IWS № 1. «The concept of homeopathy and its basic principles. State regulation of production of homeopathic medicines. Features of prescribing homeopathic recipes. Nomenclature of homeopathic medicines.»

ODESSA NATIONAL MEDICAL UNIVERSITY DEPARTMENT OF DRUGS TECHNOLOGY

APPROVE

Head of Department

__ (Borisyuk I.Yu.)

«29» august 2022 y.

METHODICAL DEVELOPMENT OF INDEPENDENT WORK OF STUDENTS (IWS)

Course 3 Faculty Pharmaceutical

Course Homeopathic drugs

Topic N_2 1 «The concept of homeopathy and its basic principles. State regulation of production of homeopathic medicines. Features of prescribing homeopathic recipes. Nomenclature of homeopathic medicines.»

Methodical recommendations on IWS developed by:

Head of Department

(Borisyuk I.Yu.)

The practical lesson was discussed at the methodical meeting of the department «29» august 2022 y.

Protocol № 1

Odessa - 2022

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Methodical recommendations of IWS

Topic: «The concept of homeopathy and its basic principles. State regulation of production of homeopathic medicines. Features of prescribing homeopathic recipes. Nomenclature of homeopathic medicines.» - 6 h.

Objective: to get acquainted with the place of homeopathy in modern medicine, a brief historical outline of the development of homeopathy in Ukraine, the classification of homeopathic dosage forms and the main directions of standardization of production of homeopathic medicines.

Basic concepts: homeopathy, allopathy, homeopathic remedies, principle of similarity.

Plan

I. Theoretical questions for the lesson:

- 1. History of homeopathy. Period of homeopathy. Samuel Hahnemann the founder of homeopathy
 - 2. History of homeopathy in Ukraine.
 - 3. Classification of homeopathic dosage forms.
 - 4. The main directions of rationing the production of homeopathic medicines.

Homeopathy recently celebrated its bicentennial. However, medicine now faces the same challenges that Samuel Hahnemann tried to solve - "treat correctly, safely, quickly and reliably."

For a long time, allopathic and homeopathic treatment systems have developed independently in different ways. Each of them has indisputable achievements and shortcomings. However, today it is already clear that both systems must exist, enriching each other. Ways and means of converging these systems are diverse. Homeopathy - a brilliant insight of the late eighteenth century passes into the twenty-first century, retaining its basic provisions, but filled with new content, ideas of use, breadth of application.

Currently, the popularity of treatment with biological medicine is growing among patients. Physicians who have received traditional medical education are often helpless in the face of many biological or naturopathic therapies .

Unfortunately, we are experiencing the threat of environmental disturbance and are anxiously watching the impact of this process on the body's internal environment. Allergy of the population, the emergence of drug diseases and antibiotic resistance of strains of microorganisms, are increasingly forcing to reconsider the boundaries of indications in pharmacotherapy.

The development of chemistry in the twentieth century has led to an avalanche-like increase in the arsenal of synthetic drugs, which by their origin belong to the category of xenobiotics, which are foreign substances to the body. They proved to be quite attractive for establishing the dependence of the structure - the compound and its physiological mechanism of action. Thus, synthetic drugs have supplanted complex drugs of natural origin, and at the same time increased the number of problems of their negative impact on the body. Already in the 1970s, the pharmacotherapeutic crisis was clearly manifested, which arose against the background of the terminological chaos of drugs and their irrational

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use. Signs of the crisis are a slow increase in the desired therapeutic efficacy of drugs and a marked increase in their negative effects. These issues are the focus of medicine, toxicology, biology and pharmacology.

In the current situation, we must strive to expand therapeutic opportunities. The doctor, disoriented by numerous new drugs from the arsenal of chemo-antibiotic-hormonal drugs, seeks help in a therapeutic system that does not harm the sick person. Such a therapeutic system is homeopathy.

In order to understand what homeopathy is, a more precise definition of concepts such as traditional allopathic medicine and homeopathy should be given.

Under traditional allopathic medicine is understood as official, studied in universities and universities around the world, medicine. Medications are usually used to combat the disease or its symptoms in accordance with the principle *of " Contraria contrariis curantur*" (the opposite is treated as the opposite). Therefore, this principle of treatment is called allopathic (another disease), that is, efforts to combat the disease.

In contrast to this approach, homeopathy (acting in the same direction or similar to disease) is a therapy, the basic principles and approaches of which, since 1790, developed by Samuel Hahnemann and formulated by him as "Similia similibus curantur" (similar treated similarly). In this case, a small dose of the drug is used, which in larger doses can cause a picture in a healthy body similar to the disease. Homeopathic medicine gives the diseased body a directed impetus and helps to activate its own defenses and, thus, its main effort is to restore the disturbed balance in the body, which is considered the root cause of the disease.

Homeopaths, using the principle of similarity in prescribing drugs, use small doses of those drugs that in large doses cause similar symptoms in a sensitive healthy person.

The homeopathic method is a method of holistic individual therapy, not the treatment of any single organ. Each patient differs in the nature of their subjective feelings from other patients with the same disease.

Homeopathy as a method of therapy with ultra-low doses of drugs has a number of undoubted advantages:

- pronounced therapeutic and prophylactic effect;
- action at the level of the whole organism;
- > availability of clear principles and rules of application;
- ▶ lack of substrate-toxic properties, and hence side effects and complications arising during therapy;
 - lack of individual intolerance and addiction.

