and hard capsules Production emulsions, suspensions, ointment and suppositories". Physico-chemical and technological properties powders and granules.	2
18.	Production tablets method direct pressing and with previousgranulation Industrial production tablets covered shell control quality Production medical capsules	4
19.	Industrial production soft medical means Industrial production suppositories	4
20.	Production of plasters and TTS. Production of nano- and radiopharmaceuticals drugs	4
	In total hours	48

6. Independent work

		Number hours
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No n/p	Kinds IW	Daily	Correspo ndence
Unit 1. Pharmacy drug technology			
1.	Preparation to practical classes	54	140
2.	Preparation to offset offset	6	6
Unit 2. Industrial technology medical means			
3.	Preparation to practical classes	54	138
4.	Preparation to exam	6	6
	In total hours	120	290

7. Methods teaching

Lectures: multimedia lectures with elements of discussion communication with university graduates education

Practical classes: conversation, solving situational problems, demonstration and practice manipulation skills (including the demonstration of films, visual equipment, means small mechanization, operations and processes production medicines in conditions pharmacies and industrial enterprise, practice of practical skills using pharmacy and industrial equipment.

Independent work: independent work with the textbook, independent work with the bank of tests tasks Step-2, independent solution situational tasks

8. Forms control and methods assessment (in including criteria assessment results teaching)

Current CONTROL: testing, orally poll, solution tasks

Final control: differentiated assessment (at the end of the 3rd year of study), exam (at the end IV year teaching).

Assessment current educational activity on practical occupations :

- Assessment theoretical of knowledge with topics occupation:
 - methods: poll, testing, solution situational tasks
 - maximum score - 5, minimal assessment - 3, unsatisfactory rating – 2.
- Rating practical skills with topics occupation:
 - methods: assessment correctness implementation practical skills
 - maximum score - 5, minimal assessment - 3, unsatisfactory rating – 2.

Rating by one practical occupation there are arithmetic mean by by all components and maybe have only the whole value (5, 4, 3, 2), which is rounded off method statistics

Criteria current assessment on practical occupation

Rating	Criteria assessment
"5"	The winner takes an active part in the discussion of the most difficult issues on the topic class, gives at least 90% correct answers to standardized tests task, without errors responds on written task, performs practical work and draws up the protocol.
"4"	The acquirer participates in the discussion of the most difficult issues on the topic, gives no Less 75% correct ones answers on standardized test task, assumes individual insignificant errors in answers on written task, performs practical work and issues protocol.
"3"	The acquirer participates in the discussion of the most difficult issues on the topic, gives no Less 60% correct ones answers on standardized test task, is assumed significant errors in answers on written task, performs practical work and issues protocol.
"2"	Getter not takes participation in discussed complex questions with topics, gives Less 60% correct ones answers on standardized test task, is assumed rough errors in answers on written task or in general not gives answers on them, not performs practical work and not draws up the protocol.

To final control in form exam are allowed only those acquirers, which have fulfilled the

requirements of the training program in the discipline, have no academic debt, their the average score for the current educational activity in the discipline is at least 3.00 and they passed the test control by tests "STEP - 2" not less than on 90% (50 tasks).

Test control is carried out in the educational and production complex of innovative technologies teaching, informatization and internal monitoring quality education University on to the last classes on the eve of the exam.

Assessment results teaching acquirers during final control – exam

Content assessed activity	Number points
Respond on theoretical question	2
Respond on theoretical question	2
The solution calculation tasks	1

Criteria for evaluating the results of the students' training during final control - exam

Rating	Criteria assessment
Excellent "5"	The winner worked systematically during the semester, he showed during the time exam versatile and deep knowledge software material, can successfully perform task, which provided for program, mastered content basic and additional literature, realized the relationship of individual sections of the discipline, their importance for the future profession, revealed creative abilities in understanding and using the curriculum material, manifested ability to independent renewal and replenishment knowledge; level competence – high (creative);
OK "4"	Getter discovered complete knowledge curriculum material, successfully performs provided for program task, mastered the main the literature recommended by the program proved to be sufficient level of knowledge with disciplines and capable to their independent renewal and renewal in the course of further education and professional activity; level competencies - sufficient (constructive-variational)
Satisfactorily "3"	Getter which discovered knowledge the main curriculum material in the amount necessary for further training and the next onework by profession, copes with performance tasks, provided for program, allowed separate mistakes in the answers on exams and at performance of exam tasks, but has the necessary knowledge for overcoming admitted errors under management scientifically-pedagogical employee; level competence – average (reproductive)
Unsatisfactorily "2"	The applicant did not demonstrate sufficient knowledge of the main curriculum material, made fundamental mistakes in the execution of the provisions program tasks, not maybe without help the teacher use knowledge at further training, not managed master skills independent works; level competence – low (receptive-productive)

9. Distribution points which receive acquirers higher education

Received average mark by educational discipline for acquirers, which successfully mastered working program educational disciplines, converted with traditional four-point scales in points for 200-point scale, as given in tables:

Table conversion traditional evaluations in multi-point scale

Traditional four-point scale	Multi-point 200-point scale
Perfectly ("5")	185 - 200
Good ("4")	151 - 184
Satisfactorily ("3")	120-150
Unsatisfactorily ("2")	Lower 120

A multi-point scale (200-point scale) characterizes the actual success of each acquirer from assimilation educational components. Conversion traditional evaluations (average mark by educational discipline) in 200-point is performed information and technical department University.

