MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY

PROGRAM

COMPREHENSIVE PRACTICE-ORIENTED QUALIFICATION EXAM

(exam name / name of the qu alification exam / name of the practice-oriented exam)

training for **second (Master's) level of higher education**
(Higher Educational Level Name)

in specialty **«226 Pharmacy, Industrial Pharmacy»**
(Code and Specialty Name)

field of knowledge **«22 Healthcare»**
(Code and Knowledge Field Name)

of educational program **«Pharmacy»**
(Educational Program Name)

in specialization(s) _____
(Code and Specialization Name)

2023
(Year of creation)

CONSIDERED AND APPROVED**:** **National University of Pharmacy**
(the full name of the institution of higher education)

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The program was considered and approved at a meeting of the Central Methodological Council

Record from «21» of September 2023 №1

Head of the Central Methodological Council _____ prof. Andrii FEDOSOV
(sig.) (first name LAST NAME)

1. GENERAL PROVISIONS

Explanatory note

The comprehensive practice-oriented qualification exam in pharmacy is an integral part of the certification of applicants for a master's degree in the educational program Pharmacy, specialty 226 Pharmacy, industrial pharmacy, which is carried out in accordance with the Decrees of the Cabinet of Ministers of Ukraine № 334 «On approval of the Procedure for the Unified State Qualification Exam for applicants for a master's degree in the specialties of the field of knowledge "Healthcare» of March 28, 2018 and № 497 «On the Certification of Applicants for Degrees of Professional Higher Education and Degrees of Higher Education at the First (Bachelor's) and Second (Master's) Levels in the Form of a Unified State Qualification Examination» of May 19, 2021.

The comprehensive practice-oriented qualification exam in pharmacy is conducted by the Examination Board of the National University of Pharmacy, which operates based on the "Regulations on the Certification of Applicants for Higher Education and the Examination Board at the National University of Pharmacy" (ПОЛ А 2.2-38-136).

During the comprehensive practice-oriented qualification examination in pharmacy, the quality of professional and practical training of higher education applicants is checked and evaluated, and its compliance with the requirements for the training of specialists in specialty 226 Pharmacy, Industrial Pharmacy of the educational program Pharmacy is established.

List of program learning outcomes of the educational program

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

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

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

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

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

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

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

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

PLO 11. To use methods for assessing performance indicators; to identify reserves to increase labor efficiency.

PLO 13. To carry out sanitary and educational work in professional activity in case of outbreaks of infectious, viral and parasitic diseases.

PLO 14. To determine the advantages and disadvantages of medications of different pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic and pharmacodynamic features. To recommend to consumer's over-the-counter medications and other products of the pharmaceutical range with the provision of counseling and pharmaceutical care.

PLO 16. To determine the influence of factors influencing the processes of absorption, distribution, deposition, metabolism and excretion of the drug and due to the condition, features of the human body and physico-chemical properties of medications.

PLO 17. To use clinical, laboratory and instrumental research data to monitor the efficacy and safety of medicines.

PLO 18. To select biological objects of analysis, to carry out the definition of xenobiotics and their metabolites in biological environments and to estimate the received results taking into account their distribution in an organism.

PLO 20. To carry out a set of organizational and managerial measures to provide the population and health care facilities with medicines and other products of the pharmaceutical range. To carry out all types of accounting in pharmacies, administrative records, processes of commodity analysis.

PLO 21. To calculate the main economic performance of pharmacies, as well as taxes and fees. To form all types of prices (wholesale, purchase and retail) for medicines and other products of the pharmaceutical range.

PLO 22. To manage pharmaceutical organizations and determine its effectiveness using management functions. To make management decisions based on the formed leadership and communication skills of pharmaceutical personnel for strategic planning of enterprises.

PLO 23. To take into account the data on socio-economic processes in society for the pharmaceutical provision of the population, determine the effectiveness and availability of pharmaceutical care in terms of health insurance and reimbursement of the cost of medicines.

PLO 25. To promote health, including disease prevention, rational use and use of medicines. To perform your professional duties in good faith, comply with the law on the promotion and advertising of medicines. To have psychological communication skills to build trust and understanding with colleagues, doctors, patients, consumers.

PLO 26. To choose rational technology, to make medicines in various dosage forms according to the prescriptions of doctors and orders of medical institutions, to issue them before release. To perform technological operations: weigh, measure, dose a variety of medications by weight, volume, etc. To develop and draw up technological documentation for the manufacture of medicines in pharmacies.

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

PLO 28. To organize and conduct rational procurement of medicinal plant raw materials. To develop and implement measures for the protection, reproduction and rational use of wild species of medicinal plants.

PLO 29. To ensure a competitive position and effective development of pharmaceutical organizations on the basis of research work on all elements of the marketing complex.

PLO 30. To ensure quality control of medicines and document its results. To manage quality risks at all stages of the life cycle of medicines.

PLO 31. To carry out all types of quality control of medicines; to draw up quality certificates for the batch of the medicinal product and the certificate of analysis, taking into account the requirements of current regulations, the State Pharmacopoeia of Ukraine and the results of quality control. To develop specifications and methods of quality control in accordance with the requirements of the current State Pharmacopoeia of Ukraine.

PLO 32. To determine the main organoleptic, physical, chemical, physicochemical and pharmacotechnological indicators of medicines, to substantiate and choose methods of their standardization, to carry out statistical processing of results in accordance with the requirements of the current State Pharmacopoeia of Ukraine.

List of educational components included in the comprehensive practice-oriented qualification exam

Pharmaceutical drug technology
Industrial technology of drugs
Pharmaceutical chemistry
Pharmacognosy with the basics of resource science
Organization and economics of pharmacy
Pharmaceutical management and marketing
Clinical pharmacy and pharmaceutical care

2. CONTENT OF THE COMPREHENSIVE PRACTICE-ORIENTED QUALIFICATION EXAM PROGRAM

Educational component Pharmaceutical drug technology
(name)

Summary of the educational component:

The educational component " Pharmaceutical drug technology " is aimed at students of higher education acquiring the theoretical foundations and practical skills and abilities of manufacturing drugs in the conditions of pharmacies, taking into account the requirements of proper pharmacy practice; rules for drawing up technological documentation for the manufacture of medicinal products, rules for their storage and packaging; acquisition of knowledge on the characteristics, classification and assortment of ready-made medicinal forms; the formation of theoretical knowledge and professional skills among students of higher education by studying the influence of excipients on the quality of medicinal products, which makes it possible to more fully realize the scientific and creative potential of future specialists. Mastering the theory and practice of manufacturing medicinal forms is necessary for a specialist to perform the duties of a specialist, which is provided for by the legal and procedural legislation and the relevant order of the Ministry of Health of Ukraine.

Content of the educational component:

Topic 1. General questions of drug technology. State control over the production of drugs. Dosing in pharmaceutical practice.

Basic pharmaceutical concepts: medicine, pharmacy, biopharmacy, pharmacist, etc. Definition of drug technology as a scientific discipline, its tasks at the modern stage and directions of development. Technological terms: medicinal product, medicinal raw material, medicinal form, medicinal substance, medicinal preparation, etc.

Types of pharmacy regulatory documents (pharmacopoeia, orders, instructions, etc.). Provisions of good pharmacy practice (GPP)) regarding the manufacture of medicinal products in pharmacy conditions. Requirements of the general article of SPU 5.N.1 "Extemporaneous medicinal products": definition, manufacture, internal pharmacy quality control, packaging, labeling, conditions and storage periods. Requirements of the US Pharmacopoeia and the international PIC/S convention for the preparation of drugs in pharmacies: manufacturing conditions, equipment, stability of drugs, primary packaging.

Requirements of proper pharmacy practice regarding the preparation of non-sterile dosage forms in pharmacies

(requirements regarding the technological process, documentation; medicinal and auxiliary substances; packaging; intra-pharmacy quality control of extemporaneous medicinal products).

Stability of extemporaneous medicinal products: definitions, types, factors affecting the stability of medicinal products.

Documentation when preparing drugs in pharmacies, its types and tasks.

Classification of dosage forms: dispersological, by aggregate state, depending on the method of use and routes of administration.

The recipe, its meaning. Recipe structure. Rules for prescribing prescriptions according to regulatory documents (orders of the Ministry of Health of Ukraine). Cases of incorrect prescribing of prescriptions received by pharmacies. Rights and obligations of a pharmacist in relation to incorrectly written prescriptions in accordance with the requirements of the order of the Ministry of Health of Ukraine.

Topic 2. Preparation of simple and complex powders with drugs, different in prescribed quantity, bulk weight and structure of the particles in pharmacy conditions.

Preparation of solid medicinal products in pharmacies in accordance with the requirements of the National Health Service, orders of the Ministry of Health of Ukraine and other regulatory documents (DFU, American pharmacopoeia, PIC/S documents, etc.).

Characteristics of powders as a dosage form, their classification. SPU requirements for powders. Ways of prescribing powders.

General rules and stages of the technological process of preparation of solid dosage forms in pharmacies. Detailing; the main physico-chemical laws that affect the process of refining powder ingredients. The degree of grinding of medicinal substances depends on the medical purpose of the medicinal product.

Factors affecting the order of mixing components in the preparation of complex powders. Rules for preparing complex powders with medicinal substances prescribed in equal and different amounts. Rules for the introduction of medicinal substances with different physical and chemical properties into powders. Technology of powders with ingredients that differ in density, bulk mass, particle structure (amorphous, fine-crystalline, coarse-crystalline) in pharmacies and at enterprises. Rules for the selection of packaging material in accordance with the physical and chemical properties of the powder components. Permissible deviations in the mass of individual doses of powders. Evaluation of the quality of powders in accordance with the requirements of the State Pharmacopoeia and other National Standards for packaging, registration before release, and storage (orders of the Ministry of Health of Ukraine).

Topic. 3. Preparation of complex powders with poisonous and strong-effective substances. Triturations.

Rules for prescribing poisonous, narcotic and potent medicinal substances, the procedure for storage, dispensing and use in accordance with the requirements of the orders of the Ministry of Health of Ukraine. Verification of single and daily doses of poisonous and potent medicinal substances in powders. Narcotic substances used in the technology of powders and norms of their one-time release. Preparation of complex powders with poisonous, narcotic and potent medicinal substances prescribed in small (less than 0.05) quantities. Characteristics of triturations, their preparation, storage, use for preparation of powders. Quality assessment, packaging, preparation for release, storage of powders in accordance with the requirements of the State Pharmacopoeia and other NDs (orders of the Ministry of Health of Ukraine).

Topic 4. Preparation of complex powders with dyeing, aromatic and poorly powdered substances.

A list of dyeing and aromatic substances and condition of their storage in obedience to the requirements of order of MH of Ukraine. Peculiarities of powders technology with dyeing substances and sanitary terms of their preparation. Rules of introduction of aromatic substances to the medical forms. List of medicinal substances, which grind down in presence of an auxiliary liquid.

Characteristics of hard gelatine capsules; use cases for packaging powders. Quality control, packaging design to delivery, storage of powders with colouring, aromatic substances and substances that ate ground in dyeing presence of an auxiliary liquid in accordance with - die requirements of State Pharmacopoeia and other regulations (orders of the Ministry of Health of Ukraine).

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

Characteristics of the extracts used in powders, their classification according to the SPU. Preparation of solutions of thick extracts, conditions and term of their storage. Features of the technology of complex powders with dry, thick and solutions of thick extracts. The use of semi-finished products for the preparation of complex powders, their advantages. Areas of improvement of powder technology: expansion of the range of semi-finished products; introduction of small mechanization in the process of preparation of powders in pharmacies and mechanization of the processes of mixing and dosing of powders in industrial conditions. Quality assessment, packaging, preparation for release, storage of powders with extracts and semi-finished products in accordance with the requirements of the State Pharmacopoeia and other ND (orders of the Ministry of Health of Ukraine). The main signs of instability of powders.

Topic 6. Preparation of species in pharmacies.

Species: characteristics, classification and methods of their prescription. Stages of the technological process of assembly preparation. Rules for the introduction of different groups of medicinal substances (water-soluble, water-insoluble, essential oils, substances soluble in ethanol) into the composition of the assembly. Technology of metered species. Equipment used in assembly production. Quality assessment, packaging, preparation for release, storage of collections in accordance with the requirements of the State Pharmacopoeia and other ND (orders of the Ministry of Health of Ukraine).

Topic 7. Preparation of concentrated solutions.

Characteristics of solutions, as disperse systems, their classification. Obtaining of purified water in pharmacies and at enterprises. Requirements relating to purified water in accordance with the norms established by the State Pharmacopoeia,

instructions to the orders of the Ministry of Health of Ukraine. Calculations of the amount of medicinal substances and water for the preparation of concentrated solutions in different ways: using the measuring tableware; taking into account the coefficient of volume increase (CVI); taking into account the density of the solution. Rules for the preparation of concentrated solutions for the burette system in accordance with the order of the Ministry of Health of Ukraine. Deviations permissible in the total volume of liquid dosage forms. Control of quality of concentrated solutions, conditions of their storage and keeping records of prepared solutions according to orders of the Ministry of Health of Ukraine. The structure of the burette system, the rules of care and use of it.

Topic 8. Preparation of liquid dosage forms by mass-volume method by dissolution of dry medicinal substances and use of concentrated solutions.

Characteristics of liquid dosage forms as disperse systems, their classification, requirements to them. Solubility of medicinal substances as one of the basic physical and chemical characteristics necessary for the preparation of solutions. Ways of prescribing and indicating concentration of solutions. Checking of doses of poisonous and strong-effective substances in medicines. Rules for the preparation of liquid medicinal forms using concentrated solutions in accordance with the instruction on the preparation of liquid dosage forms in pharmacies, approved by the order of the Ministry of Health of Ukraine. Preparation of solutions containing up to 3 % and more than 3 % of dry medicinal substances, concentrated solutions of which are absent. Adding to solutions of syrups, aromatic waters, galenic medicines, etc. Evaluation of quality, packaging, preparation for dispensing, storage of liquid medicines in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 9. Special cases of preparation aqueous solutions. Drops.

Definition of difficult prescriptions and ways to eliminate difficulties. Types of difficult cases of preparation of aqueous solutions, which are most often encountered in pharmacies: slow and heavy dissolution or insolubility of medicinal substances in the prescribed solvent; decomposition of substances that are easily oxidized; deterioration of solubility in a coherent presence. Special technological techniques to overcome the difficulty in preparing solutions: preliminary grinding of substances and the use of a heated solvent; the use of crossed-out purified water and the corresponding auxiliary materials; addition of adjuvants and use of complex formation in the preparation of solutions; soluble dissolution.

Characteristics of drops as dosage forms, their classification by method of application. Checking of doses of poisonous and strong-effective substances in drops. Rules for preparing drops using concentrated solutions and by dissolving dry substances. Creation of eutectic mixes. Preparation of drops in non-aqueous solvents in pharmacies and at enterprises. Evaluation of quality, packaging, preparation for dispensing, storage of aqueous solutions and drops in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 10. Preparation of liquid dosage forms by diluting of the standard pharmacopoeian liquids. Non-aqueous solutions.

Nomenclature of standard pharmacopoeian liquids; their concentrations, chemical and conventional names. Preparation of solutions of pharmacopoeian liquids (the rules for calculating the amount of water and pharmacopoeian liquids depending on the prescribing method), according to the order of the Ministry of Health of Ukraine.

Characteristics of non-aqueous solvents (ethyl alcohol, vegetable oils, vaseline oil, glycerol, chloroform, polyethylene oxide-400, etc.), requirements to them. Calculations for the dilution of ethyl alcohol using the formula for dilution and alcohol test tables. Preparation of solutions on volatile and non-volatile solvents in pharmacies. Safety rules for work with flammable and explosive solvents. Evaluation of quality, packaging, preparation for dispensing, storage of non-aqueous solutions in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 11. Solutions of HMC. Colloidal solutions.

Characteristics of HMC, their classification and application in pharmacy. Influence of the structure of HMC on the dissolution process of limited and unlimited swollen substances. Features of preparation of solutions of pepsin, gelatine, starch, methylcellulose, sodium carboxymethylcellulose, plant extracts. Characteristics and properties of colloidal solutions. Technology of solutions of protected colloids (collargol, protargol, ichthyol). Rules for the addition of medicinal substances to solutions of HMC and protected colloids. The main signs of instability of solutions of HMC and colloidal solutions. Evaluation of quality and storage of solutions of HMC and colloids, registration for dispensing in accordance with the requirements of orders of the Ministry of Health of Ukraine.

Topic 12. Suspensions.

Characteristics of suspensions as dosage form and disperse system; requirements for them. Cases of formation of suspensions. Factors influencing the stability of heterogeneous systems. The Stokes law. Solubilisation, its use in pharmaceutical technology. The technology of suspensions of hydrophilic and hydrophobic substances: the use of the effect of P. A. Rebinder and the rule of B. V. Deryagin. Dispersion method for preparing suspensions with hydrophilic medicinal substances. The essence of method of taking muddy. Characteristics of stabilizers and the mechanism of their action. Condensation method for the preparation of suspensions (chemical dispersion, solvent exchange). Opalescent and turbid mixtures. The main signs of instability of suspensions. Evaluation of quality, packaging, preparation for dispensing, storage of suspensions in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 13. Emulsions.

Characteristics of emulsions as dosage forms and disperse system, their classification. Requirements of the State Pharmacopoeia to oil emulsions. Types of oil emulsions and methods of their determination. Characteristics of emulsifiers, their classification and the mechanism of action. General rules and methods for preparation oil emulsions. Calculation of the amount of emulsifier, water and oil. Stages of the process of preparation emulsions. Introduction of medicinal substances with different

physical and chemical properties to the composition of oil emulsions. Features of the introduction of phenyl salicylate and sulfanilamide's. Main signs of instability of emulsions. Evaluation of quality and storage of emulsions, packaging, preparation for dispensing in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 14. Infusions and decoctions of medicinal plant raw material.

Characteristics of infusions and decoctionsas a dosage form and disperse system. Ways of prescribing infusions and decoctions. Theoretical bases of the process of extraction from medicinal plant raw materials. Factors influencing the extraction process (the relation between the quantity of raw material and the extractant, standardity, the histological structure and the degree of substrate of the raw material, the material of the infuser, the temperature, the duration of infusing and cooling, the pH of the medium, the chemical composition, etc.). Rules for the preparation of infusions and decoctionsfrom plant raw materials and the addition of medicinal substances to them in accordance with the requirements of the State Pharmacopoeia. Equipment used for the preparation of infusions and decoctions. Features of preparation of water extracts from medicinal plant raw materials containing alkaloids, cardio glycosides, essential oils, tannins, anthracene derivatives, saponins, etc. Special cases of preparation of infusions and decoctions("double" infusions, decoctionsof Senna leaves, etc.). Authors' prescriptions of water extracts (Deryagin, Qvater, Ravkin's mixtures, etc.). Evaluation of quality, storage of water extracts, storage and registration of them for dispensing in accordance with the requirements of the State Pharmacopoeia and other normative documents (orders of the Ministry of Health of Ukraine).

Topic 15. Infusions and decoctions from extracts concentrates. Mucilages.

Characteristics of standardized extracts-concentrates for the preparation of infusions and decoctions, their nomenclature. Advantages of their application in the technology of water extracts. Rules for the preparation of water extracts with the use of extracts-concentrates and the introduction of various therapeutic agents in them. Features of the preparation of water extracts from raw materials containing mucus (althea root, flaxseed, etc.) and the addition of various medicinal substances to them. Evaluation of quality and storage of water extracts in accordance with the requirements of regulatory documents, packaging and registration for dispensing (orders of the Ministry of Health of Ukraine). Areas of improvement of technology of water extracts.