Homeopathy and allopathy are united by a common goal - the treatment or improvement of the patient's condition with drugs, and distinguishes the principle of selection and appointment of drugs and, more broadly, different ideas about the nature of the disease and ways to treat it.

For allopathy (classical medicine) the disease is determined by a set of etiological, pathogenetic, clinical signs. Only the diagnosis of the disease is considered important for adequate therapy, because it determines the class of drugs that affect the disease in a known way.

Allopathy studies the etiology and pathogenesis of each disease separately - so allopathy does not have a single principle of choice of drugs. Drugs do not affect the common links of pathogenesis of diseases for all diseases, but only the individual links of the pathogenetic chain for each disease. Allopathy is based on the casual nature of the disease. Her tactics are aimed at eliminating the causes of the disease and its clinical manifestations (symptoms) and with the right choice of drugs, they must resist the factors of disease development. Treatment of a particular disease, in essence, is to act on the affected system or organ with all its inherent morphological or functional changes. It should be emphasized that allopathy does not preclude the assessment of constitutional and personal characteristics of the patient in the light of the concept of psychosomatic medicine.

Unlike allopathy, which tries to identify the nature of the disease, especially its pathogenesis, homeopathy considers as a primary object of its study of the constitutional features and reactions of the sick person. Homeopathy - applies the principle of integrity of the organism. There is a study of the patient - his physical, mental, emotional state, environmental conditions, marital status, family medical history, physical constitution. In homeopathy, the symptoms of the disease are the body's reactions to treatment. Therefore, the treatment process is except that the displacement of the disease from the body and is due to its activation. Instead of suppressing the symptoms, medications should promote the healing process. Based on this, homeopathic treatment is not a direct impact on the etiological factors and pathogenesis of the disease, but on the impact on the set of properties of the patient that determine the individuality of his body. According to homeopaths, the symptoms of the disease, which manifest themselves as it progresses, correspond to the individual characteristics of the body's response to the development of pathology and are associated with the formation of protective reactions aimed at maintaining compensation or recovery. Homeopathy is focused on the individuality of the patient, it is primarily interested in the diagnosis of the patient, not his disease. The diagnosis of the patient is determined by the selection on the principle of similarity of the necessary drugs.

Based on the above, it is clear that the scope of homeopathy is quite wide, and its capabilities are determined by the degree of preservation of the body's own regulatory capabilities, ie the ability to maintain the functioning of various systems. Homeopathy has proven to be an effective method in the treatment of childhood diseases, acute and chronic diseases, in dermatology. The main indications for the use of homeopathy are primarily functional and psychosomatic diseases, such as autonomic and hormonal disorders (bronchial asthma, neurodermatitis). Homeopathy most fully complies with the principle of individualization of treatment. In many cases, when the methods of clinical medicine do not help, homeopathic remedies are successful. Homeopathic remedies are well combined with modern pharmacological agents .

Traditional medicine and homeopathy are not antagonistic therapeutic approaches, if the evidence and the limits of the possibilities of appropriate treatments are properly taken into account. The main point of application of traditional medicine is the treatment of acute conditions, ie, the elimination of life-threatening conditions (a classic example - the treatment of myocardial infarction in the intensive care unit), as well as various surgeries. Experience has shown that high-performance homeopathic therapy can be used in the

treatment of chronic diseases (eg, various forms of rheumatic diseases) and diseases of "civilization" (classic example - allergies due to environmental pollution), ie where traditional medicine is often helpless. Instead of confrontation, we should strive for mutual and fruitful cooperation.

The basis for understanding the action of homeopathic remedies is the position that the human body is a system that has a very wide degree of self-regulation and self-improvement, which can be influenced by external factors. The therapeutic effect in this case is due to the impact on the system of self-regulation.

Homeopathy - " regulatory therapy " , a method of " eradicating the disease, not eliminating its individual symptoms " , soft, reliable without side effects correction of protective and adaptive mechanisms with extremely small doses of drugs prescribed by the " law of likeness " , leads to a fairly fast and reliable result. Its medicinal stimuli are aimed at the mechanisms of self-regulation that ensure homeostasis. Focusing on the individual, homeopathy affects the common mechanisms of self-regulation for all diseases. Homeopathic medicine is not a medicine in the conventional sense of the word. They do not have bactericidal, bacteriostatic or antitoxic properties and act only on the macroorganism , restoring its homeostasis disturbed by the pathological process. Homeopathic remedies act in the body not as " active substances " , but as " signals " .

So, homeopathy is: individual regulatory therapy (a form of drug regulatory therapy) that stimulates and normalizes the body's defenses. Its purpose is to influence the processes of self-regulation of the body with the help of drugs selected strictly individually, taking into account the reactivity of the patient.

History of homeopathy. Before Hahnemann period of development of homeopathy

The historical roots of homeopathy go back to antiquity. The first to begin the creation of scientific medicine was Hippocrates (460-375 BC), who laid the foundations of clinical medicine and first formed the principles of treatment of "like like" and "opposite to opposite".

The founder of the principle of individual approach to the patient, as part of a single and indivisible nature, Hippocrates widely considered the principles and means of therapeutic action. Even then, he prophetically pointed out: "Many drugs can be successfully used to treat the same patient, some of which are similar to the disease, while others are opposite to it." and homeopathy.

The great Greek philosopher Democritus (460-370 gg. BC) also stated: "Similar requires similar", and considering the issues of biology, medicine, linguistics, mathematics, aesthetics, etc., the principle of similarity is represented in a broad philosophical sense.

famous Roman physician and naturalist Galen (131-200 gg. BC) proposed to use extracts of various parts of plants, ie methods of preparation of tinctures, extracts, oils and alcohols, which are then used in both allopathic and homeopathic pharmacy.