In accordance to received points by 200-ball scale, achievement acquirers are evaluated according to the ECTS rating scale. Further ranking according to the rating scale ECTC allows to evaluate the achievements of students in the educational component who are studying at to one courses of one specialty, respectively to received them points.

Scale ECTS there are relative-comparative rating, which establishes belonging applicant to the group of better or worse among the reference group of fellow students (faculty, specialty). Rating "AND" by scale ECTS not maybe equal assessment "perfectly", and rating "IN" – assessment "good" etc. At conversion with multi-point scales limits evaluations "A", "B", "C", "D", "E" according to the ECTS scale do not coincide with the limits of grades "5", "4", "3" according to the traditional scale getters, which received evaluations "FX" and "F" ("2") not are introduced to list acquirers, that rank The grade "FX" is issued to the acquirers who have scored the minimum amount points by current educational activity, but which not reckoned final CONTROL. Rating "F" is exhibited to acquirers, which visited everyone occupation with disciplines, but not typed average the ball (3.00) by current educational activity and not allowed to final control

Applicants who study on the same course (one specialty), based on the number points recruited with disciplines, are ranked by the ECTS scale as such as follows:

Conversion traditional evaluations with disciplines and amounts points by scale ECTS

Rating according to the scale ECTS	Statistical indicator
AND	The best 10% acquirers
IN	The following 25% acquirers
WITH	The following 30% acquirers
D	The following 25% acquirers
THERE ARE	The following 10% acquirers

10. Methodical software:

- working program educational disciplines
- Syllabus educational disciplines
- Textbooks:
 1. Technology of medical and cosmetic products: study guide / edited by: Borysyuk I.Yu., Fizer N.S., Valivodz I.P., Akisheva A.S. - Odesa, ONMedU, 2020. - 52 with.
 2. Biopharmacy: study guide / edited by: Borisjuk I.Yu., Fizer N.S., Akisheva A.S. Odesa, ONMedU, 2020. - 98 p.
 3. Study guide for independent work of students of the Faculty of Pharmacy of the licensing exam "Step 2. Pharmacy" / V.Yu. Anisimov, O.I. Belyaeva, H.G. Vidavska, V.O. Helmboldt, A.V. Zamkova, I.V. Lytvynchuk, A.V. Nikitin, B.V. Pristupa, I.B. Petkova, Ya.V. Rozhkovskiy, S.B. Strechen, L.M. Unguryan, N.C. Fizer Odesa: Odesa.nats.med. Univ. 2019. - 240with.
- Multimedia presentations
- Situational task
- Methodical developments practical classes
- Electronic bank test tasks for subdivisions with disciplines

11. List of questions to final controls

11.1. Questions for differentiated assessment (at the end of the 3rd year of study) List of theoretical questions to differentiated credit:

1. The technology of medicinal forms as a scientific discipline, its tasks and directions of development. Definition of technological terms: medicinal product, medicinal substance, medicinal form, medicinal preparation.
2. Classification of dosage forms: dispersological (physico-chemical), by aggregate state, depending from way usage and ways introduction
3. The main ones directions state normalization production medical drugs Normative documentation, which normalizes quality, conditions storage and vacation medical means
4. The recipe, his structure and regulations discharge in accordance with by order Ministry of Health of Ukraine No 360 from 07/19/05
5. Metrological characteristics of scales: accuracy (correctness), sensitivity, stability, constancy testimony
6. Rules for weighing loose, viscous and liquid substances on pharmacy manual and technical scales substances Specify the minimum weight that can be weighed on manual one-gram scales substances lists A, IN and general list.
7. Definition powders as medical shapes, their classification and requirements SPhU to them Technological stage of preparation complex powders and their characteristic.
8. Methods prescription powders Preparation complex powders, to composition whose are included medical substances, What are different density, voluminous (bulk) mass, structure particles
9. Rules for working with poisonous, potent and narcotic medicinal substances. Trituration, their appointment, storage and design. Technology trituration on examples 10.0 trituration atropine sulfate (1:100); using trituration in powders
10. Preparation complex powders with poisonous narcotic, powerful and by others substances, prescribed in different quantities Regulations their design to vacation
11. Degree grinding medical substances in powders depending from medical application in accordance to requirements SPHU Hardly crushed medical substances Appointment auxiliary liquids and their number in grinding process.
12. Examples colorful and fragrant substances and conditions their storage according to with by order Ministry of Health of Ukraine No. 44 from 16.03.93 p. Features technologies powders with colorful and fragrant substances
13. Types of packaging material used in powder technology for substances with different physical and chemical properties Rating quality powders (size particles, homogeneity of mixing, accuracy dosage, etc.).
14. Characteristic liquid medical forms, their classification. Methods prescription and marking concentration solutions; audit dose poisonous and powerful medical substances in mixtures
15. Regulations preparation concentrated solutions for burette systems according to with instructions to the order Ministry of Health of Ukraine No. 197 dated 7.09.93 p.
16. The structure of the burette installation; rules of care and use of it. Quality control concentrated solutions, correction their concentrations; conditions storage.
17. Technology mixture, to composition whose are included dry medical substances in quantities to 3% and more in accordance to requirements order Ministry of Health of Ukraine #197 from 09/07/93 p. Rating qualities, design to vacation conditions storage liquid medicines drugs according to with SPhU
18. Definition of a standard dropper. Factors affecting dosing accuracy. Regulations use dropper; calibration non-standard dropper
19. Features technologies water solutions slow and difficult to dissolve substances (ethacridin lactate, copper sulfate, furacilin, boric acid and etc.).
20. Nomenclature standard pharmacopoeia liquids, methods prescription their in recipes and storage conditions. Preparation of solutions of ammonia and acetic acid. Specify the appropriate ones calculations
21. Features preparation solutions hydrogen chloride acid for internal and external application (give examples).
22. Preparation of solutions of hydrogen peroxide, formaldehyde, basic aluminum acetate, potassium acetate. Specify the necessary ones calculations on specific examples
23. Features dilution formalin, liquid Burova, perhydrol, liquid potassium acetate.
24. Features of the technology and calculations for diluting ethyl alcohol using dilution formulas and alcoholometric tables. Recipe design rules, in which prescribed ethyl alcohol, and design alcohol solutions

before vacation

25. Characteristics of drops as a dosage form, their classification. Checking the doses of poisonous and powerful medical substances in drops Regulations preparation drops with using concentrated solutions and by dissolution dry substances
26. Preparation of solutions of easily oxidizing substances (silver nitrate, potassium permanganate, iodine). Specify the concentration of iodine in solutions and Lugol for internal and external use.
27. Characterization and classification of high molecular weight compounds (HMWs). Influence of the structure molecules Navy on process dissolution limited and unlimited swelling substances
28. Application of the Navy in pharmacy. Preparation of solutions of unlimited swelling substances on example pepsin.
29. Features technologies solutions limited swelling Navy: gelatin, starch, methycellulose.
30. Characteristic and features colloidal solutions factors, what condition their stability. The essence of colloid protection Name the protected drugs colloids
31. Determination of suspensions as a dosage form and as a dispersed system. Cases of formation suspensions factors, What affect on stability suspensions Rating quality suspensions and design their before vacation in accordance with requirements SPhU
32. Dispersive method obtaining suspensions with hydrophilic substances Using regulations B. V. Deryagin.
33. Preparation suspensions with medical substances with sharply and not sharp expressed hydrophobic properties Stabilizers, their quantitative selection. Technology suspensions sulfur
34. Condensation method of preparation of suspensions. Potions are opalescent and cloudy, conditions their formation. Features technologies mixture with ammonia and anise drops, extracts different consistency
35. Definition of emulsions as a dosage form and dispersion system. Classification of emulsions, requirements to them Emulsifiers, their compressed characteristic.
36. Types of oil emulsions and methods of their determination. Stages of emulsion technology. Calculations oils, emulsifier, water. Definition readiness primary emulsion.
37. Introduction medical substances with different physical and chemical properties in oily emulsions Rating quality emulsions, their storage and design before vacation
38. Characteristic infusions and decoctions as dispersed systems and medical forms; requirements, What are put forward to them Technology decoctions from raw materials, What contains tanning substances, anthraglycosides, saponins.
39. Value correlation quantity medical vegetable raw materials and extractant, coefficient water absorption, temperature, duration infusion and cooling at cooking infusions and decoctions.
40. Differences in the technology and rules of administration of medicinal substances in infusions and decoctions medical raw materials and standardized extracts-concentrates. Paths improve technologies water hoods Value enzymes and microflora in technologies infusions and decoctions
41. Characteristics of liniments as a medicinal form and their classification depending on nature the applied base, medical purpose and physico-chemical properties of the ingredients. Rating qualities of liniments and design them before vacation.
42. Features technologies homogeneous and heterogeneous liniments Preparation suspension, emulsion and combined liniments (give examples).
43. Characteristic ointment as medical forms and dispersed systems Features preparation dermatological ointment with resorcinol, zinc sulfate, acid salicylic Influence foundations on biological accessibility medical substances from ointments.
44. Classification of ointments by medical purpose, place of application, consistency and physical and chemical properties medical substances paste, their classification; features preparation dermatological pastor
45. Homogeneous ointments and their characteristic. The main ones technological stage preparation and regulations introduction medical substances in homogeneous ointments.
46. Suspension (trituration) ointments; their classification and technology depending percentage content medical substances Official suspension prescriptions ointment
47. Emulsion ointments; their characteristics and technology. Preparation of ointments with protargol, cholargol, tannin, dry and thick extracts.