Topic 16. Liniments and homogeneous ointments.

Characteristics of liniments as dosage forms and disperse systems; their classification depending on the nature of the dispersion medium, the physical and chemical properties of the ingredients and medical purpose. Rules for preparation liniments of various types of disperse systems: solutions, suspensions, emulsions, combined. Pharmacopoeia prescriptions and difficult cases of preparation liniments, their technology. Characteristics of ointments as dosage forms and disperse systems, their classification (by medical purpose, place of application, consistency and physical and chemical properties of medicinal substances that are part of ointments), requirements of the State Pharmacopoeia to them. Requirements for ointment bases, their classification. List of ointment bases that are recommended by SPU, principles of their selection. Characteristics of hydrophobic and hydrophilic bases. The main technological steps and rules for the preparation of homogeneous ointments such as solutions, alloys. Pharmacopoeian prescriptions of ointment-solutions. Evaluation of quality and storage of liniments and ointments in accordance with the requirements of normative documents, packaging and preparation for dispensing (orders of the Ministry of Health of Ukraine).

Topic 17. Ointments suspension and ointment-emulsion.

Characteristics of diphilic (hydrophilic-lipophilic) ointment bases and emulsifiers for their preparation. Characteristics of ointments-suspension (triturational) and their technology depending on the percentage of medicinal substances. Officinal prescriptions of ointments-suspensions. Features of introduction in dermatological ointment resorcinol and zinc sulfate. Pastes, their classification. Features of preparation dermatological pastes. Characteristics of ointments-emulsions of different types and their preparation, depending on the properties of medicinal and auxiliary substances. Features of the composition and technology of cooling ointments. Rules for introducing protargol, tannin and vegetable extracts of different consistency in the ointment. Evaluation of quality of diphilic ointments, storage and preparation for dispensing in accordance with the requirements of the State Pharmacopoeia, other normative documents (orders of the Ministry of Health of Ukraine).

Topic 18. Combined ointments. Creams. Gels.

Characteristics of combined ointments and general rules of their preparation. Stages of technological process of preparation of combined ointments taking into account physical and chemical properties of medicinal substances. Preparation of ointments using intra-pharmacy products (concentrates and semi-finished products). Methods of quality control of combined ointments, their storage and preparation for dispensing according to the requirements of the State Pharmacopoeia, other normative documents (orders of the Ministry of Health of Ukraine). The main signs of instability in ointments. Directions of perfection of ointments and liniments of extemporaneous preparation. Characteristics of creams and gels, general rules for its preparation.

Topic 19. Preparation of suppositories by rolling method.

Characteristics of suppositories as dosage forms and as disperse systems. Classification of suppositories. Requirements of the State Pharmacopoeia to them. Methods of prescribing suppositories; checking of doses of poisonous and strong-effective medicinal substances in them. Pharmacopoeian prescriptions and difficult cases of preparation of suppositories, their technology. Bases for suppositories; the requirements imposed on them, and a brief description. Features of prescribing sticks and calculating the base for them. Characteristics of technological stages of preparation of suppositories by the rolling method. Rules for the introduction of medicinal substances with different physical and chemical properties in the bases; features of the administration of protargol, collargol, tannin, dry and dense extracts. Methods of evaluating the quality of suppositories, packaging, registration

for dispensing, rules for storage in compliance with the requirements of normative documents, relevant instructions (orders of the Ministry of Health of Ukraine).

Topic 20. Preparation of suppositories by casting method.

Bases for suppositories used in the preparation of suppositories by the casting method; the requirements put forward to them, and a brief description. Calculations of the quantity of suppository bases for the preparation of suppositories by the pouring method. The notion of replacement coefficient. Characteristics of technological stages of preparation of suppositories by the pouring method. Rules for the introduction of medicinal substances with different physical and chemical properties in the bases when using the pouring method. Main signs of instabilities of suppositories. Evaluation of quality of suppositories, packaging, preparation for dispensing, storage conditions in accordance with the requirements of normative documents (orders of the Ministry of Health of Ukraine).

Topic 21. Requirements for the preparation of sterile and aseptic medicines in pharmacy conditions.

Requirements of GPP for preparation of sterile and aseptic dosage forms in pharmacies. Aseptic conditions for the preparation of medicines. The procedure for monitoring compliance with the sanitary-and-epidemic regime in pharmacies. Requirements for premises, equipment and sanitary-hygienic requirements for the preparation of medicinal products in aseptic conditions. Requirements for personal hygiene of the staff of pharmacy establishments, which prepare medicines in aseptic conditions. Characteristics of solvents used for the preparation of injectable dosage forms. Obtaining, storing and controlling quality of water for injection. Requirements for medicinal and auxiliary substances used for preparation medicines in aseptic conditions. Non-aqueous solvents. Fatty oils, requirements for them and preparation for use.

Requirements for packaging materials used for the preparation of medicines in aseptic conditions. Classification of sterilization methods. Thermal sterilization methods and equipment used for this purpose. The procedure for controlling the temperature regimes of sterilizers. Sterilization modes of individual objects and the order of registration of results of sterilization in corresponding journals. Requirements for quality control of sterile and aseptic dosage forms. Types of documentation that is being prepared for the preparation of individual and serially prepared medicines (general technological instructions, technological instructions for individual and serial medicines, production records).

Topic 22. Solutions for injections.

Characteristics of injectable dosage forms; the requirements put forward to them by the State Pharmacopoeia and their realization. Technological stages of preparation of solutions for injections. Filtration of solutions and check them for no mechanical impurities. Progressive quality control of solutions for injection, corking, registration for dispensing and storage in accordance with the requirements of the State Pharmacopoeia and in accordance with the requirements of normative documents (orders of the Ministry of Health of Ukraine).

Topic 23. Solutions for injections required stabilization.

Causes of destruction (decomposition) of medicinal substances in solutions for injections. Characteristics of stabilizers used for the preparation of solutionsfor injections; their classification. The principles of the selection of stabilizers and the calculation of their quantity. Stabilization of solutions of medicinal substances, which are supported by hydrolysis. Antioxidants, their classification. Stabilization of solutions of substances that are easily oxidized. Features of preparation of solutions for injections of glucose and sodium hydrocarbonate. Evaluation of quality of solutions for injections, corking, registration for dispensing and storage in accordance with the requirements of normative documents (orders of the Ministry of Health of Ukraine).

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

The value of isotonating of solutions for injections. Methods for calculating isotonic concentrations (using equivalents for sodium chloride). Principles of choosing of isotonating substances. Infusion (physiological) solutions; requirements of the State Pharmacopoeia and other normative documents to them. Classification of solutions for infusion for their medical purpose and composition. The nomenclature of the most commonly used plasma replacement and anti-shock solutions in the form of ready-prepared dosage forms of industrial production. Features of the technology of solutions for infusion, depending on the composition of active substances. Rules for preparing solutions for injections with thermolabile substances and suspensions for injections. Emulsions for parenteral nutrition. The main signs of instability of solutions, suspensions and emulsions for injections. Evaluation of quality of solutions, suspensions and emulsions for injection, corking, registration for dispensing and storage in accordance with the requirements of normative documents (orders of the Ministry of Health of Ukraine).

Topic 25. Ophthalmic dosage forms. Dosage forms with antibiotics.

Characteristics of medical forms used for the treatment of ophthalmic diseases; requirements to them in accordance with the state control system. Isotonating of eye drops, lotions, and washes. Prolonging the effect of eye drops. Ensuring the stability of eye drops, assortment of preservatives. Features of the technology of eye drops, depending on the physical and chemical properties of medicinal substances. Rules for preparation lotions and washings. Characteristics of the bases used for the preparation of eye ointments. The technology of eye ointments and the peculiarities of introducing zinc sulfate and resorcinol in it. Characteristics of dosage forms with antibiotics; the requirements put forward to them and factors influencing their stability. Features of the technology of liquid and solid dosage forms with antibiotics (lotions, washes, rinses, eye and ears drops, etc.). Technology of ointments and suppositories with antibiotics; characteristics of the bases for their preparation. Evaluation of quality of ophthalmic dosage forms and dosageforms with antibiotics, corking, registration for dispensing and storage in accordance with the requirements of normative documents (orders of the Ministry of Health of Ukraine).

Topic 26. Medicinal forms for infants and children under 1 year of age. Radiopharmaceuticals. Geriatric drugs.

Characteristics of dosage forms for infants and children under 1 year of age; requirements for them. Features of preparation of liquid dosage forms, powders, suppositories, ointments for infants and children under 1 year of age, capping,

preparation for release and storage in accordance with the requirements of the ND. Assessment of the quality of dosage forms for newborns and children under 1 year of age.

Topic 27. Internal pharmacy preparations. medicines made "for stock". Incompatibilities.

Definition and types of in-pharmacy preparations (IPP) according to the Federal Drug Administration. Application of IPP in the technology of solid, liquid, soft, sterile and aseptic dosage forms. Semi-finished products. Definition, preparation conditions. Testing, labeling, terms and conditions of storage. Medicinal products manufactured "for stock". Definition, nomenclature, labeling, storage terms and conditions. Functions and duties of a pharmacist for preparing IPP. Technological instruction. Requirements of the SPU to its structure. Cases of incorrect prescribing of prescriptions received by pharmacies (overdosing, lack of seals, prescribing in a non-Latin language, incorrect medical purpose, etc.). Rights and obligations of a pharmacist in relation to incorrectly written prescriptions in accordance with the requirements of the order of the Ministry of Health of Ukraine. Causes of physical and physicochemical incompatibilities. Classification of chemical incompatibilities according to the types of reactions taking place and their manifestation during the interaction of the ingredients of dosage forms. Characteristics of pharmacological incompatibilities. Types of antagonism. "Conditional" incompatibilities, their medical application.

Recommended literature for preparing for the comprehensive practice-oriented qualification exam

1.Pharmacy — based technology of drugs : the manual for applicants of higher education / O. I. Tykhonov , T. G. Yarnykh, O. A. Rukhmakova, G. B. Yuryeva; ed. by O. I. Tykhonov and T. G. Yarnykh. - Kharkiv : NUPh : Golden Pages, 2019. - 488 p.
2.Workbook for Pharmacy-based Technology of Drugs: A tutorial for the 3-rd year English-speaking applicants of higher education of “Pharmacy” specialty / T. G. Yarnykh, O. I. Tykhonov, O. A. Rukhmakova, M. V. Buryak, V. V. Kovalyov, I. V. Herasymova – Kh.: NUPh, 2019. – 149 p.
3.Workbook for preparation to the licensed examination “KROK-2” in pharmacy-based technology of drugs: for English-speaking applicants of higher education of specialty “Pharmacy”: Practical aids. For individual work / T. G. Yarnykh, O. A. Rukhmakova, V. V. Kovalyov, M. V. Buryak – Kh.: NUPh, 2017. – 56 p.
4.Tests. Pharmacy-based technology of drugs: A handbook for the out-of-classwork of English applicants/ T. G. Yarnykh, O. I. Tykhonov, O. A. Rukhmakova, G. B. Yuryeva, M. V. Buryak, V.V.; ed. by T.G. Yarnykh. – Kh.: NUPh, 2019. – 156 p.

Educational Component ___Industrial Technology of Drugs___

(name)

Summary of the educational component:

The component "Industrial Technology of Drugs" is part of the core curriculum for professionally-oriented training of specialists in the field of "226 Pharmacy, industrial pharmacy." It is designed for students in full-time, part-time, and distance education programs. This component provides theoretical knowledge and develops practical skills related to the general requirements for the production of pharmaceutical products of various pharmaceutical groups within the context of industrial pharmaceutical enterprises.

Content of the educational component:

Topic 1. Regulatory Documentation in the Production of Medicinal Products. Material Balance.

The main activities of the Ministry of Health of Ukraine and the State Pharmacological Center. Regulatory documents in Ukraine. Basic principles of the registration system. Registration dossier. Production protocols, validation forms, and cards. Categories of regulatory documentation in the industrial production of medicinal products according to GMP rules. Key terms used in the production of medicinal products. The purpose and significance of material balance; rules for its compilation at each stage of production; calculation of its main indicators.

Topic 2. Theoretical Foundations of Extraction. Intensification of Extraction Processes.

Theoretical foundations of extraction. Stages of extraction and their characteristics. Factors affecting the completeness and speed of extraction. Requirements for extractants. Methods for intensifying the extraction of compounds from plant raw materials.

Topic 3. Production of Tinctures. Alcoholometry.

Characteristics and classification of tinctures. Methods for their preparation and purification. Technological scheme of tincture production, equipment used. Quality control of tinctures as a pharmaceutical form, packaging, and storage conditions. Methods of ethanol production (from raw materials containing starch, carbohydrates, synthetic method). Rules for determining the concentration of alcohol, dilution, and accounting for alcohol use. Basic principles of ethanol recovery and rectification.

Topic 4. Production of Liquid Extracts.

Characteristics and classification of extracts. Main stages of liquid extract production. Technological scheme of liquid extract production, equipment used. Quality control of liquid extracts.

Topic 5. Production of Solid Extracts.

Production of solid extracts. Theoretical foundations of the evaporation process, equipment, and its principles of operation. Technological scheme of solid extract production. Standardization, packaging, and storage conditions.

Topic 6. Production of Dry Extracts.

Production of dry extracts. Theoretical foundations of the drying process, equipment used. Technological scheme of dry extract production. Standardization, packaging, and storage conditions.

Topic. GMP Requirements for the Production of Parenteral Preparations. Injectable Medicinal Products.**

Basic principles of Good Manufacturing Practice (GMP) for medicinal products, requirements for the production of sterile products. Classification of clean rooms, cleanliness classes.

Topic 8. Composition of Ampoule Glass and Determination of its Main Quality Indicators.

Glass for the production of ampoules and vials, its classes and grades. Basic requirements and quality indicators of ampoule glass. Production of ampoules and their preparation for filling.

Topic 9. Production of Injectable Solutions without Stabilizers.

Production of injectable preparations without stabilizers, purification of solutions, types of filters.

Topic 10. Production of Injectable Solutions with Stabilizers.

Production of injectable solutions with stabilizers, aseptically prepared, using non-aqueous solvents.

Topic 11. Filling Ampoules, Hermetization, and Sterilization of Solutions.

Methods of filling ampoules, sealing methods. Sterilization of injectable solutions. Technological scheme of production; equipment used.

Topic 12. Quality Control of Injectable Solutions.

Quality control of injectable solutions according to the State Pharmacopoeia of Ukraine (SPhU).

Topic 13. Production of Infusion Solutions.

Characteristics of infusion solutions, their use. Classification and requirements for infusion solutions. Prospects for the development of infusion solutions, range of medicinal products. Production of infusion solutions. Technological scheme of production; equipment used. Quality control.

Topic 14. Industrial Production of Ophthalmic, Otic, and Nasal Medicinal Forms.

Main characteristics of ophthalmic, otic, and nasal medicinal forms. Methods of production, equipment used. Physico-chemical and biological features of creation, prolongation. Quality control. Technological schemes of production of ophthalmic, otic, and nasal medicinal products.

Topic 15. Production of Pressure-Containing Preparations.

Classification of aerosols, advantages and disadvantages. Main components of aerosol packaging, types of valve-spray systems, classification of propellants and aerosol concentrates. Production of aerosols, quality control according to the State Pharmacopoeia of Ukraine (SPhU). Technological scheme of production; equipment used.

Topic 16. Physical-Chemical and Technological Properties of Powders and Granules.

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

Topic 17. Production of Tablets by Direct Compression and with Preliminary Granulation.

Industrial production of tablets using direct compression and preliminary granulation. Study of equipment for comminution, sieving, and mixing of raw materials, and its working principle. Granulation methods; equipment used. Excipients in tablet production. Technological scheme of production.

Topic 18. Industrial Production of Film-Coated Tablets.

Coating tablets with shells. Types of coatings and methods of application. Pressed, sugar-coated, and film-coated tablets. Technological scheme of production of film-coated tablets; equipment used. Production of sustained-release tablets, excipients for ensuring prolonged action.

Topic 19. Production of Medical Capsules. Quality Control of Tablets and Capsules According to ДФУ Requirements.

Definition of capsules, requirements of ДФУ to them. Types of capsules and their purposes. Excipients in capsule production. Methods of manufacturing soft and hard gelatin capsules, filling them with medicinal substances. Quality control according to ДФУ. Tubatin. Spansules. Rectal gelatin capsules. Technological aspects of manufacturing capsules with modified release. Technological scheme of production of soft and hard gelatin capsules; equipment used. Quality control of tablets and capsules according to ДФУ requirements.

Topic 20. Industrial Production of Ointments, Gels, Pastes, Creams, and Liniments.

Ointments, gels, pastes, creams, liniments as dosage forms, their characteristics, and classification. Advantages and disadvantages. Requirements for ointments, classification of bases, and general requirements. Excipients in the production of soft dosage forms. Technological schemes of production of soft dosage forms; equipment used. Structural-mechanical (rheological) characteristics of ointments. Quality control. Packaging and labeling.

Topic 21. Production of Suppositories. Quality Control of Suppositories According to ДФУ Requirements.

Suppositories, types and requirements for them. Characteristics of bases and excipients. Methods of manufacturing. Technological scheme of production; equipment used. Quality control of suppositories according to SPhU.

Topic 22. Production of Plasters and TTS.

Classification of plasters. Excipients used in their production. Technological scheme of production; equipment used. Quality control of plasters. An alternative method of drug administration - transdermal therapeutic systems (TTS). Types and categories of TTS. Requirements for active substances included in TTS. Structure of membrane and matrix TTS. Excipients used in creating TTS. Quality indicators of TTS. Technology for improving TTS.

Topic 23. Production of Nano- and Radiopharmaceuticals.

Production and application of radiopharmaceuticals. Assortment and composition of radiopharmaceuticals on the pharmaceutical market of Ukraine. Features of their technology and quality control. Use of nanotechnology in drug production. Basic principles and directions of nanotechnology. Nanopreparations. Features of their production. Carriers for drug transport (liposomes, nanospheres, nanocapsules, colloidal carriers with monoclonal antibodies, etc.).