Galen based his treatment on the principle of opposites, divided the drugs according to the symptoms of diseases - painkillers, hypnotics, laxatives, etc.

In the early sixteenth century, Paracelsus, a famous physician of the Middle Ages, criticized many of Galen's claims. In particular, he stated: "... No hot disease can be cured

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by cold, nor cold - by heat. But it often happens that something like this heals its own ... ". In Liber Paramium, he wrote: "Look outwardly for what is inherent in the nature of your internal disease." Speaking of cough, sore throat, catarrh, he wrote: "These terms do not give us anything about the similarity of drugs; the term should be used to compare the like with the like, and such a comparison helps to find a cure for the disease.

Similar statements can be found in the famous Belgian physician Van Helmont: "Illness cures disease."

Long before the development of the method of vaccination by Louis Pasteur, Nostradamus used extracts from purulent secretions of patients in the treatment of bubonic plague, appropriately dissolved in alcohol, both for internal and external use.

It is also known that in the eighteenth century G. Stahl wrote: "I am convinced that the disease recedes before the means that themselves cause such conditions."

Subsequently, the principles of similarity of symptoms of symptoms and symptoms caused by the action of drugs, repeatedly noted by many European and Arab authors .

Samuel Hahnemann - the founder of homeopathy

The founder of homeopathy, as an independent system of treatment in medicine, is rightly considered a German scientist - Friedrich Christian Samuel Hahnemann.

He was born on April 10, 1755 in Saxony, in the small town of Meissen . He received his medical education in Leipzig (1775), from 1777 in Vienna, then in Erlangen. In 1779 he defended his dissertation. In 1781 he supplemented his medical education by studying pharmacy in Dessau.

After graduating from university, Hahnemann devoted several years to medical practice. He was not satisfied, but rather disappointed with the possibilities of medicine. He later began teaching at the Leipzig Academy. His areas of interest were chemistry and pharmacology.

According to the composition of his personality, Hahnemann was an extraordinary man, characterized by great activity in work. Experimental sciences have not yet been formed, and almost the only opportunity to study drugs were experiments on themselves. He studied the drugs he read about.

The first Leipzig period of S. Hahnemann's life began in 1789. By this time he already had a reputation as a scientist and experienced general practitioner. He became the author of the following works: "On arsenic poisoning", "Teaching to thoroughly cure old premature and rotten ulcers", "Guide for doctors to sexually transmitted diseases"; invented a method of making soluble mercury, described the chemical properties of bile and gallstones, and so on.

Medical practice did not bring S. Hahnemann satisfaction. At that time, therapies were used to exhaust patients: large doses of diaphoretic, emetic, diuretic and laxatives, frequent and abundant bloodletting. All this led to despair, gave rise to a sense of helplessness and futility of medicine. Hahnemann is gradually moving away from medical practice, immersed in literary work, including translations.

In 1790 Hahnemann translated Medicine of Edinburgh Professor W. Cullen ("Matter of Medicine"). In the section on Hina, he was struck by the contradictions in the description of its therapeutic effect, and Hahnemann took Hina in a therapeutic dose, observing its

effect. To his surprise, the symptoms he noted coincided with the symptoms of malaria, which he had previously suffered from. He developed a typical recurrent fever.

The innate sense of harmony and philosophical composition of the mind required a search for regularity. It became clear to him that henna therefore took an exceptional position in the treatment of malaria, which itself is able to cause the same picture. This analogy became for Hahnemann the principle of choosing drugs for treatment.

The principle postulated by S. Hahnemann received numerous private confirmations. For example, mercury drugs in toxic doses affect the body, affecting many organs and systems, with significant damage to the colon (severe ulcerative colitis). Meanwhile, these same drugs in small doses have a beneficial effect on dysentery- like colitis. Arsenic causes cholera-like diarrhea, and in homeopathic use arsenic drugs cure diarrhea of various natures. Iodine irritates the respiratory tract, and in small doses has a beneficial effect on bronchitis. Sulfur with prolonged exposure leads to widespread dermatitis, and in homeopathy *Sulfur iodatum* cures various skin diseases . *Cantharis vesicatoria* (Spanish flies) in toxic doses causes inflammation of the bladder, and in homeopathic doses alleviates the suffering of patients with cystitis and urethritis. Horns in large doses cause severe damage to the body with vasospasm, which is complicated by the development of gangrene, and in small doses *Secali cornutum* has been used successfully in obliterating atherosclerosis, etc. Gradually, the concept that formed the basis of homeotherapy as a new treatment system matured.

Hahnemann, who does not attribute other people's discoveries to himself, writes that the principle of similarity as a possible principle of choosing drugs for treatment has long been known. His merit lies in the fact that he came to the conclusion that this should not be done with isolated cases, but always with all drugs, and this is a general principle of drug selection.

In 1977, in the journal von Tufeland, Hahnemann published his "Experience of a New Principle for Finding the Healing Properties of Medicinal Substances", which can be considered the first work to proclaim the principles of homeopathy, and this date can be considered the birth of a new direction in medicine. Hahnemann then stopped teaching at the university and returned to medical practice. He should have tested in practice the generality of the principle of similarity, further expressed by the formula that you already know: "Simila similibus curantur" ("Like is treated like"). In its final form, the concept of homeopathy is presented in the first edition of "Organon".