48. Ointment combined type their technology. Bring examples Preparation ointment with using intrapharmacy blanks (concentrates and semi-finished products). Rating quality ointments and decoration their before vacation according to the SPhU.
49. Characteristics of suppositories as a dosage form and dispersion systems; their classification depending on the purpose. Suppository bases, their classification. Characteristics of hydrophilic bases.
50. Requirements SPhU to suppositories, value their geometric forms Prescription suppositories and checking the doses of poisonous and potent medicinal substances in them. Composition and preparation gelatin-glycerol foundations for suppositories Introduction soluble and insoluble medical substances in water-soluble bases.
51. Stages of the technological process of suppositories by the pumping method. Introduction to the composition suppository masses of medicinal substances soluble in water and other indifferent liquids depending from prescribed quantity.
52. Stages technological process preparation suppositories method outpouring. What are direct and inverse substitution coefficients of medicinal substances and in which cases their apply?
53. Definition medical forms for injections and requirements SPhU edition to them Paths introduction injectable solutions List stage technological the cooking process solutions for injections and give them I will compress characteristic.
54. Asepsis, its value for software sterility and pyrogenicity solutions for injections Creation aseptic conditions in pharmacies according to with by order Ministry of Health of Ukraine No. 275 from 15.05.06 p. Concept about pyrogenic substances and audit pyrogenicity drugs for injections in accordance to the requirements of the SPhU.
55. The concept of stabilization of solutions for injections. Mechanism of stabilization of salt solutions weak bases and strong acids, salts of weak acids and strong bases (on specific examples).
56. Value isotonicity injectable solutions Methods calculation isotonic concentration medical substances Point examples calculations by by law Raul (cryoscopic method) and with using isotonic equivalent by sodium chloride.
57. Characteristic medical forms, what are used in of ophthalmology (drops, lotions, washes, emulsions, suspensions, ointments, powders). Requirements for eye medicine forms; their justification and implementation.
58. Features of the technology of eye drops depending on the solubility of the included ingredients to their composition, and calculations isotonicity drops.
59. Characteristic basics, which are used for preparation eye ointment, and requirements to them Evaluation of the quality of ophthalmic dosage forms, registration before release, storage rules in accordance to requirements.
60. SPhU requirements for dosage forms with antibiotics. Conditions for their preparation. Features introduction antibiotics to medical forms.

List practical skills, assimilation whose is controlled under time differentiated offset

1. Read recipes in Latin language analyze their components parts and evaluate the correctness of the prescription.
2. Detect physical, chemical and pharmacological incompatibility Solve question about possibility preparation and vacation medical drugs with taking into account compatibility components prescription
3. Work with tare scales and manual scales when weighing different types of aggregated medical substances.
4. Carry out preparatory and the main ones technological operations at packaging medical substances (to tarry, weigh, measure).
5. Select taro packaging material when dosing loose, thick and viscous substances and liquids.
6. Calibrate non-standard dropper and dose liquid drops.
7. Expect number components prescription general volume or mass of medicine drug.
8. Choose the best option of technology and prepare a medicine according to it preparation with constant quality assessment.
9. Carry out the main technological operations of preparation of simple and complex powders with medicinal substances, prescribed in equals and different quantities, What are different structure of particles, size and shape of crystals, state of aggregation, bulk mass (weigh out, grind, mix, dose).