Recommended literature for preparing for the comprehensive practice-oriented qualification exam

1. Industrial drug technology: tutorial for control. Laboratory classes for students of specialty Production of liquid extracts. "Pharmacy"/ Yu. V. Yudina, Yu. V. Shmyreva, Stages of technological process. S.V. Stepanenko [et. al]. – Kharkiv: NUPh : Equipment. Technological Original, 2012. – 254 p.
2. Train aid for preparation for the licensed integrated test-based exam «Krok 2. Pharmacy» in specialty «226 Pharmacy, industrial pharmacy» for students of the Faculty for Foreign Citizens' Education / A. A. Sichkar, S. V. Stepanenko, D. P. Soldatov, O. S. Kukhtenko. – Kharkiv: NUPh, 2021. – 73 p.
3. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 1. – 1128с.
4. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2014. – Т. 2. – 724 с.
5. Державна Фармакопея України / Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів» – 2-е вид. – Харків: Державне підприємство «Український науковий фармакопейний центр якості лікарських засобів», 2015. – Т. 3. – 732 с.
6. Практикум з промислової технології лікарських засобів : навч. посіб. для здобувачів вищ. освіти денної та заочної форм навчання / О. А. Рубан [та ін.] ; за ред. О. А. Рубан. – 2-ге вид., допов. та випр. – Харків : НФаУ, 2019. – 213 с.
7. Промислова технологія лікарських засобів : навч. посіб. для самостійної роботистудентів / О. А. Рубан, В. Д. Рибачук, Л. М. Хохлова та ін. – Х. : НФаУ, 2015. – 120 с.
8. Методичні рекомендації з підготовки до підсумкового модульного контролю з дисципліни «Промислова технологія лікарських засобів» для здобувачів вищої освіти другого(магістерського) рівня підготовки денної та заочної форм навчання спеціальності «226 Фармація, промислова фармація» / О. А. Рубан, Ю. С. Маслій, Л. М. Хохлова, В. Д. Рибачук, С. А. Куценко. – Х. : НФаУ, 2021. – 22 с.
9. Навчальний посібник з підготовки до ліцензійного інтегрованого іспиту «КРОК 2. Фармація» зі спеціальності «226 Фармація, промислова фармація» для здобувачів вищої освіти денної та заочної форм навчання / за ред. О. А. Рубан. – Х. : НФаУ, 2021. – 78 с.
10. Допоміжні речовини у виробництві ліків : навч. посіб. для студ. вищ. фармац. навч. закл. / О. А. Рубан, І. М. Перцев, С. А. Куценко, Ю. С. Маслій ; за ред. І. М. Перцева. – Х. : Золоті сторінки, 2016. – 720 с.
11. Технологія ліків промислового виробництва : підруч. для студентів вищ. навч. закл. : в 2-х ч. / В. І. Чуєшов, Є. В. Гладух, І. В. Сайко та ін. – 2-е вид., перероб. і допоп. – Х. : НФаУ :Оригінал, 2012. – Ч. 1. – 694 с.
12. Технологія ліків промислового виробництва : підруч. для студентів вищ. навч. закл. : в 2-х ч. / В. І. Чуєшов, Є. В. Гладух, І. В. Сайко та ін. – 2-е вид., перероб. і допоп. – Х. : НФаУ :Оригінал, 2013. – Ч. 2. – 638 с.
13. Промислова технологія лікарських засобів : базовий підручник для студ. вищ. навч. фармац. закл. (фармац. ф-тів). / Є. В. Гладух, О. А. Рубан, І. В. Сайко та ін. – 2-е вид., випр. тадопов. – Х.: НФаУ: Новий Світ-2000, 2018. – 526 с.

Educational component _____ Pharmaceutical chemistry _____
(Name)

Summary of the educational component:

The educational component "Pharmaceutical chemistry" belongs to the mandatory educational components of the cycle of professionally oriented training of specialists in specialty 226 "Pharmacy, industrial pharmacy", it is the basis for studying medicinal products, understanding their action and is necessary for the implementation of practical activities of specialists in pharmaceutical specialties. Pharmaceutical chemistry, as a science based on the general laws of chemical sciences, studies the methods of obtaining and creating, the structure, chemical and physical properties of medicinal products, the relationship between the chemical structure and the effect on the body, quality control methods, changes that occur during storage, and rational use of medicines.

Content of the educational component:

Topic 1. The subject and tasks of pharmaceutical chemistry. General approaches to pharmacopoeial analysis.

Drugs quality control system. Peculiarities of pharmaceutical analysis. Stability. Factors affecting the stability of medicinal products. Pharmacopoeial analysis. The State Pharmacopoeia of Ukraine, its structure. Modern strategies for creating innovative medicines. General provisions, general articles and monographs of the pharmacopoeia. The structure of a monograph on a substance.

Description of the appearance of the medicinal substance and assessment of its solubility as a general indicative characteristic of the tested substance. Quality parameters of medicinal products: relative density, viscosity, boiling point, melting and solidification temperature, refractive index, specific optical rotation, pH of solutions.

Topic 2. General principles of identification of medicinal substances.

Identification of medicinal substances by chemical methods. Peculiarities of identification of drugs of inorganic and organic origine.

Topic 3. Use of spectral and chromatographic methods for identification of medicinal substances. Standard samples and

reference spectra.

The use of IR and UV spectroscopy methods, chromatographic methods in the identification of medicinal products. Peculiarities of using standard samples of medicinal substances and standard spectra.

Topic 4. Limit test. Pharmacopoeia requirements for the determination of impurities by chemical methods.

Origin and character of impurities, methods of their detection. Sources and causes of impurities in medicinal products. Physical and physico-chemical methods for determining impurities: transparency and degree of turbidity of liquids, degree of coloring of liquids, acidity and alkalinity, loss in mass during drying, water according to the Fisher method. Pharmacopoeia tests for impurities (chlorides, sulfates, ammonium salts, etc.). Reference solutions for the determination of impurities. Methods of assessing the content of impurities.

Topic 5. Limit test. Use of physical constants and physico-chemical methods in purity tests.

Use of such characteristics as specific optical rotation, refractive index, spectral and chromatographic methods for establishing the purity of medicinal products, determination of residual quantities of organic solvents.

Topic 6. Assay of drugs by titrimetric methods.

Determination of nitrogen in organic compounds after mineralization, acid-base titration in aqueous and non-aqueous media, argentometry, complexonometry, iodometry, iodatometry, cerimetry, bromatometry, nitritometry, mercurimetry, dichromatometry, permanganatometry, iodochlormetry. Gravimetry.

Topic 7. Assay of medicinal products by physicochemical methods: polarimetry, refractometry, spectrophotometry, photocolorimetry, chromatography.

Methods based on thermodynamic properties of substances. Combination of extraction, chromatographic and optical methods of analysis.

Topic 8. Quality control of individually manufactured medicinal products. Express analysis of mono- and multi-component medicinal products.

Legal and technical documentation regulating the quality control of medicinal forms. Forms of in-pharmacy control and features of its implementation. Features of qualitative and quantitative express analysis of mono- and multi-component medicinal forms. Assessment of the quality of manufacturing medical forms. Analysis of concentrates and intra-pharmacy preparations according to the requirements of the Pharmacopoeia.

Topic 9. Chemical bases of action of medicines (general principles). Chemical reactions of metabolic transformations.

Classification of medicines; their nomenclature. Influence of physicochemical parameters of medicinal substances on their pharmacological properties. Stages of development of drugs. The main ways of drug metabolism.

Topic 10. Chemical bases of rational use and quality assurance of drugs from the group of narcotic and non- narcotic analgesics.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, production methods and pharmaceutical analysis of individual representatives: morphine hydrochloride, codeine, ethylmorphine hydrochloride, trimeperidine hydrochloride, fentanyl, tramadol; paracetamol, metamizole sodium monohydrate, phenazone, phenylbutazone.

Topic 11. Chemical bases of rational use and quality assurance of drugs from the group of non-steroidal anti-inflammatory drugs.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, production methods and pharmaceutical analysis of individual representatives: sodium salicylate, acetylsalicylic acid, methylsalicylate, salicylamide, indomethacin, sodium diclofenac, mefenamic acid, meloxicam, ibuprofen, dexibuprofen, nimesulide, celecoxib

Topic 12. Chemical bases of rational use and quality assurance of drugs from the group of sedative and anticonvulsant drugs.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, production methods and pharmaceutical analysis of individual representatives: phenobarbital, cyclobarbital, benzobarbital, barbital, pentabarbital, valproic acid (sodium valproate), phenytoin, carbamazepine, potassium/sodium bromide, bromisoval, chloral hydrate, primidone.

Topic 13. Chemical bases of rational use and quality assurance of drugs from the group of hypnotics and tranquilizers.

General characteristics, classification, mechanism of action, structure-activity relationship, properties,

metabolism, methods of preparation and pharmaceutical analysis of individual representatives: chlordiazepoxide, diazepam, nitrazepam, oxazepam, hydazepam, zopiclone, zolpidem.

Topic 14. Chemical bases of rational use and quality assurance of drugs from the group of neuroleptics.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: chlorpromazine hydrochloride, levomepromazine hydrochloride, trifluoperazine hydrochloride, haloperidol, droperidol.

Topic 15. Chemical bases of rational use and quality assurance of drugs from the group of psychostimulants and antidepressants.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, production methods and pharmaceutical analysis of individual representatives: caffeine, sodium caffeine benzoate, amphetamine sulfate; fluoxetine hydrochloride, amitriptyline hydrochloride.

Topic 16. Chemical bases of rational use and quality assurance of medicines from the group of nootropics and analeptics.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism,

production methods and pharmaceutical analysis of individual representatives: racemic camphor, niketamide (cordiamine); piracetam, gamma-aminobutyric acid (aminalon), glutamic acid, sodium oxybutyrate.

Topic 17. Chemical bases of rational use and quality assurance of cholinergic and anticholinergic medicines.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: pilocarpine hydrochloride, neostigmine methyl sulfate (proserin), aceclidine, physostigmine salicylate; atropine sulfate, methacin iodide, platyphyllinum hydrotartrate.

Topic 18. Chemical bases of rational use and quality assurance of adrenergic and antiadrenergic drugs.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: adrenaline tartrate, norepinephrine tartrate, phenylephrine hydrochloride (Mezaton), ephedrine hydrochloride, clonidine hydrochloride (Clofelin).

Topic 19. Chemical bases of rational use and quality assurance of medicines from the group of local anesthetics.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: benzocaine (anesthesin), lidocaine hydrochloride (xycain), procaine hydrochloride (novocaine), tetracaine hydrochloride, bupivacaine hydrochloride.

Topic 20. Chemical bases of rational use and quality assurance of expectorant, mucolytic and irritant drugs.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: acetylcysteine, ambroxol hydrochloride, sodium benzoate, terpine hydrate; racemic menthol, validol, ammonia solution.

Topic 21. Chemical bases of rational use and quality assurance of diuretic drugs.

Загальна характеристика, класифікація, механізм дії, зв'язок структура-активність, властивості, метаболізм, способи одержання та фармацевтичний аналіз окремих представників: ацетазоламід (діакарб), фуросемід, гідрохлортіазид, індапамід, спіронолактон, кислота етакринова, теофілін-етилендіамін, теобромін. General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, production methods and pharmaceutical analysis of individual representatives: acetazolamide (diacarb), furosemide, hydrochlorothiazide, indapamide, spironolactone, ethacrynic acid, theophylline ethylenediamine, theobromine.

Topic 22. Chemical bases of rational use and quality assurance of cardiotonic drugs: cardiac glycosides. Medicines affecting the blood coagulation system. Hypolipidemic agents.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: digoxin, strofanthin, corglycon; pentoxifylline, calcium chloride, menadione sodium bisulfite, aminocaproic acid; atorvastatin, simvastatin, rosuvastatin.

Topic 23. Chemical bases of rational use and quality assurance of antiarrhythmic drugs.

General characteristics, classification, mechanism of action, structure-activity relationship, properties,

metabolism, methods of preparation and pharmaceutical analysis of individual representatives: procainamide hydrochloride, quinidine; amiodarone; propranolol hydrochloride, bisoprolol fumarate

Topic 24. Chemical bases of rational use and quality assurance of antihypertensive drugs: angiotensin-converting enzyme (ACE) inhibitors, spasmolytics.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: captopril, enalapril maleate; papaverine hydrochloride, bendazol hydrochloride.

Topic 25. Chemical bases of rational use and quality assurance of antianginal drugs: nitrovasodilators, calcium channels blockers.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: glycerol tri-nitrate (nitroglycerin), pentaerythritol tetranitrate; nifedipine, verapamil hydrochloride, diltiazem hydrochloride, amlodipine besylate.

Topic 26. Chemical bases of rational use and quality assurance of antiallergic drugs.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: diphenhydramine hydrochloride, promethazine hydrochloride, loratadine, desloratadine, cetirizine, levocetirizine, fexofenadine hydrochloride, ketotifen.

Topic 27. Chemical bases of rational use and quality assurance of drugs affecting the gastrointestinal tract: antisecretory (H_2-histamine receptor blockers, proton pump inhibitors), antacids, and astringents.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: ranitidine, famotidine; omeprazole; aluminum hydroxide, magnesium oxide, basic magnesium carbonate, basic bismuth nitrate, bismuth subcitrate.

Topic 28. Chemical bases of rational use and quality assurance of hepatoprotectors, laxative and antidiarrheal drugs.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: morpholinium thiazotate (thiotriazoline), methionine; bisacodyl, sodium picosulfate, magnesium sulfate, lactulose; loperamide hydrochloride.

Topic 29. Chemical bases of rational use and quality assurance of medicines used in disorders of thyroid gland functions.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: sodium levothyroxine, liothyronine, sodium/potassium iodide; thiamazole (mercazolil).

Topic 30. Chemical bases of rational use and quality assurance of insulin preparations and synthetic hypoglycemic agents (sulfonylureas, biguanides).

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: insulins; carbutamide, tolbutamide, chlorpropamide, glibenclamide; metformin hydrochloride.

Topic 31. Chemical bases of rational use and quality assurance of drugs from the group of steroid hormones: glucocorticosteroids and their fluorine-substituted derivatives.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: cortisone acetate, hydrocortisone acetate, prednisone; dexamethasone, betamethasone dipropionate.

Topic 32. Chemical bases of rational use and quality assurance of drugs from the group of sex hormones and their synthetic analogues.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: testosterone propionate; progesterone, pregnin; estradiol dipropionate, ethinylestradiol.

Topic 33. Chemical bases of rational use and quality assurance of medicinal products of the group of water-soluble vitamins.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: ascorbic acid, calcium pangamate, calcium pantothenate, nicotinic acid, nicotinamide, pyridoxine hydrochloride, thiamine hydrochloride / thiamine hydrobromide, riboflavin.

Topic 34. Chemical bases of rational use and quality assurance of drugs of the group of fat-soluble vitamins. Enzymatic drugs.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, production methods and pharmaceutical analysis of individual representatives: retinol acetate, ergocalciferol, cholecalciferol, tocopherol acetate; pancreatin, trypsin, hyaluronidase, streptokinase.

Topic 35. Chemical bases of rational use and quality assurance of drugs of the antibiotic group: β-lactams (penicillins, cephalosporins, carbapenems, monobactams), tetracyclines, amphenicols, aminoglycosides, macrolides. β-lactamase inhibitors.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: benzylpenicillin sodium, ampicillin sodium, amoxicillin trihydrate, oxacillin sodium; cefazolin sodium, cefalexin monohydrate, ceftriaxone sodium; imipenem; aztreonam; doxycycline monohydrate; chloram-fenicol; streptomycin sulfate; azithromycin; clavulanic acid.

Topic 36. Chemical bases of rational use and quality assurance of drugs of the sulfonamide group.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: sulfanilamide, sodium sulfacetamide, sulfathiazole, phthalylsulfathiazole, sulfadimethoxine, sulfamethoxazole, sulfasalazine.

Topic 37. Chemical bases of rational use and quality assurance of medicinal products derived from nitrofuran, 8-hydroxyquinoline, and quinolone carboxylic acids.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: nitrofural, nitrofurantoin, furazolidone, nitroxoline, ofloxacin, norfloxacin, ciprofloxacin hydrochloride, gatifloxacin.

Topic 38. Chemical bases of rational use and quality assurance of anti-tuberculosis drugs.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: isoniazid, fti-vasid, pyrazinamide, ethambutol hydrochloride, sodium para-aminosalicylate, calcium benzamidosalicylate.

Topic 39. Chemical bases of rational use and quality assurance of antiprotozoal and antiviral drugs.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: quinine sulfate, quinine hydrochloride, quinine dihydrochloride, chloroquine; metronidazole; acyclovir, oseltamivir, zidovudine, ribavirin, sofosbuvir, remdesivir, enisanium iodide.

Topic 40. Chemical bases of rational use and quality assurance of antitumor drugs

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: Cyclophosphane, thiophosphamide, myelosan, mercaptopurine, methotrexate, fluorouracil, cisplatin, vinblastine, doxorubicin, phosphestrol.

Topic 41. Chemical bases of rational use and quality assurance of antiseptic and disinfectants.

General characteristics, classification, mechanism of action, structure-activity relationship, properties, metabolism, methods of preparation and pharmaceutical analysis of individual representatives: iodine, sodium tosylchloramide, iodoform, chlorhexidine bigluconate, hydrogen peroxide, potassium permanganate, salicylic acid, benzoic acid, boric acid, sodium tetraborate, zinc sulfate, protargol, formaldehyde solution, methenamine, ethanol, phenol, resorcinol.

Recommended literature for preparing for the comprehensive practice-oriented qualification exam

1. State Pharmacopoeia of Ukraine: in 3 volumes / SE Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products". - 2nd edition. - Kh.: State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2015. - Vol. 1. - 1128 p.
2. State Pharmacopoeia of Ukraine: in 3 volumes / SE Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal

Products". - 2nd edition. - Kh.: State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicines", 2014. - Vol. 2. - 724 p.
3. State Pharmacopoeia of Ukraine: in 3 volumes / SE Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products". - 2nd edition. - Kh.: State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2014. - Vol. 3. - 732 p.
4. Фармацевтична хімія : підруч. для студентів вищ. фармац. навч. закл. і фармац. ф-тів вищих мед. навч. навч. закл. III-IV рівнів акредитації / за заг. ред. проф. П. О. Безуглого. – 3-тє вид., випр., доопрац. – Вінниця : Нова Книга, 2017. – 456 с.
5. Pharmaceutical chemistry. Lectures for English-speaking students: the study guide for students of higher schools / V.A. Georgiyants, P.O. Bezugly, G.O. Burian, A.I. Abu Sharkh, K.A. Taran ; edited by V.A. Georgiyants, P.O. Bezugly. – Kharkiv: NUPh ; Original, 2013. – 576 p.
6. Pharmaceutical analysis : the study guide for student of higher schools / V. A. Georgiyants, P. O. Bezugly, I. V. Ukrainets et al ; edited by V. A. Georgiyants. – Kharkiv : NUPh : Golden Pages, 2018. – 494 p.
7. Медична хімія : навч. посіб. для студентів вищ. навч. закл. / І.С. Гриценко, С.Г. Таран, Л.О. Перехода, та ін. ; за заг. ред. І.С. Гриценка. – Харків : НФаУ : Золоті сторінки, 2017. — 552 с.
8. The European Pharmacopea. 8th edition. – Published by the Directorate for the Quality of Medicines & Healthcare of the Council of Europe. – Council of Europe, 67075 Strasbourg Gedex, France. – 2013.
9. Order of the Ministry of Health of Ukraine from 17.10.2012 № 812 Про затвердження Правил виробництва (виготовлення) та контролю якості лікарських засобів в аптеках (Із змінами, внесеними згідно з Наказами Міністерства охорони здоров'я № 441 від 01.07.2014, № 1195 від 09.11.2016).

Educational component Pharmacognosy with the basics of resource science
(Name)

Summary of the educational component:

Pharmacognosy with the basics of resource science is a highly specialized applied science that studies the biological, biochemical and medicinal properties of plants, natural raw materials and their products; provides knowledge, skills and abilities in the identification of medicinal plants, determination of stocks, procurement, storage and analysis of medicinal plant raw materials (MPM), as well as individual products of plant and animal origin. The educational component is based on the chemical classification of medicinal plants, introduces higher education students to the ways of biosynthesis of medicinal plants, the patterns of distribution of medicinal plants in nature, the peculiarities of the exploitation of medicinal plant thickets, the organization of their protection and reproduction in natural conditions. The sequence of teaching the course of pharmacognosy with the basics of resource science corresponds to the sequence of biochemical processes in the plant organism, takes into account the biogenetic features of different groups of BAC. First, medicinal plants and medicinal plant raw materials, which contain primary metabolites (carbohydrates, lipids, peptides and proteins), are considered, then - compounds of secondary biosynthesis, formed through mevalonic acid or the shikimate pathway, etc.