Samuel Hahnemann's major work, The Organ of Medicinal Art, is considered a fundamental classic work in homeopathy around the world. Published the first edition in 1810, 20 years after the discovery of S. Hahnemann's homeopathic method of treatment, "Organon" contains philosophical, theoretical and practical aspects of homeopathy . The book has been republished many times and translated into many languages. The fifth edition of "Organon" in the Russian translation of V. Sorokin was published in 1884. Of particular interest is the sixth edition of "Organon", carefully reworked by S. Hahnemann at the age of 86, during the last period of his medical practice in Paris.

The preface to the Organon was written by S. Hahnemann in 1833 and confirmed by him during the preparation of the 6th edition of the book. The preface compares the old medical school (allopathy) with its constantly weakening effects of patients (at that time

repeated bloodletting, numerous leeches, blood-sucking jars, enemas, etc.) with homeopathy, which "avoids everything, even a little weakening patient "and" is a saving and blessed work. "Without such a comparison, sharp and mutually exclusive, at that time it would be impossible to identify, establish and develop a homeopathic system of treatment, coexisting today with other areas of treatment, enriched by great successes and achievements.

The first part of "Organon" contains the main theoretical ideas of the author and his position on the mechanisms of homeopathic and therapeutic effects (similar is treated by similar). The ideal of treatment, according to S. Hahnemann, is "rapid, gentle and final recovery of health ... the shortest, most reliable and safe way based on easy-to-understand principles. But a doctor is also a "health care provider" because he knows the factors that are troubling to health and that cause death, and he knows how to protect healthy people from them. "The doctor must be a true practitioner of the art of healing, and the true purpose of the doctor is "not in scientific chatter, but in helping the suffering." S. Hahnemann calls for treatment without theorizing.

The second section "Organon" contains practical recommendations for the use of homeopathy. To properly and effectively treat, the doctor must examine the patient, know the effects of drugs and use them correctly. Among the "excitatory" causes of acute diseases are the negative effects of the environment, mental influences and "acute miasms". Some of them "can affect each person no more than once in a lifetime, such as smallpox, measles, whooping cough, scarlet fever, mumps, etc.", while others - "often relapse while maintaining the basic nature of their manifestations ". WITH. Hahnemann notes that acute illnesses "are often temporary exacerbations of latent psoriasis." This text is also close to the modern reader. For example, acute nephritic syndrome in most cases is exacerbated by chronic nephropathy, the nature of which is specified by nephrobiopsy. Among chronic diseases S. Hahnemann distinguishes between true and false. The first are miasmatic diseases (syphilis, sycosis and psora), the second is the result of drug abuse or the result of exposure to certain harmful substances (eating disorders, use of stimulants, etc.). In acute diseases, the patient's vitality is able to overcome them or miasms in a short time overcome the vitality. So, according to S. Hahnemann, the results of acute miasmatic diseases are recovery or death. It is necessary to add: whether transition of a disease to a long or chronic form is possible.

The final section "Organon" is devoted to measures that support homeopathic treatment. S. Hahnemann confirms the action on the "principle of life" of the "dynamic force of mineral magnets, electricity and galvanism". He has a positive attitude towards "animal magnetism", proposing to call it Mesmerism out of respect for Mesmer. "A person's strong will, acting on the patient with the best of intentions through contact and even without it, and even at some distance, can dynamically transmit the vital energy of a healthy hypnotist," "the power of strong good will can sometimes work wonders." These considerations S. Hahnemann today does not seem distant and unacceptable to us. Massage is especially effective when it is "done by a strong and friendly person", but this method "should not be excessively applied to hypersensitive patients". It is useful to add baths to the general treatment in the period of recovery and improvement of the patient's condition "with due attention to the condition of the convalescent, water temperature, duration and

frequency of repetition of procedures." Apparently, the creator of homeopathy does not deny the role of music therapy: "The most tender sounds of the flute are heard from afar ... can fill a tender heart with sublime feelings and dissolve it in religious ecstasy."

His authority as a skilled physician is growing every year, the practice is expanding. However, S. Hahnemann is constantly faced with dissatisfaction, envy and opposition of doctors and pharmacists. Between 1793 and 1810, S. Hahnemann was forced to move frequently from one city to another, practicing in Molschkben, Göttingen, Pyrmont, Braunschweig, Wolfenbüttel, Kenningslutter, Alpton, Hamburg, and Maheme. In parallel with the practice, a voluminous "Pharmacy Lexicon" was compiled by S. Hahnemann's fame as an authoritative connoisseur of pharmacy.

The most important stage in the formation and spread of homeopathy was the second Leipzig period of S. Hahnemann's life (1811-1821 gg.), When he taught at the university. Contrary to the opposition of many enemies, he successfully defended his dissertation at the Faculty of Medicine, presenting a thorough historical and medical study "On Helleborism of the Ancients." Unusual depth of study of the subject, brilliant knowledge of a huge number of ancient sources, persuasiveness and logic of the presentation eliminated all the objections of even the most hostile opponents. Having received the right to teach at the largest European university, S. Hahnemann gathered around him many students and followers. This was a period of rapid development of knowledge and practical experience in homeopathy, the accumulation of thorough descriptions of the pathogenesis of homeopathic medicines.

In 1811 he published his book "Pure Medicine" in 6 volumes, which describes 60 drugs. In 1828 the book "Chronic Diseases" was published in 5 volumes. In these books, in addition to the law of similarity, two other rules of homeopathy are described: the use of small doses and the need to test the effects of drugs on a healthy person.