10. Evaluate quality prepared powders and write passport written control.
11. Conduct check dose poisonous and powerful substances and norms disposable vacation narcotics and equated to them substances in powders.
12. Carry out the main ones technological operations preparation trituration and complex powders with poisonous and potent medicinal substances prescribed in small quantities (weigh out, grind, mix, dose).
13. Carry out basic technological operations for the preparation of complex powders with dyes, odorous and difficult to grind medicinal substances (weigh, grind, mix, dose).
14. Carry out the main ones technological operations preparation powders with extracts (dry, thick, solutions thick extracts) and semi-finished products (weigh out, to grind mix, dose).
15. Use State pharmacopoeia, another normative documentation and reference literature for search necessary information of preparation concentrated solutions.
16. Assess the correctness of prescriptions, check the doses of poisonous and powerful medical substances in liquid medical forms.
17. Use State pharmacopoeia, another normative documentation and reference literature for finding the necessary information on issues of liquid preparation medical forms with the use of concentrated solutions.
18. Carry out the main ones technological operations on cooking liquid medical drugs with the use of concentrated solutions and dissolution of medicinal substances (weigh, to measure dissolve, filter).
19. Expect number water, medical and auxiliary substances for preparation solutions and drops.
20. Use State pharmacopoeia, another normative documentation and reference literature for finding the necessary information on matters of preparation solutions with standard pharmacopoeial liquids.
21. Expect number water and pharmacopoeia liquids in dependencies from way their prescription
22. Calculate the amount of alcohol and water for preparing alcohol of a given concentration, using the formula breeding and alcoholometric tables.
23. Carry out the calculation of medicinal and auxiliary substances for the preparation of medicinal products forms.
24. Carry out the main ones technological operations on cooking infusions and decoctions by help extracts-concentrates and water hoods from raw materials, What contains mucus (to grind, sift, weigh out, to extract percolate, dissolve).
25. Use State pharmacopoeia, another normative documentation and reference literature for finding the necessary information on preparing liniments and ointment.
26. Calculate the percentage content of medicinal substances soluble in the base, which are included in prescription ointments and amount of excipients for preparation medicinal drug.
27. Carry out the main ones technological operations on cooking suppositories method deflation (weigh out, to grind dissolve, to melt pour out in shapes, cool, take out of forms).
28. Carry out the main ones technological operations on cooking suppositories method outpouring.
29. Carry out basic technological operations related to the preparation of injection solutions (weigh out, dissolve, filter, carry out CONTROL on absence mechanical impurity, hermetically stopple, to issue before sterilization, sterilize).
30. Calculate the isotonic concentration of medicinal substances using isotonic equivalent by sodium chloride.

11.2. Exam questions (at the end of the 4th year of study). List of theoretical questions to exam:

1. General principles of production of finished medicinal forms. Ready medicines, their role in security population. Expansion assortment medical means industrial production, organization production pharmaceutical enterprises.
2. Workshop principle of production organization. Complex mechanization and aesthetics. Machinery security and security labor Technological process.
3. Maximum cleaned drugs and drugs individual substances, receiving new galenovy drugs Methods cleaning BAS.
4. Grinding. Types of grinding. Peculiarities of crushing of solid bodies. The main methods grinding. Grinding work (energy consumption).
5. Powders Classification. Technology powders: grinding day off material, separation by

sizes particles, mix individual components. Packaging and packaging. Biopharmaceutical aspects
powders

6. Medical solutions Classification (water, alcoholic, glycerin, oily, aromatic water, syrups). Methods of their preparation at chemical and pharmaceutical enterprises (dissolution, chemical interaction).

7. Standardization solutions by content active substances and density Solutions peroxide hydrogen, formaldehyde, Burov's solution, basic lead acetate solution. Alcohol solutions iodine packaging Packaging. Storage.

8. Extractive drugs Theoretical foundations extraction Extraction vegetable, animal, microbiological raw materials and tissue culture.

9. Factors affecting the extraction process: histological structure, degree and character grinding, porosity, coefficient wash and absorption, size surface raw materials, concentration difference, temperature, duration of extraction, effect of extractant (extractants abilities, selectivity, resorption, viscosity, size superficial tension and reactions environment to increase the speed and completeness of extraction). Viscosity. Surface- are active substances Hydrodynamics layer plant raw materials.

10. Methods of extraction: maceration and its modifications, percolation, repercolation with division raw materials on levels parts and on unequal parts, countercurrent extraction in batteries extractors and extractors continuous action, circulatory extraction.

11. Intensification process extraction - turbo extraction (vortex), extraction raw materials on rotary-pulsation device RPA, extraction with application ultrasound, variable pressure (four-body installation of the "carousel type"), extraction by help electric charges, extraction with using electroplasmolysis and electro dialysis.

12. Theoretical foundations of the extraction process: desorption, dissolution, leaching, diffusion, osmosis. The use of the basic provisions of the theory of molecular and convective diffusion in the process extraction.

13. New ones technologies production phytopreparations.

14. Apparatus for extraction: maceration tanks, communicated and non-immunized batteries extractors. Extractors of continuous action.

15. Recuperation and rectification alcohol Recuperation alcohol with worked out raw materials displacement water and distillation from water pore Equipment.

16. Tinctures. Classification. Obtaining. Maceration, possibilities of its intensification (partial, whirlwind, extraction with application vibrators, pulsators, rotary and pulsating devices, ultrasound, extraction in suspended layers raw materials). Percolation.

17. Extracts. Characteristic. Classification by consistency and extractant, What is applied liquid extracts - methods obtaining (remaceration, percolation, repercolation, counter current extraction).

18. Cleaning. Standardization. Storage. Nomenclature of liquid extracts. Thick and dry extracts - methods obtaining (bismaceration, percolation, repercolation, countercurrent extraction, circulatory extraction).

19. Cleaning water hoods Cleaning alcohol hoods Evaporation. Drying extracts. Standardization. Nomenclature of aqueous thick extracts (sagewort, dandelion, licorice) dry (sweets).

20. Extracts-concentrates. Characteristic. Classification. Methods obtaining liquid extracts-concentrates: percolation, repercolation, method Tsandi. Methods obtaining

dry extracts-concentrates: fast flowing repercolation, maceration Standardization. Polyextracts. Storage.