Content of the educational component:

Topic 1. General part of Pharmacognosy. Pharmacognostic methods: macro- and microscopical analysis of the MPM from different morphological groups, microchemical reactions and thin-layer chromatography of some groups of BAC.

Topic 2. Carbohydrates. Glycosides. General characteristic. Chemical analysis of MPM. Determination of the swelling index of the plant material. MP and MPM containing polysaccharides: marshmallow species, plantain species, coltsfoot, flaxseed, laminaria species; glucose, honey, starch and its derivatives, inulin, pectin, gums.

Topic 3. Lipids and lipoids. General characteristic of fatty acids, fats and lipoids. Medicinal plants, raw material and products containing fats and lipoids. Analysis of fatty acids. Olive, almond, peach, castor, sunflower oil. Cod liver oil. Cocoa butter. Waxes. Products of soja processing (oil, proteins, phospholipids).

Topic 4. Proteins. General characteristic. MP and raw material of herbal and animal origin containing proteins. Beekeeping products: pollen, apilac, propolis. Bee and snake venom. Phytotoxins of mushrooms, lectins. Enzymatic medicines of herbal and animal origin. Leeches, velvet antlers.

Topic 5. Vitamins. General characteristic. MP and MPM containing vitamins. Rosehip, pot marigold, sea buckthorn, blackcurrant, rowan, nettle species, corn, shepherd’s purse.

Topic 6. Macro- and microelements. Organic acids. General characteristic. MP and MPM containing organic acids, silicic acid derivatives. Pomegranate, hibiscus, cranberry.

Topic 7. Glucosinolates (thioglycosides) and cyanogenic glycosides. MP and MPM containing glycosides and non-glycosidic compounds of sulfur. Mustard species, bitter almond.

Topic 8. Terpenoids. Iridoids. Bitters. General characteristic of MP and MPM containing iridoids and bitters. Yellow gentian, bogbean, centaury species, dandelion, high bush cranberry, hops.

Topic 9. Essential oils. General characteristic. Analysis of essential oils. MP and MPM containing essential oils. Correlation between the chemical composition of essential oil and pharmacotherapeutic effects in aromatherapy. Coriander, lavender, melissa, peppermint, sage, eucalyptus species, common valerian, juniper, caraway, linden species, German chamomile, Roman chamomile, elecampane, wormwood, yarrow, birch species, calamus, Labrador tea, aniseed, fennel, common thyme, creeping thyme, pot marjoram, menthol, thymol, camphor.

Topic 10. Diterpenoids. Resins and balsams. General characteristic. MP and MPM containing diterpenoids, resins and balsams.

Topic 11. Triterpenoids. Steroids. Saponins. General characteristic. Methods of qualitative and quantitative analysis.

MP and MPM containing saponins**.** Natural sources of hormones and bile acids**.** Liquorice species, horse chestnut, horsetail, Java tea, ginseng, Japanese angelica-tree, locoweed. Raw material for semisynthesis of glucocorticosteroids. Yam species, puncture vine, fenugreek, maral root, agave species, Adam's needle etc.

Topic 12. Cardiac glycosides. General characteristic. Methods of qualitative and quantitative analysis. MP and MPM containing cardiac glycosides. Purple foxglove, Grecian foxglove, big-flowered foxglove, strophanthus species, spring pheasant's eye, lily-of-the-valley, erysimum.

Topic 13. Phenolic compounds. General characteristic. Methods of qualitative and quantitative analysis. MP and MPM containing simple phenols and their glycosides. Bearberry, cowberry, rhodiole, pansy species, echinacea species.

Topic 14. Coumarins and chromones. General characteristic. Methods of qualitative and quantitative analysis. MP and MPM containing coumarins and chromones. Melilot, horse chestnut, parsnip, greater ammi, figs.

Topic 15. Lignans. General characteristic. MP and MPM containing lignans. Schizandra, eleuthero, mayapple, milk thistle.

Topic 16. Xanthones. General characteristic. Methods of qualitative and quantitative analysis. MP and MPM containing xanthones: Hedysarum.

Topic 17. Flavonoids. General characteristic. Methods of qualitative and quantitative analysis. MP and MPM containing flavonoids**.** Japanese pagoda tree, cornflower, black chokeberry, motherwort species, water pepper, redshank, knotgrass, marsh cudweed, immortelle, hawthorn species, threelobe beggarticks, liquorice, restharrow, locoweed.

Topic 18. Quinones. General characteristic. Methods of qualitative and quantitative analysis. MP and MPM containing quinones. **Anthraquinones**: alder buckthorn, common buckthorn, rhubarb, horse sorrel, aloe, Alexander and Tinnavely senna, dyer's madder, St. John's wort species.

Topic 19. Tannins. General characteristic. Methods of qualitative and quantitative analysis. MP and MPM containing procyanidins and tannins. Smoke tree, bistort, alder species, greater burnet, oak species, tormentil, bilberry, bird cherry.

Topic 20. Alkaloids. General characteristic. Methods of qualitative and quantitative analysis. MP and MPM containing alkaloids. Belladoona, henbane, stramonium species, bush pea species, opium poppy, tulip poppy, celandine, barberry, ergot, nux vomica, rauwolfia species, Madagascar periwinkle, common periwinkle, passionflower, veratrum, Cayenne pepper, ephedra, colchicum species.

Topic 21. **Medicinal plants and raw material containing different biologically active compounds. Tissue cultures.** General characteristic. Isolated tissue culture. Chaga, kalanchoe. Other natural sources of BAC: microorganisms, fungi and lichens. Antibiotics.

Topic 22. Merchandising analysis. Methods of sampling, identification of MPM. Quality control methods (QCM) for the raw material of natural origin. MPM analysis according to the relevant QCM. Analysis of herbal species and teas.

Topic 23. Ways of MPM processing. Analysis of medicinal fees and teas.

Topic 24. Resource science of medicinal plants. Raw material database of medicinal plants of Ukraine. Selection of objects of resource studies. Methods of determining reserves of wild medicinal plants.

Recommended literature for preparing for the comprehensive practice-oriented qualification exam

1. Pharmacognosy: textbook for higher school students / V.S. Kyslychenko, L.V. Upyr, Ya.V. Dyakonova, V.Yu. Kuznetsova, I.G. Zinchenko, O.A. Kyslychenko; ed. byV.S. Kyslychenko. – Kharkiv : NUPh : GoldenPages, 2011. – 552 p.; il.
2. Pharmacognosy: textbook for students of higher / V.S. Kislychenko, L.V. Lenchyk, I.G. Gurieva et al.; ed. by V.S. Kyslychenko. – Kharkiv : NUPh : Golden Pages, 2019. – 584 p.
3. Text book of Pharmacognosy and Phytochemistry / A. Dhole, V. Dhole, V. Yeligar, Ch. Magdum. Pharma Career Publication, 2019. – 778 p.

Educational component Organization and Economics of Pharmacy

Summary of the educational component:

The educational component "Organization and Economic of Pharmacy" is part of the cycle of mandatory components of professionally oriented training of specialists in specialty 226 Pharmacy, industrial pharmacy. Its study ensures that students of higher education acquire theoretical knowledge and practical skills regarding the organization of the activities of a pharmaceutical organization in the system of pharmaceutical care to the population, in particular, the provision of the population with medicines and other products of the pharmacy assortment, the organization of the reporting and accounting system in pharmacy with the filling of relevant documents, the implementation of analysis and planning of the main socio-economic indicators of pharmacy.

Content of the educational component:

Topic 1. Introduction into pharmacy practice. Role of a pharmacist in health care system. Historical aspects and new paradigm for pharmacy practice.

Modern approaches to the pharmacy practice. Role of a Pharmacist in Health Care System. The main aspects and new paradigm of the pharmacy practice.

Topic 2. Organization structure of pharmacy as a trading-production enterprise, nomenclature of staff positions in pharmacy

Main tasks and functions of pharmacy, classification, organizational structure, nomenclature of staff positions in pharmacy, structure and appointment of pharmacy rooms. Tasks and functions of departments. Equipment of pharmacies. The

external design of pharmacies**.**

Topic 3. Basic principles of organization of pharmaceutical aid for population. Main International Standards. GPP.

Basic principles and tasks of the organization of the pharmaceutical providing of population at macro- and microeconomical levels. Levels of management and organizational structure of pharmaceutical industry in Ukraine. International standards, regulative pharmaceutical activity (GLP, GCP, GMP, GDP, GPP). The proper pharmacy practice (GPP) – definition, targets, elements.

Topic 4. State regulation of pharmaceutical activity. Government control and regulation of pharmaceutical activity. Licensing in pharmaceutical industry

World Health organization (WHO), International Pharmaceutical Federation (IPF) as organs, regulated pharmaceutical activity in the conditions of globalization of economics. Regulation as function of state management. Levels of management and organizational structure and controls the pharmaceutical activity. Basic definitions of licensing concept of the pharmaceutical industry (production of medicines, wholesale, retail sales of medicines): licensee; organs of licensing; licensed terms. Legal and socio- economic value of licensing of pharmaceutical activity. System of licensing of pharmaceutical activity in Ukraine (legislative base, organizational structure, problems and prospects of development). Contents of the licensed rules of pharmaceutical activity. General organizational requirements

Topic 5. A national drug policy as a common framework to solve problems in pharmaceuticals.

Organizational structure of pharmacy industry management

A national drug policy as a common framework to solve problems in pharmaceuticals. Basic principles of the National Drug Policy (NDP). Key components of the National Drug Policy. Legislation and regulations of NDP

Topic 6. Pharmaceutical providing of the population in the conditions of medical insurance

Basic tasks and functions of medical insurance in the modern market conditions. The general principles of health and pharmaceutical care system functioning: the Beveridge Model; the Bismarck Model; the National Health Insurance Model; the Out-of-Pocket Model. Basic advantages of each model. Obligatory and voluntary medical insurance in the system of socio-economic and market relations. Legislative base, which regulates the obligatory and voluntary medical insurance in Ukraine. Features of the pharmaceutical providing and reimbursement in the world and in the conditions of introduction of obligatory medical insurance in Ukraine

Topic 7. Organization of pharmaceutical care. Conception of responsible self-medication. The Medicine Classifications in pharmaceutical practice. Organization of the OTC-medicines realization

The conception of self-medication and OTC drugs. Pharmaceutical aid as modern notion, its structure. Principles of Practice for Pharmaceutical Care. Requirements to the pharmacies and organization of pharmaceutical care. Non-prescription and OTC drugs. Criteria for OTC medicines. Responsible self- treatment

Topic 8. The Organization of prescription department in pharmacy. Rules of excerption and reception of recipes

Criteria of taking of preparations to prescription and non-prescription list in the countries of EU and in Ukraine. Recipe – determination, functions, classification. Common rules of excerption of recipes. Organization of work of pharmacist on the reception of recipes. Rules of excerption of medications and registration of recipes: the form № 1 (F №1); the form № 3 (F №3). Tasks and functions of the department. Staff of the department. Duties of the pharmacist for receiving of prescriptions and dispensing of extemporal drugs. Equipment of the department

Topic 9. Rules of pricing for different recipe forms. Determination of taxa laborum for the extemporal medications

Common rules of pricing of extemporal medicines. Taxa laborum – determination, economic essence, structure. Order of pricing of different extemporal medical forms s**.**

Topic 10. The order of the turnover of the narcotic, psychotropic drugs and precursors. Accounting of these medicines. Organization of the prescribed ready-made drugs department activity

Adjusting of turn of narcotic, psychotropic matters and precursors at the international and state level. Classification of narcotic, psychotropic matters and precursors. Features of licensing of the activity, related to the turnover of narcotic, psychotropic matters and precursors. Normative-legal adjusting of separate stages of turnover of narcotic tools, psychotropic matters and precursors**.**

Topic 11. Organization of the quality control system of pharmaceutical products. The order of carrying out of the entrance control

Providing of medicine quality as an international problem. System of providing of medicine quality in Ukraine. State registration and certification of medicine as a mechanism of state control of the quality of medicines. Pharmacy in the structure of System of medicine quality control. Organization of entrance control. Conducting of intrachemist types of medicine quality control that made in the conditions of pharmacy**.**

Topic 12. Supply organization of pharmacy enterprises. Organization of work with commodity supplies. International rules INCOTERMS.

Organization of work of wholesale link (pharmacy firm). Organizational structure of wholesale companies. Requirements of GDP. Contents of contracts on the purchase-sale of commodities, their basic parts.

The good pharmacy practice Purchase and inventory control. International standards, which regulate work with the commodity supplies in pharmacies (farm. firms): «Good Procurement Purchases Practice» (GPPP) and «Good Storage practice» (GSP). Basic terms «INKOTERMS». Tasks and functions of the storage department. Duties of the pharmacists in the storage department**.**

Topic 13. The organization of the automatization and information work in pharmacy

Role of pharmaceutical information and automatization in the organization and carrying out of pharmacy work. The characteristic of documentary sources of pharmaceutical information

Topic 14. Organization of the system of accounting and accounting in pharmacies (pharmaceutical firms).

The theoretical bases of the system of accounting. The accounting and its meaning in the economics of the pharmacy. Registration measuring instruments**.**

Topic 15. Accounting as an informative system of enterprises in pharmacy

The Purpose and the Objectives of Accounting. The main principles of accounting in pharmacy. Generally accepted accounting principles (GAAP)**.**

Topic 16. Kinds of account and their interrelations

Kinds of accounting and reporting, their characteristic and regulation. Users of the accounting information**.**

Topic 17. The financial statements of the pharmacy

The classification of the resources of pharmacy. Structure of economic means and sources of their formation. The annual financial statements of the pharmacy: Balance sheet; Income statement; Owner's equity statement; Cash flaw

Topic 18. The accounting cycle. Accounting of cash flow in pharmacies (pharmaceutical companies)

Bookkeeping accounts, its structure. The method of double recording, its contents. Classification of bookkeeping accounts. Computing depreciation**.**

Topic 19. Bookkeeping transactions, their purpose and classification

Bookkeeping transactions, their purpose and classification. Rules for entering transactions. The general ledger and trial balance of the pharmacy**.**

Topic 20. The general ledger and trial balance of the pharmacy. Adjusted trial balance. Worksheet. Closing entries

The purpose of preparing the Adjusted Trial Balance. Preparing of adjustments. The closing entry process. Cash and Cash equivalents. Cash flow cycle. Cash flow statement (cash inflows and outflows).

Topic 21. Forms and systems of payment and the account of work and wages in pharmacies (pharmaceutical companies)

Organization of labor payment in enterprises and establishments. Raises and additional charges to posts salaries. Forms of payment of labor, their description. Order of calculation of extra charges to salary**.**

Topic 22. Organization of inventory of commodities in pharmacies (pharmaceutical firms). Reporting of pharmacy establishments

The organization of work with commodities. Kinds and purpose of the inventory. The essence and meaning of primary intra-economic reporting. Centralized accounting system. Procedure for drawing up and approving reports. Characteristics and structure of the "Product report" and "Report on the economic activity of the pharmacy"**.**

Topic 23. Basic principles and methods of forming of the system of prices on medications

Pricing of medicinal products as a national and international problem. The concept of cost and price of medicines. Types of prices, their functions. Basic principles of drug pricing. Mechanisms of state price regulation. Structure of prices for medicinal products of industrial production. Methodology for calculating trade mark-ups and forming retail prices for ready-made medicines and pharmacy products. Reference pricing.

Topic 24. Bases of pharmaeconomics: principles, calculations and methods. Analysis and planning of the main performance indicators of pharmacies.

Essence and significance of economic analysis. Subject, objects, methods of the pharmacoeconomics. Characteristics of the basic methods and indicators of the pharmacoeconomics. Characteristics and socio-economic importance of the pharmacoeconomics. Classification of analysis methods. Stages of complex analysis of economic activity. Planning methodology: planning principles and methods, planned indicators. Financial planning.

Topic 25. Description of economic trading-financial indicators of pharmacies and pharmaceutical firms. Economic analysis of sales and compounding

The value of planning and forecasting in management. Planning methodology: principles and methods of planning, planning indicators. Normative and balanced planning methods. Methods of planning trade turnover. Planning the inventory standard. Method of planning the receipt of goods.

Topic 26. Planning of activity of pharmacies (pharmaceutical companies). Economic analysis of expenses of pharmacy

Characteristics of economic indicators of trade and financial activity of pharmacy establishments. Characteristics and classification of expenses. Factors affecting the amount and level of costs.

Topic 27. Economic analysis of trading imposing, profit, profitability

Characteristics, economic calculations of trade surplus. Characteristics, economic calculations of trade overlays. Factors affecting the amount and level of trade overlays. The results of trading and financial activities of pharmacy establishments - profit and profitability.

Topic 28. Analysis of financial results of activity of enterprise on the basis of data of the financial reporting. Taxation of pharmacies (pharmaceutical firms). Audit of the financial reporting. Audit of calculations with budget

Characteristics of taxes as a socio-economic category. Simplified taxation, accounting and reporting system. Financial reporting as the source of information for basic parameters of audit. Audit of the financial reporting. Audit of calculations with budget.

Topic 29. Financial-credit system in the conditions of market economy. Crediting of pharmacies

Financial and credit system in market conditions. Economic feasibility of lending. Optimal capital structure of the enterprise. Discounting. Basic principles of lending to pharmacies. Types of loans and their characteristics. Sources of financing of working capital.

Recommended literature for preparing for the comprehensive practice-oriented qualification exam

1. Analysis of financial-economic activity of pharmacies, pharmaceutical firms. Training manual for applicants of higher education on specialty "Pharmacy" on discipline «Organization and economics of pharmacy» / Kotvitska A. A., Volkova A.V., Kalaycheva S.G., Tereschenko L.V., Zaytseva Yu. L., Korzh Yu.V. – Kharkiv: NUPh, 2020. – 78 p.
2. Organization of pharmaceutical providing of the population / Under ed. prof. Nemchenko A.S.,Zhirova I.V. - Kharkov, 2014.- 268 p.
3. The system of the accounting in the pharmacy. Training manual for applicants of higher education on specialty Pharmacy on discipline «Organization and economics of pharmacy» / Kotvitska A. A., Volkova A.V., Kalaycheva S.G., Tereschenko L.V., Zaytseva Yu. L., Korzh Yu.V. Kharkiv: NUPh, 2020. 78 p.
4. Workbook with methodical recommendations in organization and economics of pharmacy. Part 2 / Kubarieva I.V., Volkova A.V., Kalaycheva S.G., Tereschenko L.V., Zaytseva Yu. L., Korzh Yu.V. Kharkiv: NUPh, 2020. 66 p.
5. Organization and economics of pharmacy: collection of test tasks for preparing to licensed test exam «KROK 2» for students in specialty Pharmacy for foreign students (Language of Instructions – English) / A.V. Volkova, A.V. Cherkashyna, L.V. Tereschenko. – Kharkiv: NUPh, 2021. – 55 p.
6. Organization and economics of pharmacy: method. Recommendations for preparation in the course exam and comprehensive practice-oriented qualification examination in Pharmacy for students in specialty Pharmacy for foreign students (Language of Instructions – English) / A.A. Kotvitska, A.V. Volkova, A.V. Cherkashyna, et al. – Kharkiv: NUPh, 2021. – 32 p.