Along with the success of homeopathy, the growing authority of S. Hahnemann and his school, the forces of his opposition grew. There was a lawsuit between him and Leipzig pharmacists, who demanded to transfer the manufacture of any drug into their own hands. As a result, S. Hahnemann was officially ordered to prescribe all his homeopathic medicines exclusively through the usual allopathic pharmacies, which are in the hands of fierce opponents of homeopathy. This was tantamount to banning homeopathic medicine in Leipzig.

In the summer of 1821 S. Hahnemann was forced to move to the small town of Kothen under the patronage of Duke Ferdinand of Anhalt-Ketten, a supporter of homeopathic treatment. WITH. Hahnemann, whose fame for the art of medicine had already spread throughout Germany, regained the freedom of medical practice with the right to self-prepare and dispense homeopathic remedies. Patients began to flock to Kothen not only from all regions of Germany, but also from neighboring countries.

During these years, S. Hahnemann published a capital in a multi-volume work "Chronic Diseases", which was based on the concept of miasms. The most important principles of homeopathy - potentiation or dynamization of medicines, proof and explanation of the effectiveness of small doses - were also thoroughly clarified and detailed. In 1831, when cholera spread in Europe, S. Hahnemann proposed the use of homeopathic

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remedies (camphor, veratrum, copper salts) to treat this serious disease that claimed thousands of lives. The positive effect of homeopathy was confirmed by many doctors of the time, in particular, in Austria, Hungary, England, Italy, Russia, etc.

The last, Parisian period of Hahnemann's life was full of intensive medical practice. He became one of the most popular doctors in Paris, surrounded by respect and esteem. However, even at this time, attacks on Hahnemann's teachings continued.

Due to age and unbearable stress, Hahnemann's health began to deteriorate. On July 2, 1843, at the age of 89, he died and was buried in the Pere Lachaise Cemetery in Paris, where the Latin phrase "*Non inutilis vixi*" ("I lived in vain") was embossed on a monument with a bust of S. Hahnemann.

For two centuries, homeopaths around the world have been adhering to the basic life principle of this great man: to treat "faithfully, safely, quickly and reliably." He was, without a doubt, an outstanding personality, mad in character, genius in the magnitude of his talent.

The right to prepare homeopathic remedies

According to Article 74 of the Fundamentals of the Legislation of Ukraine on Health Care (dated November 19, 1992), persons who have the appropriate special education and meet the uniform qualification requirements may engage in pharmaceutical activities. Such requirements are established by the order of the Ministry of Health of Ukraine № 195 of 25.12.92 "On approval of the List of higher and secondary special educational institutions, preparation and acquisition of knowledge in which give the right to engage in medical and pharmaceutical activities." Persons who have undergone pharmaceutical training in educational institutions of foreign countries are admitted to professional activities, including business positions, after checking their qualifications in the manner prescribed by the Order of the Ministry of Health of Ukraine № 118-C of 19.08.94 "On admission to medical and pharmaceutical activities in Ukraine of citizens who have undergone medical and pharmaceutical training in educational institutions of foreign countries.".

Stages of creation of homeopathic medicines

The procedure for issuing permits for the use and introduction of homeopathic medicinal products was developed in accordance with Order № 152 of 18.08.95 of the Ministry of Health of Ukraine "On approval of the Procedure for issuing permits for use and introduction into the production of medicinal products". The procedure for issuing a permit for the use and introduction into the production of homeopathic medicinal products is developed in accordance with Annex 91/507 to the "Basic requirements for the verification of medicinal products of the European Economic Community" (75/318). In this regard, the European Homeopathic Committee was established in 1990. This Committee has established that decisions in the field of homeopathy must be taken at the level of the Homeopathic Community, which is necessary for the expansion of international trade in homeopathic remedies, guaranteeing their quality and safety. In considering these issues, the European Parliament has spoken out in favor of recognizing the European Pharmacopoeia; adoption of a directive on the legality of complementary medicine.

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Homeopathic medicinal products that have been registered and entered in the State Register of Medicinal Products are permitted for clinical use and introduction into production in Ukraine.

All provisions apply to homeopathic medicines used to treat humans and animals.

In this regard, a homeopathic medicine is a product made in accordance with the homeopathic pharmacopoeia. Homeopathic remedies may contain several active substances.

Stages of registration of domestic homeopathic medicines and issuance of a permit for their use and introduction into production

All homeopathic medicinal products may be approved for clinical use and industrial production in Ukraine after their registration at the Pharmacological Center of the Ministry of Health of Ukraine in accordance with the order of the Ministry of Health of Ukraine No 120 of 15.05.1998 "On state registration of medicinal products" and No 220 of 19.09.2000 . "On approval of the procedure for examination of materials for medicinal products submitted for state registration (re-registration), as well as examination of materials on amendments to registration documents during the validity of the registration certificate."

To register, legal entities submit to the Pharmacological Center of the Ministry of Health of Ukraine documents corresponding to the following groups of domestic drugs:

a) new homeopathic medicines;

homeopathic medicines with one active substance;

- c) complex homeopathic medicines that contain two or more species and active substances ;
- d) complex homeopathic medicinal products, which together with known new active substances;
 - e) domestic drugs manufactured using imported pharmacological substances;
- e) homeopathic medicinal products manufactured in the factory (packaging of the finished dosage form), which are registered in the form of an intra-pharmacy preparation.