21. Obtaining enzyme drugs with animal raw materials proteolytic actions (pepsin, trypsin, chymotrypsin). Obtaining enzyme drugs with animal raw materials hyaluronidase actions (lidase, ronidase). Application. Storage.

22. Tablets. Definition. Characteristic. Kinds and nomenclature. Theoretical foundations tableting

23. The main ones groups auxiliary substances, which are applied in production tablets: binding, loosening agents, antifriction agents, dyes, substances that prolong the action of medicinal products. Diluting substances. Influence of excipients on therapeutic effectiveness drugs

24. Stages of the technological process of obtaining tablets. Preparation of auxiliary and medical substances, mixing ingredients.

25. Features production some parenteral medical forms. Production non-aqueous solutions for injections.

26. Cultivation cells and fabrics in animals and a person and plants.

27. Value granulation Granulation dry, wet (squeezing, in irritating boilers and plate-shaped granulators, suspended layers, spraying drying), granulate powdering. The influence of the type of granulation on the bioavailability of drugs. Analysis granulate: definition physical and chemical properties, granulometric composition, humidity, fluidity, pressed Granulators and machinery which wipe dryers- granulators (SG-30).
28. Pressing. Tablet presses: impact and rotary. Comparative characteristics of tablets presses and principle their works Influence pressure pressing on therapeutic efficiency tablets Directly pressing.
29. Methods causing shell Goal causing. Technology teasing: running in, grinding, glossing, polishing. Abductors. Film coating.
30. Types and properties of film coatings. Assortment of film formers, plasticizers, solvents. Technology of film coatings. Apparatus. Pressed coatings. Technology film coatings Apparatus.
31. Technology coating pressing Machinery double and triple pressing. Tablets prologue actions Multi-layered pills Fools Magneto-controlled pills.
32. Rating quality tablets: external appearance, deviation from secondary mass, precision dosage, quantitative contents active substances, decay, solubility, strength on crushing and abrasion. Control devices (rotating baskets, device HNDHFI, Stokes device etc.).
33. Medical capsules. Microcapsules. Types medical capsules Assortment. Auxiliary substances in production gelatinous capsules Methods receiving: immersion ("wetting"), pressing, drip method.
34. Decay, solubility, strength and thickness shell, speed and completeness release medicines with capsules factors, What affect on biological accessibility medical substances Rectal, vaginal capsules. Tubatyn Prospects development capsules Packaging.
35. Microencapsulation medical drugs Methods receiving microcapsules. Prospects development technologies of microencapsulation of drugs.
36. Plasters. Mustard seeds. Characteristic. Classification. Receiving technology. Equipment: reactors, installation USPL-I, chamber-loop dryer and others Leaden, complex, epilene, resin wax, rubber, adhesive plaster elastic anointed, bactericidal, callous, pepper, liquid (cleol, collodion, glue BF-6, kolaplast, microplastic, furoplast, liquid Novikova, liquid callous).
37. Features of the production of ophthalmic, nasal and ear medicines, requirements to them control them quality according to the SFU and types packages.
38. Mustard seeds. Technology mustard seeds Packaging. Storage.
39. Rectal dosage forms. Characteristics of suppositories. Equipment for production and packaging of suppositories: Franco-Crespi (Italy), line of the company "Hefliger and Karg", "Sarong200S" (Germany). Standardization. Nomenclature. Storage.
40. Aerosols. Characteristic. Classification. Inhalation aerosols. Composition and principle of operation aerosol balloon.
41. Kinds aerosol systems Characteristic content aerosol balloon warehouses, What issued from the package in the form of foam (water-alcohol, non-aqueous foams). Excipients for receiving aerosols (solvents, solubilizers, South Africa film formers and etc.), propellants.
42. Paths completion aerosol packages Modern systems aerosol drugs.
43. Methods of filling aerosol cans (under pressure and at low temperature). Quality assessment: strength and tightness of the packaging. Content dosing accuracy. Qualitative and quantitative composition. Prospects development pharmaceutical aerosols Nomenclature. Ingalipt. Cameton. Proposal Legrazol. Nitazol. Neotisol. Lifusol. Transportation and storage medical aerosols
44. Sterile and aseptically produced dosage forms. Solutions for injections in ampoules. Medicine factory production, prepared in aseptic conditions. Dosage forms for injections: solutions in ampoules, suspensions, emulsions, powders, tablets.
45. Requirements for dosage forms for injections: absence of mechanical inclusions, sterility, pyrogenicity, stability and others Sources pollution injectable solutions Classes purity premises Requirements to staff, work clothes, equipment.
46. Solvents. Obtaining water for injections in factory conditions. Distillation devices. Demineralized water. Methods receiving: electrodialysis, ionic exchange, reverse osmosis. Using demineralized water Factory devices for its receiving. Non-aquatic solvents. Fatty oils and their requirements. Preparation of vegetable oils. Alcohols, ethers, amides.
47. Materials for making ampoules and vials. Glass. Obtaining, technical requirements for him Classes

glass Research chemical and thermal stability ampoules Using polymeric packaging materials, syringe tubes.