Educational component Pharmaceutical management and marketing

Summary of the educational component:

The subject of the educational component "Pharmaceutical Management and Marketing" is the general management processes of pharmaceutical organizations, needs, means of satisfying them and bringing them to consumers, methods of marketing research. Knowledge of the theoretical foundations of marketing will allow specialists to stimulate the sale of goods and services, study, form and forecast demand, develop and analyze the sales and price policy of organizations. A feature of the educational component is the adaptation of management and marketing theory to the realities of the pharmaceutical market.

Content of the educational component:

Topic 1. Theoretical bases of management.

Meaning and concepts of management. The evolution of management theory: D. Wharton's management course, the essence of F. Taylor's theory, A. Fayol's school of administrative management, E. Mayo's "human relations" school. Development directions and trends in management theory of the 21st century. Peculiarities of management in pharmacy. Approaches to management: approach from the positions of selection of different schools in management, process, system, situational. Management process. Management levels: institutional, managerial, technical. Management of the pharmaceutical system at the modern stage. Foreign management models: American, Japanese and European.

Topic 2. Organization as a management object. External environment of pharmaceutical organizations.

Concept of organization in management theory, requirements for organization. General features of the organization. Types of organizations. The life cycle of a pharmaceutical organization: stages and their characteristics.

The internal environment of pharmaceutical organizations. Internal variables of pharmaceutical organizations and their relationship. Goals of the organization, types of goals, requirements for goals. Structure of the organization, requirements for organizational structures. Tasks, categories of tasks. Technologies. People, main aspects of the human variable and individual personality characteristics.

The external environment of pharmaceutical organizations. General characteristics of the external environment: interrelationship of factors, complexity, mobility, uncertainty. Factors of the external environment of direct influence: consumers of pharmaceutical products, suppliers, intermediaries, competitors, contact audiences. Legislative acts and state bodies regulating the activities of pharmaceutical organizations in Ukraine. Factors of the external environment of indirect influence: political, economic, demographic, socio-cultural, scientific and technical, international factors. The influence of external factors on the activity of pharmaceutical organizations.

Topic 3. Successful management. Power. Leadership.

Components of successful activity of a pharmaceutical organization. Effective organization of work in pharmacy enterprises. Manager's activities. Requirements for a successful manager. Self-management. Time management. Functions and organization of work of the head of the pharmacy. A system of management methods. Methods of direct and indirect influence. Power. leadership Approaches to the concept of the essence of leadership. Classification of forms of power. Socio-psychological styles of management of collectives of pharmaceutical enterprises and pharmacies. Building a highly effective team.

Topic 4. Management functions.

Management functions, management cycle. Planning as a function of management, types and principles of planning. Strategic planning, its essence and stages. Mission and vision of the pharmaceutical organization. The essence of SWOT analysis. Types of strategic alternatives. Concept of tactics, policy, procedures, rules. Criteria for assessing the strategic plan.

Organization as a function of management. Organizational process: its aspects, sequence of organizational structure development. Organizational management structure, its types: linear, functional, linear-staff, linear-functional, divisional, matrix, network.

Motivation as a function of management. Model of motivation through needs. Content and process theories of motivation: M. Tugan-Baranovsky's theory of needs, A. Maslow's hierarchy of needs, K. Alderfer's ERG theory, D. McClelland's theory of needs, F. Herzberg's two-factor theory, theories "X" and "Y" D. McGregor, "Z" theory by U. Ouchi; the theory of expectation of V. Vroom, the theory of justice of J. Adams, the complex model of L. Porter and E. Lawler, Motivation in the system of pharmaceutical and pharmacy enterprises.

Control as a function of management, types and stages of the process of controlling the activities of a pharmaceutical organization.

Topic 5. Management of decision making process.

Management decisions, general characteristics and classification. Approaches to making managerial decisions, stages of the process of making and implementing a rational decision. Requirements for management decisions. Factors affecting the decision-making process. Models and methods of decision-making in pharmacy.

Delegation of authority and responsibility.

Topic 6. Communication processes in the management.

Concepts and types of communications. The main elements and stages of the communicative process. Obstacles in organizational and interpersonal communications and ways to overcome them. Forms and organization of business communication. Organization of business meetings and business discussions. Business negotiations and organization of reception of visitors. The specifics of the pharmacist's business communication with the client.

Topic 7. Management and office work of pharmaceutical organizations. Management and informatics.

Concept, purpose and classification of documents as sources of management information. The role of clerical work in management. Document circulation of pharmaceutical organizations. Stages of document flow: drafting and registration of business papers, their registration and execution control. Storage of documents. Accounting and consideration of proposals, applications. Modern technical means in management. Management and informatics: automated control systems and information and management systems in pharmacy, the main areas of use of AMS in the health care system and in pharmacy, automated workplace. Possibilities of using APM in the activity of pharmacy enterprises. CRM systems: characteristics, purpose.

Topic 8. Management and entrepreneurship.

Economic and entrepreneurial activity. Principles and organizational forms of entrepreneurship. Types and forms of entrepreneurial activity. Peculiarities of entrepreneurial activity in pharmacy. Stages of organization of a pharmaceutical (pharmacy) enterprise. Stages of a business agreement. State regulation and deregulation of business activity. Organizational and legal forms of associations of enterprises: association, corporation, concern, consortium. Business planning. The structure of the business plan. Business risk and ways to reduce it. Types of damages. Social activity of the enterprise. Business ethics.

Topic 9. Management of human resources and personnel of the organization.

Characteristics of labor resources and personnel of the organization. HR policy in pharmacy. Problems of personnel employment. Employment services of the population in Ukraine. Principles and tasks of personnel management. Controlling personnel. Personnel marketing. Recruitment and selection of personnel. Personnel movement and accounting. Personnel turnover. Rotation of pharmaceutical personnel. Management of the development of labor resources of the organization.

Topic 10. Group dynamics and management. Management by conflicts, stresses

Group dynamics in the system of pharmaceutical and pharmacy enterprises. Formal and informal groups. Factors affecting the effectiveness of group work. Conflict management: the concept of conflict and its causes, types of conflicts and methods of their management. Changes within the organization and their management. Nature of stress, means of its reduction.

Topic 11. Labor relations in market conditions

Code of Labor Laws of Ukraine. Basic labor rights and responsibilities of employees. Collective agreement: content, registration, monitoring of obligations. Employment contract. Contract. Grounds for termination of the employment contract. Working time and rest time. Labor discipline. Labor protection of employees of pharmaceutical enterprises. Legal regulation of women's work and youth work. Individual labor disputes. Labor relations in foreign countries: collective agreement, obligations of employees and employers, types of labor contracts and disciplinary sanctions.

Topic 12. Estimation of management organization's efficiency

Evaluation of the organization's activity: criteria of economic efficiency, approaches to the study of organizational efficiency. Business activity, profitability assessment indicators of economic activity. Organizational management effectiveness: approaches and mechanisms, components of effective management, corporate culture. Criteria and approaches (behavioral, compositional, multiple) to the assessment of management efficiency. Key performance indicators KPI.

Topic 13. Fundamentals of pharmaceutical marketing.

The importance of marketing in modern conditions. Definition and main components of marketing. Peculiarities of pharmaceutical marketing. Stages of evolutionary development of marketing. The main elements of the marketing complex: product, price, sales, promotion. Principles of marketing. Marketing functions: analytical, production, sales, management and control. Types, subjects and tasks of pharmaceutical marketing. The market as an object of marketing: concepts, conditions of existence, classification criteria, infrastructure, conjuncture. The main elements of the market. State, structure and trends of the pharmaceutical market. Socio-economic aspects of the pharmaceutical market. General characteristics of the world pharmaceutical market.

Topic 14. Management by the pharmaceutical marketing.

Management of pharmaceutical marketing. Marketing concepts. The concept of social and ethical marketing. Planning

of marketing activities of the enterprise. Marketing plan: essence, options, sections. in pharmacy. Organizational structure of marketing services. Organizational models of marketing services: functional, commodity, regional, segmental, matrix. Stages of organization of marketing services. Tasks and functions of the pharmaceutical marketing service.

Topic 15. Marketing research and information.

Purpose, objects and methods of marketing research. The main directions of marketing research. Research methods in marketing. Stages of marketing research. The value of pharmaceutical marketing information. Directions of information marketing activities in the pharmaceutical industry. General requirements for marketing information. Principles of formation of marketing information at pharmaceutical enterprises. Sources and structure of marketing information at the enterprise. Marketing information system (MIS), structure and principles of operation. Features of pharmaceutical information marketing systems.

Topic 16. Study of the market of medicines.

Study of the drug market. The value of market research. Content and direction of comprehensive market research. Marketing environment of the enterprise: micro- and macro-environmental factors. Quantitative characteristics of the market: conjuncture, capacity, market share, market saturation, dynamics and average consumption of goods. Market segmentation: meaning, concepts, criteria, main methods. Requirements for market segments. The peculiarity of the segmentation of consumers of medicinal products. Target market, "market window" and "market niche". Research of consumers and typology of drug consumption. Factors influencing consumer behavior. Characteristics of the concepts "need", "demand", "consumption". Study of drug consumption. Retail audit, its essence and purpose. Methods of determining the need for medicinal products. Study of product demand and supply. Types of demand: negative, absent, hidden, decreasing, irregular, full, excessive, irrational. Demand for medicinal products: realized, unsatisfied, emerging demand.

Topic 17. Product in the system of marketing. Assortment policy of pharmaceutical enterprises and pharmacies.

Marketing concept of the product. Classification of goods. Classification of medicines, medical products. Consumer value of the goods. Consumer properties of medicinal products. Key factors of market success: individualization of goods, "critical mass of goods", multifunctionality of goods, technical package. Life cycle of the product. Stages of the product life cycle and their characteristics: stage of development and testing, market entry, growth, maturity, saturation, decline. Marketing activity at the stages of the product life cycle. Positioning of goods. Criteria for positioning medicines. Competitiveness of the product: the concept, the main components, the methods of evaluation. Product quality management. Certification of medicines. Assortment policy of pharmaceutical and pharmaceutical companies. Ingredients and Principles of Assortment Policy. Product range, its main characteristics: width, depth, alignment, saturation. Product nomenclature. Areas of analysis of the product range. Formation of the product range of production and trading enterprises. Features of the formation of a range of pharmaceutical products of pharmaceutical companies.

Topic 18. Product and Innovation Policy of Pharmaceutical Enterprises

General concepts of commodity policy, its tasks. Areas of implementation of the product policy of pharmaceutical enterprises. Marketing strategy and tactics of enterprises. The main models of strategic decision-making: product / market development matrix (I. Ansoff), competition matrix (M. Porter), growth / market share matrix (Boston Consulting Group - BKG matrix), "attractiveness - competitiveness" model (McKinsey matrix). Basic strategies of market coverage: undifferentiated marketing, differentiated marketing, concentrated (targeted) marketing. Trademark: concept, main types, functions. Trademark, its role in forming the image of the enterprise. Brand. Packaging of pharmaceutical products from the point of view of marketing. Corporate style, its elements. Innovative policy of pharmaceutical enterprises. Technological and marketing orientation of innovations in pharmacy. A new product in the marketing system. The process of developing a new product. Peculiarities of positioning of original and generic medicines.

Topic 19. Marketing aspects of pricing of pharmaceutical enterprises and pharmacy

Theoretical foundations of market pricing. Characteristics of the price from the point of view of marketing. The main functions of the price from the point of view of marketing: accounting, stimulating, distributive, the function of balancing demand and supply, the price function as a criterion for the rational placement of production. Pricing factors: internal and external. Types of markets: market of pure free competition, market of monopolistic competition, oligopolistic market, market of pure monopoly. Price and non-price competition. Demand, supply and price. Price elasticity of supply and demand. Factors affecting the elasticity of demand for medicinal products. Factors affecting the amount of product supply. Pricing policy of the enterprise. Pricing strategies. Stages of the pricing process. Pricing objectives of pharmaceutical enterprises. Pricing methods. Peculiarities of determining the price of new goods, including new medicines. The influence of state regulation on the firm's marketing strategies.

Topic 20. Distribution activity of pharmaceutical enterprises

The concept of product distribution (sales). Sales policy of enterprises. The reasons for the existence and development of sales activity, its tasks. Product distribution (sales) channels, their functions. The structure of distribution channels. Efficiency of distribution channels. Approaches to choosing the number of intermediaries at each level of the distribution channel: intensive distribution, exclusive distribution, selective distribution. Principles of selection of sales agents. Advantages of cooperation between product manufacturers and intermediaries. Reasons for using intermediaries in the pharmaceutical market. Management of sales channels. Types of conflicts arising in product distribution channels: vertical, horizontal, multi-channel. Ways of conflict resolution in product distribution channels. Sales methods and systems. Vertical marketing systems (VMS): corporate (integrated), contractual, managed. Horizontal marketing systems, multi-channel marketing systems. The system of sales of pharmaceutical products in Ukraine: compliance with international guidelines. Marketing tasks of wholesale and retail trade of medicines. Concepts, types and rules of logistics. Functions and principles of logistics. Peculiarities of the logistic approach to the management of production and sales activities in pharmacy.

Topic 21. Marketing policy of communications.

Push Strategy and Pull strategy of attracting consumer to the product. A complex of marketing communications and its formation. Marketing communications planning. Features of the target audience of pharmaceutical manufacturing and wholesale and retail enterprises. Features and tasks of the formation of demand for medicines. Means of marketing communications at the stages of product life cycle. Basic ethical criteria for the promotion of medicines by WHO. WHO requirements to medical representatives of the firm.

Theme 22. Advertising in the system of pharmaceutical marketing

Advertising and its role in the communication policy of enterprises. Main areas and roles of advertising. The task of product advertising. Classification of advertising, types and means (channels) of advertising. Requirements for advertising. Components of the advertising process. Functions and features of advertising. Features of drug advertising. The task of advertising in the pharmaceutical industry. Advertisement of non-prescription drugs. Advertising role of packaging. Digital marketing. Regulation of advertising of medicinal products. Peculiarities of regulating the advertising of medicinal products in Ukraine and the world. Stages of planning and organizing an advertising campaign. Advertising budget planning methods. Evaluation of the effectiveness of advertising measures.

Topic 23. Sales promotion and other means of marketing communications.

Sales promotion of pharmaceutical products. Objects of stimulation: buyers, intermediaries, sellers. Goals and means of sales promotion for pharmaceutical buyers. Goals and means of stimulating intermediaries and sellers. Monitoring and evaluation of the results of sales promotion. Personal Sales, its benefits. Stages of the effective sales process. Presentation: approaches to implementation, main tasks and principles. The role of resellers and medical (pharmaceutical) representatives in promoting the product. Net and direct marketing. Branding.

Topic 24. "Public relations" as a means of marketing communications. Merchandising in pharmacies. Concept and essence of public relations. Goals, main functions and principles of public relations. The main activities of public relations. Public relations in the management and marketing system. Exhibitions and fairs, the significance of their holding. Advertising at the point of sale. Merchandising in pharmacies and enterprises: the basic provisions for the design of the pharmacy, its sales hall, the rules for displaying pharmaceutical products, the principles of product placement in showcases and on shelves.

Topic 25. Marketing control.

Marketing control system. The purpose and main objects of marketing control. Components of marketing control systems. The directions and stages of the marketing control at the enterprise. Non-economic indicators of marketing control. Strategic control and marketing audit. Components of marketing audit. Stages of marketing audit (audit).

Differences in internal and external audit of marketing activity of the enterprise.

Topic 26. International marketing in pharmacy

The essence and specifics of international marketing. Main functions of international marketing. Tasks of international marketing in the field of pharmacy. Stages of international marketing policy formation by a national company. The environment of international marketing. Forms of entry of enterprises to foreign markets: export, joint venture, direct investment. Types of joint ventures. Expediency and methods of entering the foreign market. Strategies of international marketing. Stages of international marketing strategy development. Marketing research of foreign markets. Stages, typology and methods of international marketing research of medicines. Information provision of marketing research of the foreign pharmaceutical market. International Code of Marketing and Social Research. International complex of marketing. Management of international marketing. Control of international marketing.

Recommended literature for preparing for the comprehensive practice-oriented qualification exam

1. Management and Marketing in Pharmacy [Electronic resource]: the textbook for foreign students of higher pharmaceutical schools : in 2 parts / Z. Mnushko [at al.], ed. by prof. Z. Mnushko ; National University of Pharmacy. – Electronic text data. – Kharkiv: Publishing center “Dialog”, 2016. – Part I : Management in Pharmacy. – 1 electronic opt. disk (CD-R). – 2,5 Mb. – System requirements: Adobe Acrobat Reader. – Title from the disk label.
2. Management and Marketing in Pharmacy [Electronic resource]: the textbook for foreign students of higher pharmaceutical schools : in 2 parts / Z. Mnushko [at al.], ed. by prof. Z. Mnushko ; National University of Pharmacy. – Electronic text data. – Kharkiv : Publishing center “Dialog”, 2016. – Part II : Marketing in Pharmacy. – 1 electronic opt. disk (CD-R). – 3,7 Mb. – System requirements: Adobe Acrobat Reader. – Title from the disk label.
3. Working book. Pharmaceutical marketing and management: educational -methodical manual / V.V. Malyi, I.V. Pestun, I.V. Sofronova, et al. – Kh. : NUPh, 2020. – 276 p.
4. Pharmaceutical marketing and management: educational manual / V. V. Malyi, S. V. Zhadko, I. V. Bondarieva and others; edited by V.V. Malyi. – Kharkiv : NUPh, 2022. – 226 p.

Educational component Clinical Pharmacy and Pharmaceutical Care

Summary of the educational component:

«Clinical pharmacy and pharmaceutical care» is mandatory educational component, which provides theoretical knowledge and practical skills in the field of clinical medicine and clinical pharmacology, analysis and correction of medical therapy, selection of the most rational drug and their combinations for a particular patient, contributes to the formation of skills to apply knowledge of clinical pharmacy in professional activities during the pharmaceutical care provide.

The subject of educational component study is the principles of rational use of drugs, ways of prevention of adverse

drug reactions, approaches to pharmaceutical care.

Content of the educational component:

Topic 1. Basic principles of clinical pharmacy and clinical pharmacology. Adverse drug reactions. Principles of Good Clinical Practice

The content of clinical pharmacy and its tasks. The relationship of clinical pharmacy with related educational components. The role of clinical pharmacy in the system of pharmaceutical education. The world experience of clinical pharmacy development. Ethics and deontology in medicine and pharmacy. Deontological aspects of "pharmacist – doctor", "pharmacist – patient", "pharmacist – visitor" of a chemists relationships. The role of a pharmacist in carrying out the rational medicinal therapy, increase of its efficiency and safety.

Definitions of the concepts "chemical name", "international non-proprietary name", "trade name" of a medicine. Original (brand) and generic medicines – definition of the concept, advantages and disadvantages, requirements to generic medicines. The modern concept of self-medication. OTC-drugs. The role of a pharmacist in the self-medication system. The concept of pharmaceutical care.

Principal aspects of medical documentation: the out-patient card of patient, the case record of an in-patient, the list of medical prescription.