The volume of documents, regardless of how the drug is offered for registration:

- 1. Name of homeopathic remedy in Ukrainian and Latin.
- 2. Composition of pharmacologically active and excipients, homeopathic dilution and release form;
- 3. Bibliographic information on raw materials and beginnings and ingredients indicating their chemical composition and toxic dose, as well as a certificate of quality of all starting ingredients;
 - 4. Technological regulations or description of production technology;
- 5. Rationale for effectiveness: results of experimental and clinical studies, including literature data;
 - 6. Data on the absence of toxic effects;
 - 7. Analytical regulatory documentation (control methods);
 - 8. Stability data;
 - 9. Packaging and storage conditions;
 - 10. Sample label in Ukrainian and sample of the drug in the amount of not less than 5;
- 11. A copy of the license of a pharmacy or pharmaceutical factory for the right to manufacture homeopathic medicines in Ukraine;

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12. Indications and features of application.

To confirm the quality of homeopathic medicines to the State Pharmacological Center of the Ministry of Health of Ukraine together with the documents submitted:

- information on purity testing, identity tests, chemical and physical stability;
- certificate of quality control of the drug.

Stages of registration of imported drugs in Ukraine and issuance of permits for their use and introduction into production

To consider the issue of registration (re-registration) of imported homeopathic medicines (for 5 years) it is necessary to provide materials in triplicate to the State Pharmacological Center of the Ministry of Health of Ukraine. The amount of documentation depends on which drug is offered for registration. In this situation, homeopathic medicines are divided into the following groups:

- a) new homeopathic medicines;
- homeopathic medicines with one active substance;
- c) complex homeopathic medicines that contain two or more species and active substances ;
 - d) anthroposophical medicines.

In the process of registration of homeopathic medicines of foreign companies, the State Pharmacological Center of the Ministry of Health of Ukraine:

- conducts examination of the initial application letter, materials of experimental, clinical study of drugs, checks the availability of regulatory and technical documentation and samples of drugs in the proposed dosage forms;
 - prescribes and supervises clinical trials of drugs;
- > sends regulatory and technical documentation and samples of drugs for quality confirmation;
 - issues a certificate of registration (re-registration) of drugs.

To obtain a certificate of registration (re-registration) of imported homeopathic medicines, the applicant must go through the following steps:

- to prepay the work on the registration of drugs in accordance with the price list to the account of the State Pharmacological Center of the Ministry of Health of Ukraine after a positive response to the initial application letter;
- > provide relevant documentation to the State Pharmacological Center of the Ministry of Health of Ukraine;
- to receive an extract from the State Pharmacological Center of the Ministry of Health of Ukraine on the decision for the relevant examination of scientific and technical documentation and samples of drugs;
- with a positive decision to receive within 2 months from the date of submission of materials to the State Pharmacological Center of the Ministry of Health of Ukraine certificate of registration (re-registration) of drugs in Ukraine.

Documents are submitted to the State Pharmacological Center of the Ministry of Health of Ukraine in English with a translation into Ukrainian or Russian, certified by companies or legal entities.

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The amount of documentation depends on how the homeopathic remedy is offered for registration.

The State Pharmacological Center of the Ministry of Health of Ukraine may authorize the medical use of homeopathic medicines that are offered for single import into Ukraine at the request of the relevant health departments of local executive bodies. For this purpose, the following are submitted to the State Pharmacological Center of the Ministry of Health of Ukraine:

- > a letter stating the necessary drugs (name of the drug, manufacturer, dosage form, number of packages, total cost);
- ➤ a letter from the company offering to supply the drugs with the designation offered for delivery;
 - certificates of registration in the country of origin,
- > quality certificates issued by the manufacturer for a series of drugs that are proposed to be imported;
 - samples of drugs in dosage form (one package);
 - > a copy of the contract (agreement).

Quality control of homeopathic remedies should be carried out taking into account the following stages:

- A) Names of ingredients of the medicinal product (indicating the type and quantity)
- 1. Ingredients must include:

- 2. The following names must be given:
- the common name from the corresponding monograph is one of the homeopathic pharmacopoeias. If it is not there, the common name from the pharmacopoeia of one of the member states of the European Community should be given with reference to the relevant pharmacopoeia;
- ☑ if the title is absent in the current Homeopathic Parts and Pharmacopoeia, but is contained in its previous editions, the title from the monograph of the Homeopathic Pharmacopoeia of 1934 may be used;
- in other cases, the international name recommended by the WHO should be used, and if it does not exist, the exact scientific name;
- ☑ for ingredients without an international or exact scientific name, their origin must be indicated (for example, for the original vegetable raw materials, the parts of the plant used must be indicated).
- 3. Quantity must be expressed in units of mass or volume. The relative amount should be indicated for unit dosage forms and for other release forms in weight or volume values corresponding to the size of the package (eg 100 g or 100 ml). The units of mass or volume used for a single dose should correspond to the units selected to measure the contents of the package.
- 4. When using preservatives, evidence of their effectiveness should be provided (based on research results).
 - B) Data on production and in-house control.

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Production data should give a sufficient idea of the nature of production processes. It should be noted:

- \square the formula of preparation with indication of quantity (limiting quantities) of the applied initial substances;
- ✓ starting materials that should not remain in the original product (their characteristics);
- ☑ individual stages of production to check whether the quality of ingredients is deteriorating;
 - \square number of instructions for cooking D F,
- production stages at which sampling is carried out and in- pharmacy control is carried out.
 - C) Control of starting materials

The starting materials are all substances used in the manufacture of the medicinal product and the primary packaging.