48. Filtering materials Filtering devices (mushroom filters, HNDHFI, Salnikova, Seitz). metal, ceramic, glass, fluoroplastic membrane filters Sterilization filtering.

49. Filling ampoules. Vacuum, syringe, vapor condensation methods, their features and disadvantages Devices for filling. Soldering ampoules, linear and rotary automatic machines Soldering in streams inert gases control quality of sealing.

50. Methods of sterilization of solutions in ampoules. Thermal sterilization. Steam sterilization under pressure Radiation and cryoradiation sterilization. Sterilization mode control. Audit tightness.

51. Evaluation of the quality of finished products. Concept of sterile series. Control of sterility and pyrogenicity, pH environment, quantitative content active substances, purity Labeling and packaging ampoules Automatic machines for packaging. Problems complex mechanization and automation production of ampoules. Creation of current lines.

52. Features production in factory conditions solutions glucose, calcium chloride, magnesium sulfate, ascorbic acids hexamethylenetetramine, ergotal, euphyllinum, oily solutions camphor, hormones, them analogues.

53. Eyes medical forms Features technologies eye medical forms factory production Eyes drops. Water solutions Oily solutions Suspensions. Nomenclature: solutions of atropine sulfate, sodium sulfacyl, pilocarpine hydrochloride, scopolamine hydrochloride, ascorbic acid, phosphacol and others.

54. Biotechnology in manufacturing medical means biotechnology, its place in development scientific and technical progress in medicine and pharmacy. Modern directions of drug production on basis biotechnology.

55. Packaging of finished medicinal forms. Packaging materials. Container. Packaging of medicinal products forms.

56. State-wide standards for containers and packaging materials. Modern assortment of containers and packing material, which is used in pharmaceutical industry.

57. Prospects for the development of the technology of dosage forms. Main directions of technology development medical forms Systems with regulation release active substances Multi-layered tablets, microcapsules, microdrags Immobilized drugs: enzymes, hormones, mucopolysaccharides, iron-derived dextran, albumins, γ -globulins, nucleic acids, interferons.

58. Suspensions. Emulsions. Ointment Methods of industrial production of suspensions, emulsions, ointments. Mix phases Painting in liquid environment Grinding with using ultrasound Equipment.

59. Foundations for ointment and auxiliary substances, What are used in industrial production their. Prospects development production and scientific research ointment Production ointments in conditions pharmaceutical enterprises.

60. Features receiving modern nano- and radiopharmaceuticals drugs, their role and place in modern pharmacy and medicine.

List practical skills, assimilation whose is controlled under time exam

1. Determine disintegration tablets.
2. to fold working samples of writing for receiving given quantity (20) ampoules defined capacity (1 ml) 20% solution camphor in oil.
3. Conduct control injectable solution in ampoules on absence mechanical include.
4. to fold working samples of writing for receiving given quantity (1000 ampoules) and given concentration (20%, ampoule 1 ml) solution caffeine benzoate sodium
5. Prepared 250 Jr solution caffeine benzoate sodium Analysis showed What solution contains 21% drug How many need water to receive 20% solution?
6. Prepared 250 Jr solution caffeine benzoate sodium Analysis showed What solution contains 19% drug How many necessary to add caffeine benzoate sodium obtaining 20% solution?
7. Define contents ethyl alcohol in alcohol-water mixture by help glass breathalyzer.
8. to fold working samples of writing and prepare in vials on 5 and 10 Jr drops f.or eyes solution sodium sulfacyl 30%
9. Prepare in vials on 5 and 10 Jr go to drops solution pilocarpine hydrochloride 1% with methyl cellulose.

10. To make and to investigate tincture lily of the valley.
11. To make and to investigate tincture marigolds.
12. To make 100 Jr water fruits coriander method races with water a couple.
13. Prepare 20 kg 52 % alcohol with 96.6%.
14. Prepare and to investigate sugar syrup.
15. to fold equation material balance, to determine Entrance, spending expendable coefficient. Compile the consumption standards for obtaining 100 g of the finished product, if during the manufacture of salt chloride sodium instead 100 g 99.7 g was obtained finished product.
16. Protocol grinding solid bodies on ball mills.
17. Prepare complex licorice powder.
18. Grind 10 kg fruits mountain ash and to stem working samples of writing.
19. Determine shape, size, nature surface powder.
20. Determine factional composition powder.
21. Calculate working samples of writing for production 100 kg tablets acetylsalicylic acid acidon 0.5, the average weight of tablets 0.55. $K(\text{vitr})=1.05$.
22. Determine number starch for production 200,000 tablets phenobarbital on 0.1 d, average weighing 0.2 g (sugar 0.08, talc 0.0036).
23. Determine pressing tablets.
24. Determine strength pushing out tablets with matrices.
25. to fold industrial regulations on production tablets streptocide.
26. to cover pills amitriptyline suspension method teasing.
27. To make dragee "Hexavit".
28. Apply on pills gastric soluble film coating.
29. To make granules plantaglicid.
30. Determine get stronger tablets on abrasion.