Introduction to clinical pharmacology. Kinds of medicinal therapy. Clinical aspects of pharmacodynamics, pharmacokinetics of drug, definition of the concepts of "clinical effect", "side effect". Modern methods of assessment of pharmacological action of drugs in clinical pharmacology. Clinical efficiency of drugs. Selectivity of drug action and its clinical value. The factors affecting the clinical efficiency of drugs. Peculiarities of a human body (physiological peculiarities, the age periods, the presence of a concomitant pathology, etc.), which affect the pharmacokinetics and pharmacodynamics of drugs. Modern methods of drug therapeutic action control. Clinical pharmacological tests. Concept of "width of the therapeutic action", "therapeutic index", "minimal dose", "maximal dose", "course dose" in clinical pharmacology. Principles of control of the efficiency and safety of drug administration. The importance of clinical, laboratory and instrumental methods of patient's examination as criteria of efficiency and safety of medicinal therapy. Methodical approaches to the choice of adequate methods of efficiency control of the prescribed drugs of different pharmacological groups.

Drug monitoring, its importance. Therapeutic and toxicological monitoring; importance for clinical practice.

Interaction of the combined application of drugs: types of interaction (pharmaceutical, pharmacokinetic, pharmacodynamic) and the character of interaction manifestation (antagonistic, synergistic – potentiation, summation, additive, sensitive). Clinical manifestations of drug interaction. Combined medicines, their advantages and disadvantages.

Classification of types of adverse drug reactions (pathogenetic, by character of occurrence, forecasting, localization of manifestations, by character of the course, severity). Mechanisms of occurrence and methods of forecasting of possible development of negative effects of drugs. Dependence of negative effects on the dose, way and introduction mode. The concept of toxicodynamics and toxicokinetics of drugs. Clinical manifestations of negative effects of drugs. The basic undesirable phenomena of drug administration ("a ricochet" phenomenon, tolerance to therapy, drug dependence, etc.). The concept of placebo. Placebo-effectors. Negative placebo-effectors as a group of risk of adverse drug reaction development.

Drug effect on clinical laboratory indices and results of functional tests. Typical changes in the general analysis of blood, urine, the biochemical analysis of blood in case of various drugs administration. Ways of possible effect of drugs on laboratory indices. Chemical and pharmacological interference. Drug effect on functional tests results. Undesirable consequences of incorrect interpretation of laboratory research results. Ways of drug action reduction on results of clinical and laboratory researches. The role of a pharmacist in the process of increasing the diagnostic importance of clinical and instrumental methods of the patient's examination.

Prevention of occurrence and ways of correction of drug negative effects. The role of a pharmacist in decreasing the undesirable drug effect.

The medicinal anamnesis: definition of the concept, rules and technique of collecting, importance for increasing of the medicinal therapy efficiency.

Psychological aspects of mutual relations between a pharmacist and a patient. Compliance. Factors affecting the patients' compliance during the medicinal therapy, ways increasing compliance. The concept "quality of life" concerning patients with chronic diseases and disorders of general state. Drug effect on life duration, the life forecast and quality of life of patients. Importance of pharmaceutical care for improvement of patient’s quality of life and population’s level of health.

Good clinical practice (GCP) is international rules and standards of carrying out clinical trials of drugs. Phases and types of clinical trials. Ethical aspects and the acts that regulate the performance of clinical studies. The role of a pharmacist in carrying out clinical trials of drugs.

Topic 2. Clinical pharmacy in pulmonology

Symptoms and syndromes of the respiratory organ diseases: cough, dyspnea, thorax pain, fever, cyanosis, bronchoobstruction syndrome, respiratory distress syndrome.

The respiratory system diseases requiring obligatory intervention of a doctor (pneumonia, acute bronchitis, chronic bronchitis, bronchial asthma, chronic obstructive diseases of lungs / chronic obstructive bronchitis, emphysema of the lungs, illness of smokers’ small respiratory tracts, pleurisy, bronhoectactic disease, lung abscess, tuberculosis). Dysfunctional condition of respiratory organs , can be treated with OTC drugs in terms of responsible self-medication with the advisory help of a pharmacist. Approaches to medicinal treatment of the respiratory organs diseases.

Clinical pharmacology of antimicrobic drugs for the respiratory organs diseases (penicillin, cephalosporins, carbapenems, macrolides, fluoroquinolones). Approaches to the rational choice of AB drugs for the respiratory organs diseases.

Clinical pharmacology of bronchodilators (β_2-adrenomimetics, cholinolytics, derivatives of xanthine).

Clinical pharmacology of mucolitics, expectorants, anticough drugs of the central and peripheral action.

Clinical pharmacology of corticosteroids (systemic, inhalation), stabilizers of membranes of mastocytes.

Approaches to the rational choice of drugs for treating the respiratory organs diseases. Simultaneous administration of drugs used for the respiratory organs diseases; interaction with drugs of other pharmacological groups.

Peculiarities of drugs application for respiratory system diseases in case of accompanying pathology. Drugs with a negative affect on the respiratory organs.

Combined drugs for treating bronchoobstructive syndrome.

Adverse effects of drugs used to treating the respiratory system diseases. Forecasting, clinical manifestations, prevention and ways of elimination.

Modern special dosage forms used for treating the respiratory system diseases (the dosed aerosol and powder inhalers, spacers, nebulizers, etc.), their clinical and biopharmaceutical peculiarities, rules and conditions of the rational use.

Criteria of efficiency and safety of medicinal therapy in pulmonology.

Principles of pharmaceutical care for symptomatic treatment of respiratory organs dysfunction. OTC drugs for symptomatic treatment of respiratory organs dysfunction. Assistance in smoking cessation.

Topic 3. Clinical pharmacy in rheumatology

Symptoms and syndromes in the basic systemic diseases of the connective tissue and exchange dystrophic diseases of joints: pain in joints and muscles, morning constraint, deformation of joints, "butterfly" symptom, acne rash, fever, tofus, chorea, articular syndrome, Raynaud's syndrome, dysfunction of joints, gouty attack.

Systemic diseases of the connective tissue and exchange dystrophic diseases of joints requiring obligatory intervention of a doctor (osteoartrosis, gout, osteoporosis; rheumatism / acute rheumatic fever, chronic rheumatic heart disease/, systemic lupus erythematosus, rheumatoid arthritis, scleroderma systematica□). Dysfunctional condition of the locomotor system which can be treating with OTC drugs in terms of responsible self-medication with the advisory help of a pharmacist.

Approaches to medicinal treatment of locomotor system diseases.

Bicillin prevention and bicillin therapy in treatment of acute rheumatic fever and chronic rheumatic heart disease.

Clinical pharmacology of steroid and non-steroid anti-inflammatory drugs; basic anti-inflammatory drugs (derivatives of quinoline, cytostatics, medicines of gold), including drugs suppressing proliferation of the connective tissue.

Clinical pharmacology of metabolism correctors of the connective tissue (chondroprotectors), drugs of uricosuric actions; drugs affecting the structure and mineralization of the bone tissue (calcium drugs, etc.).

Approaches to the rational choice of drugs for treating the locomotor system diseases. Simultaneous administration of drugs used for the locomotor system diseases; interaction with drugs of other pharmacological groups; peculiarities of drug application in case of accompanying pathology. Drugs with a toxic effect on the condition of joints (chondrotoxic drugs).

Adverse reactions of drugs used for treating the locomotor system diseases. Forecasting, clinical manifestations, prevention and ways of elimination. The concept of NSAID-gastropathy. Reye's syndrome.

Modern special dosage forms used for treating the locomotor system diseases (soft dosage forms and solutions for intra-articular administration), their clinical and biopharmaceutical peculiarities, principles of the rational use.

Criteria of efficiency and safety of medicinal therapy for treating the locomotor system diseases.

Principles of pharmaceutical care of patients with pathology of the locomotor system that receive drugs according to doctor's prescription. OTC drugs for articular and muscular pain.

Topic 4. Clinical pharmacy in cardiology

Symptoms and syndromes of basic diseases of the cardiovascular system: dyspnea, orthopnea, acrocyanosis, palpitation, headache, pain syndrome, intermittent claudication syndrome, hydrops syndrome, dislipoproteinemia, arterial hypertension.

The cardiovascular system diseases requiring the obligatory intervention of a doctor (atherosclerosis, ischemic heart disease /angina pectoris, acute myocardial infarction, cardiosclerosis, essential arterial hypertension, symptomatic arterial hypertension, hypertensive crisis, chronic heart failure, abnormalities of the heart rhythm). Approaches to medicical treatment of the cardiovascular system diseases.

Clinical pharmacology of anti-anginal and hypotension drugs: nitrates and nitrate-like drugs, β-adrenoblockers, antagonists of calcium, blockers of peripheral adrenoreceptors, hypotension drugs of central action, blocker of ACE, blockers of angiotensin II receptors, diuretics.

Clinical pharmacology of hypolipidemic drugs (inhibitors of GMG-CoA reductase, fibric acid derivatives, nicotinic acid and its derivatives).

Clinical pharmacology of anti-coagulants, antiaggregants, fibrinolytics.

Clinical pharmacology of drugs which improve cerebral circulation; angioprotectors and antioxidants; drugs of metabolic action.

Combined drugs for arterial hypertension treatment.

Clinical pharmacology of cardiac glycosides, non-glycosides of positive inotropic agents. The problem of efficiency and safety of cardiac glycosides application. Clinical manifestations of cardiac glycosides intoxication, its treatment and prevention.

Clinical pharmacology of antiarrhythmic drugs.

Approaches to the rational choice of drugs for treating the cardiovascular system diseases. Simultaneous application of drugs used in cardiovascular system diseases; interaction with drugs of other pharmacological groups; peculiarities of drug application in case of accompanying pathology. Drugs having a negative effect on the safety of the cardiovascular system.

The adverse effects of drugs used in cardiology. Forecasting, clinical manifestations, prevention and ways of elimination.

Modern special dosage forms used in cardiology (retard, with the modified release of an active substance), their clinical and biopharmaceutical peculiarities, rules and conditions of their rational use.

Criteria of efficiency and safety of medicinal therapy in cardiology.

Principles of pharmaceutical care of the cardiologic profile patients receiving drugs according to doctor's prescription. OTC drugs used in cardiology.

Topic 5. Clinical pharmacy in hematology

Syndromes of basic diseases of the hemopoietic system: circulatory hypoxic, sideropenic, hematologic, neurologic, hemorrhagic, asthenoneurotic.

Diseases of the hemopoietic system requiring obligatory intervention of a doctor (types of anaemia /iron-deficiency, megaloblastic — vitamin-B_{12} – and folic acid deficiency anemia, hemolytic/; hemablastosis /acute leukemia; myeloleukemia, chronic lymphatic leukemia; erythremia/). Approaches to medicinal treatment of the hemopoietic system diseases.

Clinical pharmacology of drugs of iron and other antianemic drugs.

Clinical pharmacology of drugs stimulating or inhibiting erytro- and leukopoiesis.

Approaches to the rational choice of drugs in the hemopoietic system diseases. Simultaneous administration of drugs affecting hemopoiesis; interaction with drugs of other pharmacological groups; peculiarities of administration in case of accompanying pathology. Principles of the rational use of iron drugs and vitamins of group B. Drugs that have a toxic effect on the condition of the hemopoietic system.

Adverse effects of drugs used in hematology. Forecasting, clinical manifestations, prevention and ways of elimination.

Modern special dosage forms of iron drugs (drops, solutions for oral administration, capsules, etc.), their clinical and biopharmaceutical peculiarities, rules and conditions of the rational use.

Criteria of efficiency and safety of medicinal therapy in hematology.

Principles of pharmaceutical care of patients with pathology of the hemopoietic system.

Topic 6. Clinical pharmacy in nephrology

Symptoms and syndromes of basic diseases of kidneys and urinary ways: Pasternatsky's symptom, pain syndrome, uric syndrome, nephrotic syndrome, hydropic syndrome, syndrome of arterial renal hypertension, renal anemic syndrome, dysuric syndrome, syndrome of the chronic renal failure.

Diseases of kidneys and urinary ways requiring obligatory intervention of a doctor (acute kidney damages: acute pyelonephritis, acute glomerulonephritis; chronic renal disease: chronic pyelonephritis, chronic glomerulonephritis; infections of the urinary tract: acute cystitis, chronic cystitis; urolithiasis). Complications of renal diseases: symptomatic arterial hypertension (renoparenchimatous and renovascular one), chronic renal failure, renal anemia. Approaches to medicinal treatment of diseases of kidneys and urinary tract.

Clinical pharmacology of main drugs for treating infectious and immune-inflammatory diseases of kidneys and urinary tract (AB drugs/ β-lactams, fluoroquinolones, aminoglycosides, derivative of 8-oxychinoline, nitrofuranes, steroid and non-steroid anti-inflammatory drugs, immunosuppressants, direct anticoagulants, antiaggregants, uroantiseptics, urolytics, spasmolytics, analgesics, diuretics, hypoasotemics).

Approaches to the rational choice of AB drugs for infectious diseases of kidneys and urinary tract. Approaches to the rational choice of drugs for treating diseases of kidneys and urinary tract. The Simultaneous administration of drugs affecting the function of kidneys and urinary tract; interaction with drugs of other pharmacological groups. Peculiarities of drugs used in nephrology in case of accompanying pathology. Drugs with toxic effect on the condition of kidneys. The influence of functional condition of kidneys on the clinical efficiency of drugs, correction peculiarities of the dose regimen and administration.

Principles of treatment of kidney diseases complications: use of anti-hypertensive detoxification drugs, recombinant erythropoietins.

Adverse effects of drugs used for treating the urinary system diseases. Forecasting, clinical manifestations, prevention and ways of elimination.

Criteria of efficiency and safety of medicinal therapy in nephrology.

Principles of pharmaceutical care of patients with diseases of kidneys and urinary tract. OTC drugs used for the urinary system diseases.

Topic 7. Clinical pharmacy in gastroenterology

Symptoms and syndromes of basic diseases of the gastro-intestinal tract: appetite disorder, eructation, heartburn, nausea, vomiting, constipation, diarrhea, flatulency; syndromes of gastric dyspepsia, intestinal dyspepsia, exocrinous pancreatic impairment, insufficiency of digestion (maldigestion) and absorption (malabsorption), polyhypovitaminosis, astenoneurotic, painful, anemic; bacterial overgrowth syndrome (dysbiosis).

Diseases of GIT and pancreas requiring obligatory intervention of a doctor (gastritis and duodenitis; chronic Helicobacter-associated gastritis; stomach ulcer, duodenal ulcer, chronic pancreatitis, dyspepsia, non-infectious gastroenteritis and colitis). Complications of diseases of GIT organs: bleeding, penetration, perforation, malignancy, stenosis, vitamin B_{12}-deficiency anemia. Disorders of digestion, which can be treated with OTC drugs in terms of responsible self-medication with the advisory help of a pharmacist. Approaches to medicinal treatment of diseases of GIT and pancreas.

Clinical pharmacology of drugs used for treating hypoacid conditions. Drugs of replacement and stimulating therapy.

Clinical pharmacology of antacids and anti-secretion drugs (antacids, selective M_1-anticholinergic drugs, blockers H_2-histamine receptors, H^+, K^+-ATPh inhibitors).

Clinical pharmacology of drugs which increase protective properties of the mucous membrane of the stomach and

promote its regeneration (reparants and gastrocytoprotectors).

Clinical pharmacology of drugs for Helicobacter pylori eradication (AB drugs of group of macrolides, penicillins, tetracyclines, nitroimidazol derivatives). Combined drugs.

Clinical pharmacology of drugs, which increase the tonus and stimulate motility of GIT (agonists of acetylcholine, antagonists of dopamine receptors), as well as antiemetic, antidiarrheal and laxative drugs.

Clinical pharmacology of polyenzymatic drugs.

Drugs for elimination of the pain syndrome in diseases of GIT (spasmolytics).

Approaches to the rational choice of drugs in diseases of GIT and pancreas. Simultaneous administration of drugs affecting the function of GIT and pancreas; interaction with drugs of other pharmacological groups. Peculiarities of drug administration in gastroenterology in case of accompanying pathology. Drugs that have a toxic effect on condition of GIT and pancreas. The influence of the functional condition of the stomach, intestines and pancreas on clinical efficiency of drugs.

Adverse effects of drugs in diseases of GIT and pancreas. Forecasting, clinical manifestations, prevention and ways of elimination.

Modern special dosage forms used for treating diseases of GIT and pancreas (suspensions, gels for intake, tablets for chewing, capsules with minimicrospheres, etc.), their clinical and biopharmaceutical peculiarities, rules and conditions of the rational use.

Criteria of efficiency and safety of medicinal therapy in gastroenterology.

Principles of pharmaceutical care of patients with the gastroenterological profile. OTC drugs in diseases of the GIT and pancreas.

Topic 8. Clinical pharmacy in hepatology

Symptoms and syndromes of basic diseases of the hepatobiliary system: skin itch, fever, ascites; pain syndrome, jaundice syndrome, cholestasis, portal hypertension, hepatic impairment, intestinal dyspepsia, hepatolienal syndrome, hemorrhagic syndrome, laboratory syndromes (cytolysis, cholestasis, hepatic-cellular insufficiency).

Diseases of the hepatobiliary system requiring obligatory intervention of a doctor (chronic hepatitis, cirrhosis, cholelithiasis, chronic cholecystitis). Disorders of the functional condition of the hepatobiliary system, which can be treated with OTC drugs in terms of responsible self-medication with the advisory help of a pharmacist. Approaches to medicinal treatment of the diseases of liver and gallbladder.

Clinical pharmacology of hepatoprotectors, choleretics, cholekinetics, cholelytics, vitamins.

Clinical pharmacology of immunodepressive (corticosteroids) and hypoammoniemic drugs.

Clinical pharmacology of drugs for treating viral and bacterial infections of the hepatobiliary system (α-interferons, nucleotide analogues; penicillins, tetracyclines, cephalosporins, fluoroquinolones).

Clinical pharmacology of desintoxication therapy agents (enterosorbents, combined infusion solutions).

Clinical pharmacology of drugs for elimination of the pain syndrome (myotropic spasmolytics, M-anticholinergic drugs).

Approaches to the rational choice of drugs in diseases of thehepatobiliary system. Simultaneous administration of drugs affecting the function of the hepatobiliary system; interaction with drugs of other pharmacological groups; peculiarities of drug administration in case of accompanying pathology. Drugs that have a toxic effect on the liver condition. The influence of the functional condition of liver on the bioavailability and clinical efficiency of drugs.

Adverse effects of drugs used in hepatology. Forecasting, clinical manifestations, prevention and ways of elimination.

Modern special dosage forms in diseases of the hepatobiliary system, their clinical and biopharmaceutical peculiarities (combined infusion solutions), rules and conditions of the rational use.

Criteria of efficiency and safety of medicinal therapy in hepatology.

Principles of pharmaceutical care of patients with pathology of the hepatobiliary system. OTC drugs in diseases of the hepatobiliary system.

Topic 9. Clinical pharmacy in endocrinology

Symptoms and syndromes of basic diseases of the endocrine system: polydipsia, polyphagia, polyuria, exophthalmus, goiter, hyperglycemia syndrome, hyporglycemia syndrome, hyperthyrosis syndrome, hypothyroidism syndrome, iodine deficiency syndrome.

Endocrine diseases (diabetes mellitus type I and II, hyperthyroidism, hypothyroidism) requiring compulsory medical intervention. Typical complications of diabetes mellitus (hypo- and hyperglycemic coma, diabetic polyneuropathy, diabetic nephropathy, diabetic retinopathy, diabetic foot syndrome). The states and conditions (the syndrome of iodine deficiency, pregnancy, period of growth, residence in endemic unfavourable areas), when it is possible to use OTC drugs in terms of responsible self-medication with the advisory help of a pharmacist. Approaches to medicinal treatment of the endocrine system diseases.