1. The starting materials described in the pharmacopoeias

Data and documents related to starting materials must correspond to: monographs of the German Pharmacopoeia (especially their homeopathic part), and in the absence of such - monographs of the pharmacopoeia of one of the member states of the European Community. In this case, the indication and description of the quality control procedure may be replaced by a reference to the relevant pharmacopoeia. If the starting material listed in the pharmacopoeia was obtained by a method that allows the preservation in the finished product of any contaminants for which the monograph of this pharmacopoeia does not provide for any testing, it is necessary to further test for these contaminants.

2. Starting materials not described in pharmacopoeias

In this case, the applicant must submit a separate monograph for each source material, developed by him independently, and will be consistent with the pharmacopoeia (primarily DF). This monograph should cover the lowest breeding breeds. If the starting material is described in one of the available works, a reference to this work is sufficient, provided that it meets the following requirements.

Own monograph should contain the following characteristics:

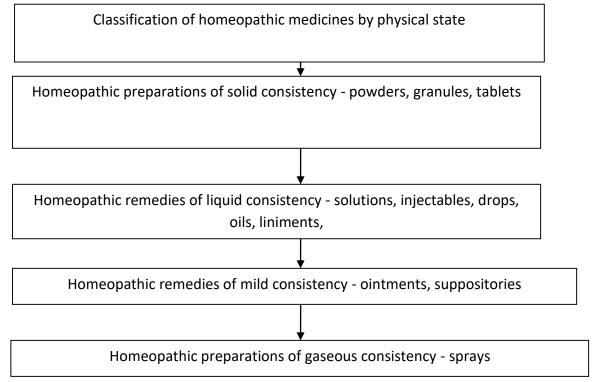
- ✓ name;
- ☑ description data on qualitative characteristics;
- \square authenticity test methods;
- ☑ purity tests (indicating the limit content);
- ✓ methods of quantitative analysis (if necessary);
- ✓ special precautions for storage.
- 3. The starting materials do not remain in the finished drug

For such starting materials, data and documents that meet the requirements listed above must be provided.

Classification of homeopathic medicines

Classification of homeopathic remedies by physical state and method of administration

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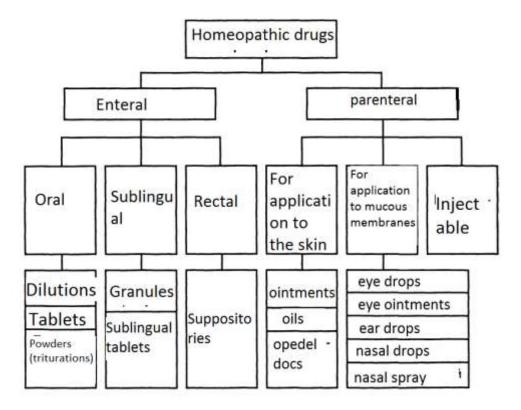


The technology of pharmaceutical drugs uses the classification of dosage forms by physical state. Despite the fact that this classification is the oldest, has many shortcomings, it is still convenient for the initial distribution of material, so it continues to be used today. Homeopathic dosage forms can be classified in a similar way.

According to this classification, all dosage forms used in homeopathy can be divided into four groups:

- I. Homeopathic preparations of solid consistency. These include powders, granules, tablets.
- II. Homeopathic medicines of liquid consistency: solutions, injectables, drops, oils, liniments (opodeldok and).
 - III. Homeopathic remedies of mild consistency: ointments, suppositories.
 - IV. Homeopathic preparations of gaseous consistency: sprays.
- A significant disadvantage of this classification is that the physical state does not contain information about the technological processes used in the manufacture.

Classification of homeopathic remedies by method of administration



Professor Tikhomirov VL proposed a classification of drugs

Following this classification, all routes of administration of homeopathic medicines can be divided into two main groups:

- Enteral (through the gastrointestinal tract);
- Parenteral (bypassing the gastrointestinal tract).

Enteral routes of administration

drug, or *oral route* of administration (*per os* - through the mouth), is the most common because it is very simple and allows you to enter most drugs in different dosage forms: dilutions, tablets, powders (triturations).

When taken orally, the drugs are absorbed mainly in the small intestine, and then through the portal vein enter the liver and then into the general bloodstream. Their effect usually begins in 15-30 minutes.

However, not all drugs are effective when taken orally. Some of them are destroyed in the gastrointestinal tract (GI tract) by hydrochloric acid of gastric juice, enzymes of the stomach and intestines. Some of them are poorly absorbed in the gastrointestinal tract (poorly penetrates the membrane of gastrointestinal epithelial cells). When administered orally, homeopathic medicines can interact with food, which also slows their absorption, so the drugs should be taken on an empty stomach, 30 minutes before meals, or an hour after meals.

Sublingual route of administration (from *sub* - under; *lingua* - language). Many homeopathic remedies (granules, tablets) are administered only through the mouth (under the tongue) without subsequent ingestion, by resorption, because the oral mucosa absorbs them quickly. At the same time substances quickly enough (in some minutes) get to blood,

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bypassing a liver.

Rectal route of administration. With the introduction of drugs through the rectum (per rectum) absorption of substances is slightly faster than when administered orally. Venous blood from the rectum through the system of lower and middle hemorrhoidal veins enters the general circulation, bypassing the hepatic barrier, which reduces the destruction of drugs in the gastrointestinal tract and liver.

In the rectum there are no unfavorable conditions for drugs, and the mucous membrane of the rectum absorbs drugs well. Therefore, the drug from the rectum enters at about the same rate into the general circulation as when administered intramuscularly.