12. Recommended literature

Main:

1. Tikhonov O.I. Pharmacy technology of medicines / O.I. Tikhonov, T.G. Jarnih – Vinnytsia: New book, 2016. – 536 p.
2. Industrial technology of medicines: a basic textbook for students. Higher. student pharmacy institutions (pharmacological institutions) / E.V. Gladukh, A.A. Ruban, I.V. Saiko et al. - Kh. : NFaU: Original, 2016. - 632 p. : Them. - (Series "National textbook")
3. Excipients in the production of drugs: training. manual for students higher pharmacy education closing / O. A. Ruban, I. M. Pertsev, S. A. Kutsenko, Yu. S. Maslii; under the editorship I. M. Pertseva. - Kh.: Gold pages 2016. – 720 p.
4. Modern pharmaceutical technologies : education manual to laboratory classes master's students daytime evening and extramural forms teaching specialty 8.110201 "Pharmacy" / under ed.AT. AND. Ruban. – Kh.: Kind-in NFaU, 2016. – 256 p.
5. Workshop on industrial technology of pharmaceuticals specialty "Pharmacy" / Sub ed. Ruban O.A. - M.: NFaU, 2015. - 374 p.

Additional literature

1. Mathematical planning experiment at conducting scientific of research in pharmacy / AND. Pecuniary, V.P. Martsenyuk, L.I. Kucherenko and others – Ternopil: TDMU Ukrmedknyga, 2008. – 367 p.
2. Normative and technical documentation and validation production Material balance: Educational method. river for audit. and external audit. student work special "Pharmacy" day and Correspondence form of education / D.I. Dmytrievskyi, G.D. Slipchenko, I.M. Hrubnyk, D.V. Rybachuk – H.: Kind-in NFaU, 2008. - 45 p.
3. Technology of medicinal products of industrial production: training. manual/ edited by Prof. D.I. Dmitrievsky. – Vinnytsia: Nova book, 2008. - 280 with.
4. Technology medicines Educational and methodical manual: Education manual for study higher education hall. /O.I. Tikhonov, P.A. Logvin, S.O. Tikhonova, O.V. Bazulin, T.G. Yarnykh, O.S.

Shpychak, O.M. Kotenko; by ed. O.I. Tikhonov, – Kh.: Original, 2009. - 432 with.

5. Spiritometry. Recovery and rectification of ethanol: Textbook. help / D.I. Dmitrievsky, L.I. Boguslavskaya, L.N. Khokhlova and others; Ed. Prof. D.I. Dmitrievsky - Kh.: Izd-vo NFaU, 2006. – 100 p.
6. Pharmaceutical encyclopedia / Chief editor. council and author of the foreword V.P. Black people - the 3rd view., processed and additional – K.: "MORION", 2016. - 1952 p.
7. Encyclopedia of Pharmaceutical Technology: 3-d Ed. / ed. by J. Swarbrick. – New York; London: Informa Healthcare, 2007. - 4128 p.
8. European Pharmacopoeia 8.0 [8th edition] / European Directorate for the Quality of Medicines & HealthCare. - Strasbourg, 2013. - 3638 p.
9. Handbook of Pharmaceutical Excipients, 6th edition / RC Rowe, PJ Sheskey, ME Quinn. – Pharmaceutical Press and American Pharmacists Association, 2009. - 521 p.
10. Extemporaneous prescriptions for therapy dermatological diseases: education manual for students medical and pharmaceutical universities / N.P. Polovka, L.I. Vishnevskaya, T.M. Kovalev and others - Kh.: Kind-in NFaU, 2017. - 91 p.
11. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian scientific officinal center quality medical means" - 2nd edition – Kharkiv: State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicines", 2015. - Vol. 1. - 1128with.
12. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian scientific officinal center quality medical means" - 2nd edition – Kharkiv: State enterprise "Ukrainian scientific officinal center quality medical means", 2014. – T. 2. – 724 with.
13. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian scientific officinal center quality medical means" - 2nd edition – Kharkiv: State enterprise "Ukrainian scientific officinal center quality medical means", 2015. – T. 3. – 732 with.
14. About the approval of the Instructions on the sanitary and anti-epidemic regime of pharmacy establishments: order Ministry of Health of Ukraine from 15.05.2006 p. No 275 // Official herald of Ukraine from 2006. No 47.
15. About approval Instructions on cooking in pharmacies medical forms with liquid dispersion medium: Order of the Ministry of Health of Ukraine dated 09/07/93 No. 197 // Vidomosti Verkhovna Council of Ukraine, 1993.
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