Clinical pharmacology of insulin drugs. Approaches to the rational choice of insulin drugs. Possible complications of insulin therapy.

Clinical pharmacology of oral hypolipidemic drugs (sulfonylcarbamide derivatives, biguanides, thiasolidindions, metglytinides, inhibitors of αglucosidase). Approaches to the rational choice. The interaction of oral hypoglycemic drugs with drugs of other pharmaceutical groups. Peculiarities of oral hypoglycemic drugs application in case of concomitant pathology. Drugs affecting the level of glycemia.

Principles of treatment of diabetes complications: use of insulin antagonists, antihypertensive, hypoglycemic drugs, angioprotectors, antiaggregants, peripheral vasodilatators, vitamins.

Clinical pharmacology of hormone drugs of the thyroid gland, antithyroid drugs, iodine drugs.

Adverse effects of drugs used in endocrinology. Forecasting, clinical manifestations, prevention and ways of elimination.

Modern dosage forms used for treating diseases of the endocrine system, their clinical and biopharmaceutical peculiarities, rules and conditions of their rational use.

Criteria of efficiency and safety of medicinal therapy in endocrinology.

Principles of pharmaceutical care of patients with the endocrinological profile. Algorithm of actions of a pharmacist and pharmaceutical care while dispensing drugs for treating iodine deficiency.

Topic 10. Clinical pharmacy in allergy

Symptoms and syndromes of allergy: itch, hyperemia, edema of skin and mucous membranes, skin rash, dyspnea, sneezing, rhinorrhea, lacrimation, bronchospasm, decrease of arterial pressure, tachycardia, hyperemia; skin syndrome, hydropic syndrome, respiratory syndrome, syndrome of acute cardiovascular failure, asthenoneurotic syndrome.

Diseases of allergic origin (acute and chronic urticaria, astenoneurotic edema, allergic rhinitis, allergic conjunctivitis, anaphylactic shock) requiring the obligatory intervention of a doctor. Symptoms and syndromes of allergic origin, which can be treated with OTC drugs in terms of responsible self-medication with the advisory help of a pharmacist. Approaches to medicinal treatment of allergic conditions.

Clinical pharmacology of drugs used for treating allergy (corticosteroids, antihistamines drugs, bronchodylators, drugs of calcium, stabilizers of mastocytes membranes, agonists of □- and □- adrenoreceptors). Detoxication therapy.

Approaches to the rational choice of drugs in diseases of the allergic origin. Simultaneous administration of antiallergic drugs; interaction with drugs of other pharmacological groups; peculiarities of antiallergic drugs administration in case of accompanying pathology.

Adverse effects of drugs used in allergology. Forecasting, clinical manifestations, prevention and ways of elimination.

Modern dosage forms used in diseases of the allergic origin, their clinical and biopharmaceutical peculiarities, rules and conditions of the rational use.

Criteria of efficiency and safety of medicinal therapy in allergology.

Principles of pharmaceutical care of allergic patients, OTC drugs used in diseases of the allergic origin.

Drug disease. Difference from other conditions caused by drug administration (overdose, intoxication, bacterial overgrowth syndrome, etc.). The causes of occurrence, basic clinical variants of manifestation of drug disease. Syndromes of drug disease (Lyell's syndrome, Stevens-Johnson syndrome). Polypharmacy as the cause of medicinal therapy complications. Pharmacological features of drugs, which cause drug disease more often. Prevention and medicament approaches to elimination of drug disease manifestations. The role of a pharmacist in drug disease prevention.

Topic 11. Basic principles of pharmaceutical care

Definition and the basic concepts of pharmaceutical care. The place of pharmaceutical care in the general system of public health services for the population. Relationship of a pharmacist and other medical workers (doctor, nurse, etc.) when carrying out pharmaceutical care. The algorithm of action of a pharmacist when carrying out the appropriate pharmaceutical care for chemist's shops visitors, patients during OTC drugs dispensing for symptomatic treatment of harmless for life health disorders. The algorithm of presentation of the appropriate drug information to visitors of chemist's/patients by a pharmacist while carrying out pharmaceutical care. The role of the pharmacist in the making up of first aid kits.

Practical functions of a pharmacist that are necessary for care realization (procedure of drug anamnesis gathering, working out the plan of monitoring of adverse drug reactions, preventive actions in possible manifestations of adverse drug reactions, etc.).

OTC-drugs. Criteria according to which medicines are classified as prescription or OTC drugs. Normative and legislative acts concerning OTC drugs dispensing.

The concept of generic and therapeutic replacement. The pharmacist's competence when choosing OTC drugs for responsible self-medication and in replacement of OTC drugs.

Categories of problems which arise during the patient’s intake of drugs; problems belonging to the competence of a pharmacist and a doctor, algorithm of their definition. Protocol of pharmacist's activity when receiving information about cases of adverse reactions and/or lack of efficacy of medicines.

Topic 12. Pharmaceutical care during OTC drugs dispensing for symptomatic treatment of indigestion

The basic symptoms of indigestion (heartburn, constipation, diarrhea, flatulence, bacterial overgrowth syndrome/dysbiosis), which can be treated with OTC drugs in terms of responsible self-medication. «Threatening» symptoms of indigestion when the intervention of a doctor is necessary (the algorithm of choosing patients for obligatory examination of a doctor).

Directions and remedies of symptomatic medicinal therapy of heartburn, constipation, diarrhea, flatulency, bacterial overgrowth syndrome (dysbiosis). The algorithm of carrying out pharmaceutical care for visitors of chemist's shops/patients with indigestion symptoms. The algorithm of the appropriate information presentation by a pharmacist about OTC drugs for treating indigestion while carrying out pharmaceutical care for visitors of chemist's shops/patients.

Modern dosage forms for treatment of indigestion and peculiarities of their use. The interaction of OTC drugs used for symptomatic treatment of indigestion with food, alcohol; peculiarities of their application in various age periods; requirements for storing drugs at home. Criteria of efficiency of therapy with OTC drugs used for symptomatic treatment of indigestion.

Non-medicament methods of elimination of symptoms of indigestion.

Topic 13. Pharmaceutical care during OTC drugs dispensing for symptomatic treatment and prevention of cold

The basic symptoms of cold (cough, rhinitis, sore throat, fever, etc.) which can be treated with OTC drugs in terms of responsible self-medication. «Threatening» symptoms of cold when the intervention of a doctor is necessary (the algorithm of

choosing patients for obligatory examination of a doctor).

Approaches and remedies of symptomatic medicinal therapy of colds. The algorithm of carrying out pharmaceutical care of the visitors of chemist's shops/patient with cold symptoms. The algorithm of presentation of the appropriate information about OTC drugs by a pharmacist for treating cold when carrying out pharmaceutical care of visitors of chemist's shops/patients.

Modern dosage forms for treatment of cold and peculiarities of their use. The interaction of OTC drugs used for symptomatic treatment of colds with food, and alcohol; peculiarities of their administration in various age periods; requirements for storing drugs at home. Criteria of efficiency of the therapy with OTC drugs used for symptomatic treatment of cold.

Non-medicament methods of elimination of symptoms of cold.

Approaches to prevention of colds. The algorithm of carrying out pharmaceutical care of visitors of chemist's shops/patient while choosing drugs for prevention of colds. The algorithm of presentation the appropriate information about OTC drugs by a pharmacist for cold prevention when carrying out pharmaceutical care of visitors of chemist's shops/patients. Modern dosage forms for cold prevention, peculiarities of their use.

Non-medicament methods of cold prevention.

Topic 14. Pharmaceutical care during OTC drugs dispensing for symptomatic treatment of joint and muscle pain

Basic symptoms of the musculoskeletal system dysfunction (joint and muscle pain), which can be treated with OTC drugs in terms of responsible self-medication. «Threatening» symptoms of the musculoskeletal system dysfunction for when intervention of a doctor is necessary (the algorithm of choice of patients for an obligatory examination of a doctor).

Directions and remedies of symptomatic medicinal therapy of pain in muscles and joints. The algorithm of carrying out pharmaceutical care for visitors of chemist's shops/patients with symptoms of the musculoskeletal system dysfunction. The algorithm of presentation the appropriate information about OTC drugs by a pharmacist for treating pain in muscles and joints while carrying out pharmaceutical care for visitors of chemist's shops/patients.

Modern dosage forms for treatment of dysfunction of the musculoskeletal system (creams, gels) and peculiarities of their use. The interaction of OTC drugs used for symptomatic treatment of pain in muscles and joints with food and alcohol; peculiarities of their administration in various age periods; requirements for storing drugs at home. Criteria of efficiency of OTC drugs therapy used for symptomatic treatment of dysfunction of the musculoskeletal system.

Non-medicament methods of elimination of muscle and joint pain.

Topic 15. Pharmaceutical care during OTC drugs dispensing for symptomatic treatment of headache

The concept about primary (migraine, strain headache) and a secondary (symptomatic) headache. Pathological conditions and diseases accompanied with headache. Factors which promote headache development.

Types of headache which can be treated with OTC drugs in terms of responsible self-medication. «Threatening» symptoms of headache requiring intervention of a doctor (the algorithm of choosing patients for obligatory examination of a doctor).

Approaches and remedies of symptomatic medicinal therapy of headache. The algorithm of carrying out pharmaceutical care for visitors of chemist's shops/patients with headache. The algorithm of appropriate information about OTC drugs presentation by a pharmacist for treating headache while carrying out pharmaceutical care for visitors of chemist's shops/patients.

Modern dosage forms for treatment of headache (quick-soluble tablets, capsules of the prolonged action, etc.) and peculiarities of their use. The interaction of OTC drugs used for symptomatic treatment of headache with food and alcohol; peculiarities of their administration in various age periods; requirements for storing drugs at home. Criteria of efficiency of the therapy with OTC drugs used for symptomatic treatment of headache.

Non-medicament methods of elimination of the headache.

Topic 16. Pharmaceutical care during OTC drugs dispensing for symptomatic treatment of disorders of the nervous system activity

The basic symptoms of disorders of the nervous system activity (anxiety, asthenia, dyssomnia) which can be treated with OTC drugs in terms of responsible self-medication. «Threatening» symptoms of disorders of the nervous system activity when the intervention of a doctor is necessary (the algorithm of choosing patients for obligatory examination of a doctor).

Approaches and remedies of symptomatic medicinal therapy of anxiety, asthenia, dyssomnia. The algorithm of carrying out pharmaceutical care for visitors of chemist's shops/patients with symptoms of disorders of the nervous system activity. The algorithm of the appropriate information about OTC drugs presentation by a pharmacist for treating disorders of the nervous system activity while carrying out pharmaceutical care for visitors of chemist's shops/patients.

Modern dosage forms for treatment of disorders of the nervous system activity and peculiarities of their use. The interaction of OTC drugs used for symptomatic treatment of disorders of the nervous system activity with food, alcohol; peculiarities of their administration in various age periods; requirements for storing drugs at home. Criteria of efficiency of therapy with OTC drugs used for symptomatic treatment of disorders of the nervous system activity.

Non-medicament methods of elimination of symptoms of the nervous system activity disorders.

Topic 17. Pharmaceutical care during OTC drugs dispensing for symptomatic treatment of skin lesions

Lesions of integuments: microtraumas (cuts, abrasions, scratches), thermal and chemical damages of surface skin layers (burns, frostbite), acne (acne rash), infectious damages (herpes of lips, mycoses, scabies, pediculosis), seborrhea, etc. which can be treated with OTC drugs in terms of responsible self-medication. «Threatening» symptoms of skin lesions requiring obligatory examination of a doctor.

The algorithm of carrying out pharmaceutical care for visitors of chemist's shops/patients with symptoms of skin lesions. Approaches to symptomatic treatment of skin lesions. OTC drugs used for skin lesions. The algorithm of the appropriate information about OTC drugs presentation by a pharmacist when carrying out pharmaceutical care for visitors of chemist's

shops/patients for symptomatic treatment of skin lesions.

Modern dosage forms for treatment and prevention of traumatic, infectious and parasitic skin lesions, peculiarities of their use. Non-medicament methods of elimination of symptoms of traumatic, infectious and parasitic skin lesions

Topic 18. Pharmaceutical care during OTC drugs dispensing for preventive and therapeutic using of anthelmintics. Pharmaceutical care of patients with local disorders of blood circulation

Definition of helminthiases. «Threatening» symptoms of helminthiases requiring intervention of a doctor. Approaches of antihelmintic therapy. The algorithm of carrying out pharmaceutical care of the visitors of chemist's shops/patient with helminthiases. The algorithm of the appropriate information presentation by a pharmacist about OTC drugs for treatment of helminthiases while carrying out pharmaceutical care for visitors of chemist's shops/patients.

Local disorders of the blood circulation: varicose veins of the lower extremities, hemorrhoid. Symptoms which are typical for local blood circulation disorders that can be treated with OTC drugs in terms of responsible self-medication. «Threatening» symptoms of varicose veins of the lower extremities and hemorrhoid requiring obligatory examination of a doctor (the algorithm of choosing patients for obligatory examination of a doctor).

The algorithm of carrying out pharmaceutical care for visitors of chemist's shops/patients with complaints of local disorders of the blood circulation.

The algorithm of the appropriate information about OTC drugs presentation by a pharmacist about OTC drugs for treating local blood circulation disorders while carrying out pharmaceutical care for visitors of chemist's shops/patients.

Modern dosage forms for treatment of local disorders of the blood circulation and peculiarities of their use. The interaction of OTC drugs used for symptomatic treatment of local disorders of the blood circulation with food, alcohol; peculiarities of their administration in various age periods; requirements for storing drugs at home. Criteria of efficiency of OTC drugs therapy used for symptomatic treatment of local disorders of the blood circulation.

Non-medicament methods of elimination of symptoms of blood circulation local disorders.

Topic 19. Pharmaceutical care during OTC drugs dispensing for elimination and prevention of vitamin deficiency

Pathological conditions and factors promoting development of vitamin deficiency. «Threatening» symptoms of vitamin deficiency requiring intervention of a doctor (the algorithm of choosing patients for obligatory examination of a doctor).

Approaches and remedies of elimination and prevention of vitamin deficiency. The algorithm of address choice of OTC vitamin-containing drugs, the dosage forms and the routes of administration. The algorithm of the appropriate information about OTC drugs presentation by a pharmacist for elimination and prevention of vitamin deficiency when carrying out pharmaceutical care for visitors of chemist's shops/patients.

Modern dosage forms for elimination and prevention of vitamin deficiency (gels, syrups, drops, etc.) and peculiarities of their use. The interaction of OTC vitamin-containing drugs with food, alcohol; peculiarities of their use for different groups of population (newborns, children, teenagers, elderly and old people, individuals with concomitant pathologies, pregnant and breast-feeding women). Requirements for storing vitamin-containing drugs at home. Criteria of efficiency of therapy with OTC drugs for elimination and prevention of vitamin deficiency. Signs of vitamin overdose, ways of its prevention and treatment

Topic 20. Pharmaceutical care during OTC drugs dispensing for special groups of patients. Interaction of drugs with food and alcohol

Pharmaceutical care as the pharmacist's responsibility for efficiency of the medicinal therapy to the individual visitor of chemist's shop/patient. Categories of the population requiring special attention during responsible self-medication. Approaches to pharmaceutical care of elderly and old people, teenagers, newborn, pregnant women and women in the period of lactation. Physiological factors stipulating the peculiarities of pharmacokinetics and pharmacodynamics of drugs in pregnant women.

The interaction of drugs and food, clinical and pharmacological aspects of interaction. The major factors, which are important for interaction of drugs and food. The ways of a possible effect of food on pharmacological properties of drugs.

Clinical and pharmacological aspects of using alcohol in medicine. Clinical and pharmacological features of alcohol. The interaction of ethanol with drugs. Clinical and pharmacological aspects of chronic alcohol abuse.

The role of a pharmacist and the place of pharmaceutical care in prevention of undesirable interaction of drugs with food and alcohol. Modern dosage forms for children, their advantages, peculiarities of administration. Possible effect of drugs on the course of pregnancy, delivery and lactation.

Recommended literature for preparing for the comprehensive practice-oriented qualification exam

1) *Fundamentals* of clinical medicine: symptoms and syndromes in the pharmacy practice : manual / I. A. Zupanets, S. B. Popov, Yu. S. Rudyk et al. ; ed. by V. P. Chernykh, V. M. Lesovoy, I. A. Zupanets. – Kharkiv : Golden Pages, 2012. – 94p.

2) *Clinical* Pharmacy (educational and methodological manual): manual for student of higher schools / I. A. Zupanets, I. S. Chekman, S. B. Popov et al., edited by I. A. Zupanets, I. S. Chekman. – Kharkiv : NUPh : Golden Pages, 2010. – 184p.

3. TASKS SUBMITTED FOR THE COMPREHENSIVE PRACTICE-ORIENTED QUALIFICATION EXAM

Methodological recommendations in preparation for the comprehensive practice-oriented qualification examination in pharmacy

4. LIST OF PRACTICAL SKILLS TO BE PRACTICED IN TRAINING CLASSES (LABORATORIES) OF EDUCATIONAL COMPONENTS

Educational component Pharmaceutical drug technology
(Name)

1. Check single, daily doses of poisonous, psychotropic, potent substances.
2. Define and eliminate physical, chemical and pharmacological incompatibilities.
3. Calculate the amount of medicinal substances for the preparation of simple and complex powders.
4. Carry out basic technological operations of manufacturing simple and complex powders with medicinal substances prescribed in equal and different amounts, what are different structure particles, size and form crystals, aggregate state, bulk mass (weigh, grind, mix, dose).
5. To carry out the main technological operations for the manufacture of trituration and complex powders with poisonous and potent substances prescribed in small quantities (weigh, grind, mix, dose).
6. To carry out basic technological operations for the production of powders with colored, fragrant and difficult-to-grind medicinal substances.
7. Carry out basic technological operations for the production of powders with extracts (dry, thick, solutions of thick extracts) and semi-finished products.
8. Use the means of small mechanization for mixing and dosing of powders.
9. Select the packaging material according to the properties of medicinal substances, prepare the drug before dispensing.
10. Calculate the amount of purified water and medicinal substances for the production of concentrated solutions.
11. Carry out basic technological operations for the production of concentrated solutions (weighing, measuring, dissolving, filtering). Use the burette system.
12. Calculate the amount of medicinal substances, concentrated solutions and water cleaned for production solutions, what contain to 3% and more 3% dry substances, the concentrated solutions of which are absent.
13. Carry out basic technological operations for the production of mixtures using concentrated solutions and medicinal substances (measure, weigh, dissolve, filter).
14. Calculate the amount of purified water, medicinal and auxiliary substances for the preparation of solutions and drops.
15. Calculate the amount of purified water and pharmacopoeia liquids depending on the method of their prescription.
16. Calculate the amount of ethanol and water for the production of alcohol solutions of different concentrations, using the dilution formula and alcoholometric tables.
17. Carry out basic technological operations for the production of non-aqueous solutions (weighing, measuring, heating, dissolving, if necessary, filtering).
18. To choose and justify the optimal technology of solutions of IUDs and protected colloids according to individual prescriptions.
19. Carry out the main ones technological operations with production solutions Navy and protected colloids (weigh, measure, heat, dissolve, if necessary, filter).
20. Calculate the amount of solvent and stabilizer when making suspensions.
21. Carry out basic technological operations for the production of suspensions from hydrophilic and hydrophobic medicinal substances (weighing, dispersing, mixing, measuring).
22. Select the appropriate emulsifier depending on the physical and chemical properties of medicinal substances included in the composition of emulsions.
23. Calculate the amount of oil, emulsifier and purified water for making an emulsion.
24. Choose and justify the method of emulsion production depending on the nature of the emulsifier.
25. Carry out basic technological operations for the production of oil emulsions (weighing, measuring, dissolving, heating, mixing, emulsifying).
26. Introduce medical substances with different physical and chemical properties to the composition of the emulsion.
27. Calculate the amount of medicinal plant raw materials and purified water for making infusions and decoctions.
28. Carry out basic technological operations for the production of infusions and decoctions (shredding, sifting, weighing, measuring, extracting, cooling, filtering, bringing to volume).
29. Use means small mechanization in process production water hoods (infusion device with electric heating, etc.).
30. Calculate the amount of extracts-concentrates and purified water for the production of liquid dosage forms (LPF).
31. Carry out the main technological operations for the production of RLF with the help of extracts-concentrates. Make water extractions from medicinal plant raw materials containing mucus.
32. Introduce to composition infusions and decoctions medical substances with different physical and chemical properties.
33. Calculate the percentage content of medicinal substances with different physico-chemical properties for the production of homogeneous and heterogeneous ointments.

34. Carry out basic technological operations for the production of liniments and ointments of various types of dispersed systems (weighing, mixing, grinding, dissolving, emulsifying).
35. Calculate the amount of medicinal and auxiliary substances for the manufacture of suppositories.
36. Choose and justify optimal version technologies with taking into account the properties of the ingredients included in the recipe.Carry out the main technological operations for the production of suppositories using the pumping and pouring method (weighing, grinding, dissolving, mixing, emulsifying, dosing, rolling out, melting, preparing suppository forms, pouring into forms, cooling).
37. Use the means of small mechanization for the production of suppositories by the method deflation and outpouring (pill box typewriter, typewriter for grinding of cocoa butter, a device for heating and melting bases, molds for casting, etc.).
38. Calculate the amount of medicinal and auxiliary substances for the manufacture of injection solutions.
39. Choose a stabilizer and justify the need to stabilize the medicinal substance in the solution according to an individual prescription.
40. Calculate isotonic concentrations of injection solutions using the sodium chloride equivalent, the value of depression, etc.
41. Choose the method and mode of sterilization of solutions for injections, eye drops, depending on the properties of the active substances.
42. Make eye drops depending on the solubility of the ingredients and their thermal stability.
43. Carry out organoleptic control of solutions for injections and eye drops for the absence of mechanical impurities.
44. Produce basis for eye ointment and ointment with antibiotics
45. To list the units of action of antibiotics in weight amounts according to their activity.
46. Check doses poisonous, powerful substances in children's medicinal forms depending on the weight and age of the child.
47. Use means small mechanization for clogging solutions for injections and eye drops.
48. To issue to vacation solutions, suspensions for injections, ocular drops, ointments, dosage forms with antibiotics, children's dosage forms.

Educational component Industrial Technology of Drugs
(Name)

1. Conducting sieve (fractional) analysis of plant raw materials.
2. Perform ethanol recovery from the cake.
3. Determination of the tincture density.
4. Determination of ethanol concentration in liquid extract.
5. Loading the percolator to obtain liquid nettle extract.
6. Determination of ethanol concentration using a glass hydrometer.
7. Determination of ethanol concentration in the proposed tincture by boiling point.
8. Determination of the concentration of the obtained ethanol solution using an areometer.
9. Preparation of 100 ml of a 70% ethanol solution from a 95% ethanol solution.
10. Standardization of dense wormwood extract based on moisture content.
11. Obtaining an extract from 10.0 g of wormwood herb using the percolation method.
12. Preparation of the required volume of ethyl alcohol. Checking the concentration of the obtained solution.
13. Quality control of injection solution for the absence of mechanical impurities.
14. Preparation of 100 ml of an injection solution of papaverine hydrochloride.
15. Filling and sealing vials with pilocarpine hydrochloride eye drops.
16. Quality control of aerosol preparations according to SPhU for container integrity.
17. Assembly of a continuous-action valve.
18. Determination of the crystallographic characteristics of powders.
19. Preparation of 10.0 g of diphenhydramine granules by the wet granulation method.
20. Particle size reduction of powders using a ball mill.
21. Determination of the bulk density of hexamethylenetetramine substance.
22. Determination of the abrasion resistance of streptocid tablets according to SPhU.
23. Determination of the average mass and deviation of streptocid tablets from it.
24. Checking the resistance of hexamethylenetetramine tablets to crushing.
25. Determination of the flowability and angle of repose of paracetamol.
26. Preparation of soft gelatin capsules by the immersion method.
27. Determination of the average mass and deviation of capsule contents according to SPhU.
28. Determination of the capsule disintegration time according to SPhU.
29. Preparation of hard gelatin capsules by the immersion method.
30. Quality assessment of the "Olimetin" preparation in gelatin capsules according to SPhU.
31. Compilation of a material balance for the production of "Levomekol" ointment.

32. Packaging and labeling of streptocid liniment.
33. Study of the dissolution of suppositories with ichthyol according to SPhU.
34. Determination of the average mass and deviation of sea buckthorn oil suppositories.
35. Evaluation of the uniformity of paracetamol suppositories according to SPhU.
36. Preparation of a simple sugar syrup.

Educational component Pharmaceutical chemistry
(Name)

1. Use analytical documentation that regulates the quality of medicinal products (State Pharmacopoeia of Ukraine, quality control methods (QC), relevant orders and instructions).
2. Carry out quality control of substances according to indicators:
   – properties (description, solubility),
   – identification (by chemical reactions),
   – checking for purity (transparency of the solution, color of the solution, acidity or alkalinity, permissible impurities (chlorides, sulfates, calcium, heavy metals, ammonium salts, etc.) and unacceptable impurities),
   – quantitative determination by chemical methods (direct titration, reverse titration, method of separate measurements, pipetting method).
3. To carry out quality control of dosage forms of industrial production of dosage forms according to the following indicators:
   – properties,
   – homogeneity of the mass of a unit of dosed medicine (for tablets),
   – volume of medicinal products for parenteral use that is extracted (for injection solutions),
   – identification (by chemical reactions),
   – quantitative determination by chemical methods.
4. Carry out quality control of medicinal forms of extemporaneous production according to the following indicators:
   – organoleptic control,
   – physical control,
   – chemical quality control,
   – quantitative chemical control.
5. Carry out quality control of substances and dosage forms using instrumental methods:
   – measuring the pH of solutions,
   – refractometry (refractive index measurement, quantitative determination of concentrates, single- and multi-component dosage forms),
   – polarimetry (measurement of the angle of rotation, calculations of specific rotation),
   – photocolorimetry (measurement of optical density, quantitative determination of dosage forms),
   – IR and UV spectroscopy (measurement of optical density, identification, determination of accompanying impurities, quantitative determination by the method of standard and specific absorption rates).
6. Give a qualified assessment of the quality of medicinal products based on the results of the analysis.

Educational component Pharmacognosy with the basics of resource science
(Name)

1. Identify medicinal plant raw materials by morphological features: Anisi fructus, Calendulae flores, Cinnamomi camphorae lignum, Convallariae herba, Ephedrae equisetine herba, Eucalypti viminalis folia, Frangulae cortex, Hippocastani semina, Menthae piperitae folia, Myrtilli cormus, Myrtilli folia, Orthosiphonis staminei folia, Ricini semina, Salviae folia, Silybi semina, Sorbi fructus, Thymi vulgaris herba, Tribuli terrestris herba.

2. Identify medicinal plant raw materials by morphological and anatomical features: Althaeae herba, Belladonnae folia, Chamomillae flores, Digitalis lanatae folia, Glycyrrhizae radices, Rosae fructus, Valerianae rhizomata cum radicibus.

3. Obtain essential (fatty) oil from medicinal plant raw materials. Conduct an organoleptic analysis and determine the main physical and chemical indicators of oil quality.

4. To identify the main class of biologically active substances (polysaccharides, fats, ascorbic acid, carotenoids, essential oil, saponins, cardioglycosides, flavolignans, flavonoids, anthracene derivatives, tannins, alkaloids) in medicinal plant raw materials.

5. Quantify the main class of biologically active substances (polysaccharides, fats, ascorbic acid, essential oil, saponins, flavonoids, anthracene derivatives, tannins, alkaloids) in medicinal plant raw materials.

Educational component Organization and economics of pharmacy
(Name)

As a result of studying the course, the applicant for higher education will be able to

- carry out the dispensing of OTC medications;

- accept recipes from the public; analyze errors, to dispense the medicines;
- price various medical and cosmetic forms,
- perform outpatient recipes records and subject-quantitative accounting of the drugs;
- perform the quality control of medicines;
- documented the receipts and the sale of goods;
- fill in the documentation the accounting of work and wages;
- determine the days of inventory, make an order;
- organize inventory and account its results;
- develop the balance sheet of the pharmacy;
- analyze the compounding and the pharmacy turnover (sales);
- calculate the ratio of inventories;
- analyze and plan distribution expenses;
- calculate income and profitability of the enterprise;
- retail price of medicines and medical products;
- plan of the pharmacy activities and its departments.

Educational component Pharmaceutical Management and Marketing
(Name)

1. Planning and organization of enterprise activities
2. Comparative analysis of the missions of some pharmaceutical enterprises
3. Comparative analysis of organizational structures of pharmaceutical organizations
4. Control of the company's activities
5. Analysis of planned and actual indicators of commercial activity of wholesale and intermediary pharmaceutical companies
6. Building a semantic differential
7. Building a tree of goals for a pharmacy
8. Analysis of the activities of pharmaceutical manufacturers (top 5 domestic and top 5 foreign)
9. Determining the sample size for marketing research
10. Survey of product consumers
11. Systematization of sources of secondary marketing information according to the problem
12. Determination of the value of the equilibrium price of the drug
13. Construction of the segmentation tree
14. Calculation of the region's need for medicine for the coming year
15. Determination of the capacity of the regional market of the producer and the buyer
16. Determination of the level of market monopolization, calculation of the Harfindel-Hirschman index
17. Calculation of the market share of the medicinal product by natural and value indicators of sales in the market segment, market share relative to the three main competitors, market share relative to the leader
18. Analysis of the price situation of the corresponding segment of the drug market.
19. Determination of the critical scope of implementation and the break-even point
20. Calculation of elasticity of demand
21. ABC analysis of the activity of a wholesale pharmaceutical company
22. Development of multimedia presentation of medicines
23. Analysis of the effectiveness of advertising costs, ROI indicator
24. Justification of the marketing strategy of the enterprise (on the example of the construction of the BKG matrix)
25. Conducting an information search regarding the analysis of pharmaceutical market participants and brands.
26. PR analysis of enterprise activity
27. Information provision of marketing research of the foreign and domestic pharmaceutical market
28. Determination of the form of exit of the pharmaceutical enterprise to foreign markets
29. Analysis of tactical and strategic deviation of sales volumes of a pharmaceutical company
30. Analysis of the results of the marketing department of a pharmaceutical enterprise

Educational component Clinical Pharmacy and Pharmaceutical Care
(Name)

1. Collection of a patient medical history.
2. Conducting a search of information about medicinal product with the support of legal and reference literature, incl. using the Internet.

3. Identification of known drugs with the support of international, trade, chemical name, their including in the certain pharmacological and pharmacotherapeutic group.
4. Determination of the characteristics of drugs, necessary for their comparison, taking into account the chemical structure, mechanism of action and pharmacological properties on the basis of literature data and support documentation.
5. Calculation of single, daily and course doses of drugs with the use of normative documentation (paracetamol, ibuprofen, polyenzymes, iron-containing drugs, β-lactam antibiotics), taking into account the individual characteristics of the person (age, sex, body weight, concomitant pathology, complications, etc.).
6. Selection (together with a physician) of optimal drugs in the specific clinical situation, drug dosage form, dose and routes of administration, taking into account the particularities of their pharmacodynamics and pharmacokinetics, interactions with medications prescribed simultaneously or early, food, alcohol, etc.
7. Information and consultation support - analysis of doctor's prescriptions and interpretation of doctor's instructions on the basis of clinical diagnosis and taking into account the individual characteristics of the patient (sex, age, presence of concomitant diseases), results of instrumental and laboratory tests.
8. Information and consultation support - determination of the advantages and disadvantages of a given drug form of specific medicinal products of various pharmacological groups, taking into account biopharmaceutical, pharmacokinetic and pharmacological features of the medicinal product for an individual patient with his specific characteristics (age, sex, physical condition, etc.).
9. Information and consultation support - determination of the risk of possible drug interactions (physical, chemical, pharmacological, pharmacodynamic), taking into account the pharmacological properties of drugs and the pathology of the patient. Identification of drug incompatibility developed due to their physical and chemical, pharmacological and bio-pharmaceutical features.
10. Information and consultation support - determination of the risk of the food modulating effect on the pharmacokinetics and pharmacological properties of drugs (time and amount of absorption, duration of action, way of excretion, the possibility of undesirable effects, etc.).
11. Information and consultation support - the implementation of pharmaceutical care of patients, consulting doctors and patients on the rational use of prescription drugs of various pharmacological groups: manifestations of clinical efficacy, method and time of administration, interaction with food, alcohol, etc.
12. Carrying out (together with a doctor) a therapeutic replacement of one drug to another.
13. Conducting a generic replacement of one drug to another.
14. Identification among pharmacy visitors the category of persons demanding obligatory consultation of the doctor and persons who can have a responsible self-treatment.
15. The procedure for choosing non-prescription drugs and providing recommendations for:
    - symptomatic treatment of functional disorders of the digestive organs (heartburn, constipation, diarrhea, flatulence), dysbiosis;
    - symptomatic treatment of manifestations of colds (runny nose, sore throat, cough, fever), as well as the prevention of colds;
    - symptomatic treatment of pain in the muscles, joint pain;
    - symptomatic treatment of headache and episodic disorders of the nervous system (asthenia, insomnia, anxiety);
    - helmintosis prevention;
    - symptomatic treatment of local circulatory disorders (diseases of the veins of the lower extremities, hemorrhoids);
    - traumatic (burns, frostbite, cuts, abrasions, bruises, scratches) and infectious (acne, herpes, fungal infections) and parasitic skin lesions;
    - elimination and prevention of vitamin deficiency.
16. Information and consultation support - the providing of pharmaceutical care for patientsin the rational use of non-prescription drugs of various pharmacological groups: manifestations of clinical effectiveness, way and time of administration, interaction with food, alcohol, etc.
17. Selection of clinical and paraclinical criteria for assessment the efficacy and safety (tolerability) of particular drugs.
18. The order and design of informing doctors about cases of irrational use of medicines.
19. The order of actions and arrangements in prevention and elimination the side effects of drug.
20. Filling out the form of report about side effect / ineffectiveness of drug, information and advisory assistance to the population when filling out the form of report about side effects/ineffectiveness of drugs/
21. Assistance to the population in the making up of first aid kits.
22. Compliance with the rules of pharmaceutical ethics and deontology; solving a set of problems related to the relationship between the doctor and the patient.

5. STRUCTURE OF THE COMPREHENSIVE PRACTICE-ORIENTED QUALIFICATION EXAM TICKET

The examination paper of the integrated practice-oriented qualification exam in Pharmacy contains the situation and 4 practical tasks adapted to the realities of the future professional activity.

The case studies cover issues related to the principles of professional activity of pharmaceutical workers. Situation tasks are developed in accordance with the educational program Pharmacy, work programs in Pharmaceutical drug technology, Industrial technology of drugs, Pharmaceutical chemistry, Pharmacognosy with the basics of resource science, Organization and economics of pharmacy, Pharmaceutical management and marketing, Clinical pharmacy and pharmaceutical care, taking into account the necessary competencies of higher education students specified in the educational program.

6. EXAMPLE OF THE COMPREHENSIVE PRACTICE-ORIENTED QUALIFICATION EXAM TICKET

EXAMPLE OF AN EXAMINATION PAPER

Ф А 2.2.1-32-242-В

MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY

APPROVED
The first vice-rector of a higher education institution from the Scientific and Pedagogical Work
_____ Name SURNAME
_____" _____20__ year

Higher education level __**master**__
(the name of Higher education level)
field of knowledge __**22 Public Health**__
(Code and Knowledge Field Name)
in specialty **226 Pharmacy, industrial pharmacy for foreign students (Language of instructions – English)**
(code and name of specialty)
Educational program __**Pharmacy**__
(name of educational program)
Educational component **Complex practically oriented qualification examination in pharmacy**
(the name of Educational component)

EXAMINATION PAPER No. 7

Analyze the proposed situation and justify your answer.

Situation

Pharmaceutical company "Merkle GmbH" (Germany) produces medicine in gelatin capsules "Actiferin".

1. Determine the average weight of capsules and deviation from it according to requirements of the SPhU. Make a conclusion about obtained results.

2. Carry out identification of ferrous sulfate heptahydrate substance by the reaction for iron and sulfates according to the monograph of the EuPh and SPhU.

3. Schematically illustrate possible sales channels of the medicine. Determine the rating of the wholesale pharmaceutical companies and choose the optimal supplier of the medicine.

Selection criterion	Weight of the criterion	Evaluation of the supplier of medicines, points	
		Supplier A	Supplier B
Completeness of the range	0.3	5	3
Prices, discounts, payment terms	0.5	5	5
Level of service	0.1	3	4
Reliability	0.1	3	4
Total	1.0		

4. Explain to a pharmacy visitor clinical and pharmaceutical features of using iron medicines. Propose effectiveness and safety criteria of their use for prophylaxis as well as for therapy of iron-deficiency conditions.

Approved at the meeting of the Central Methodical Council, protocol № _ dated __20_

Head of the Department Name SURNAME

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7. CRITERIA AND EVALUATION ORDER OF EDUCATIONAL OUTCOMES

Evaluation criteria	Points
The applicant of higher education demonstrates consistent, logical, correct and full implementation of practical skills without mistakes. The answers to the questions are complete, detailed, structured, logical.	Excellent / 90-100
Practical skills are performed by the applicant correctly, without serious mistakes, but there are 2-3 inaccuracies that are corrected independently. The answers to the questions are complete, but there are inaccuracies that are corrected by the applicant in the process of answering.	Good / 82-89
Practical skills are performed with minor mistakes or the sequence is broken while performing(which does not significantly affect the final result). The answers to the questions are incomplete, the disclosure of basic concepts is partial or the logic and structure of the presentation is violated.	Good / 74-81
There are mistakes (more than three) in the implementation of practical skills, but the applicant has the necessary knowledge to eliminate them under the guidance of a teacher. The answers to the content of the theoretical question are not complete and not structured.	Satisfactory / 64-73
Significant inaccuracies and mistakes in the implementation of practical skills, The applicant of higher education can correct them only under the guidance of a teacher. Answers to theoretical questions are not clear and complete enough, which requires additional and clarifying questions from the teacher.	Satisfactory / 60-63
Practical skills are not fulfilled or many gross fundamental mistakes are made in the execution, which affect the final result. The main content of theoretical questions is not disclosed, additional and clarifying questions of the teacher have no answers.	Unsatisfactory / 0-59

The grade from the integrated practice-oriented qualifying exam in Pharmacy is determined by the examination committee to the rating scale:

Total points on a 100-point scale	ECTS scale	Evaluation on a four-point scale
90-100	A	Excellent
82-89	B	Good
74-81	C	
64-73	D	Satisfactory
60-63	E	
0-59	FX	Unsatisfactory