Parenteral routes of administration

Intramuscular route of administration. Intramuscular administration of drugs provides good biological filtration through connective tissue membranes and capillary walls. From muscles solutions of medicines well get into blood, and in 5-10 minutes can create sufficient concentration in blood.

Intravenous route of administration . At enteral ways of administration of drugs, and also at intramuscular, a part of substance is late or inactivated in fabrics. In addition, the level of absorption of substances into the blood can sometimes vary considerably, depending on the individual characteristics of the patient, his condition. In contrast, when administered intravenously, the entire amount of the injected substance immediately enters the bloodstream, which provides high accuracy of dosing and speed of action.

Application to mucous membranes . The use of drugs in the eye (in the conjunctival sac) requires great care, as the cornea has a delicate epithelium, damage to which leads to irreversible action with the formation of albumin or ulcers, ending in the development of pain (impermeable to light).

Solutions of drugs in the eye are used in the amount of 2 drops (approximately 0.1 ml), as more conjunctival fissure does not fit and the solution flows out of it. The inconvenience of applying solutions to the eye is associated with extremely short-term action due to rapid absorption. Therefore, eye ointments are used for long-term action.

All these dosage forms - eye drops, ointments - are currently rarely prepared in homeopathic pharmacies, which is due to the need to create aseptic cooking conditions.

Solutions of medicinal substances in the form of drops, aerosols are used for drawing on mucous membranes of a nose. Mucous membranes easily absorb drugs into the blood.

Homeopathic medicines are applied to the *skin in the form of oils*, ointments and ointments.

Due to intact skin, drugs are difficult to absorb into the blood. When rubbing drugs into the skin, they penetrate the sweat and sebaceous glands, as well as hair follicles, through which they can slowly and only in limited quantities enter the bloodstream. erez painfully altered skin drugs more easily penetrate into the blood.

Classification of homeopathic remedies by method of administration is mainly of medical importance, as issues of technology are reflected in it last.

Classification of homeopathic remedies by dosage features

The classification of homeopathic remedies according to the peculiarities of dosage draws the attention of the doctor and the pharmacist-homeopath to the method of medication. However, there are a number of dosage forms that can be attributed to both groups, because: release from pharmacies in separate doses - in this case, solutions, drops, powders are not dosed, but each prescription indicates the exact dose of these dosage forms at home (for example, 6-8 drops or on the tip of a coffee spoon for powders), while for opodeldokov, ointments, oils, the dose is not specified.

This classification does not have an independent meaning, but in combination with others it is necessary.

Undosed dosage forms include:

- Rubbing;
- Ointments;
- Opodeldoki;
- Oils.

To dosed:

- Tablets;
- Granules;
- Suppositories;
- Injectable drugs.

Features of reception:

- 1. The drug is taken on an empty stomach early in the morning or at bedtime, and in the afternoon 30 minutes before meals or an hour after meals.
 - 2. The drugs are absorbed in the mouth (you can drink a sip of boiled water).
- 3. If it is necessary to combine homeopathic therapy with allopathic, the difference in the time of reception of these groups should be at least 30 minutes.
- 4. The drugs should be stored in conditions that exclude high temperatures and direct sunlight.
 - 5. Contact with metals and exposure to X-rays must be avoided.

Dispersological (technological) classification

D ispersological classification is characteristic of all material objects. Developed by a follower of NA Alexandrov, Prof. AS Prozorovsky, it characterizes all dosage forms in pharmacy technology in terms of physical and chemical properties of the substances included in it.

Homeopathic remedies should also always be considered as physico-chemical systems that have a certain internal structure.

Modern dispersological classification is equally characteristic of both allopathic and homeopathic remedies and distinguishes opposite groups: free-dispersed and bound-dispersed systems. In each group there are separate types of dispersed systems, also the presence or absence of communication between the particles of the dispersed system

Dispersologist and h on classification and kat and I

Freely dispersed systems

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Systems with air dispersion medium. This subgroup includes powders (trituration), which are obtained by grinding insoluble minerals and various chemical compounds, as well as plants or their parts (roots, seeds, etc.). In this system, the dispersion medium is air.

Systems with liquid dispersion medium. This subgroup covers all liquid dosage forms: essences, infusions, solutions, drops, oils. The essence of technological processes is reduced to dissolution, extraction, soaking or percolation. A special place in this subgroup is occupied by injectable solutions, which are not prepared in homeopathic pharmacies (produced by "Heel").

Systems with plastic or elastic dispersion medium, which can be divided into 2 subgroups: 1) shapeless systems that have the form of a solid total mass, it can not be given a geometric shape (ointments); 2) molded systems that have a certain geometric shape (suppositories obtained by pumping and pouring).

Systems with solid dispersion medium . Similar to the previous subgroup of the system can be shapeless and molded (suppositories prepared on the basis of fat and solid polyethylene glycols).

Systems with gaseous dispersion medium . This subgroup includes sprays (aerosols). **Connected-dispersed systems**

Systems without dispersion medium. This subgroup includes tablets obtained by compression, granules, pills, which do not have a dispersion medium, and the particles of the dispersed phase are unable to shift.

Impregnated connected-dispersed systems . This subgroup includes opodelko (soapalcohol liniments), as well as suppositories based on glycerol .

classification of dosage forms is the most rational and is more important than other types of classifications.

Classification of homeopathic remedies

by sources of raw materials

The preparation and quality of homeopathic medicines is governed by the rules set out in Dr. Wilmar Schwabe's book, A Handbook of Homeopathic Remedies. This guide is used by homeopathic pharmacies in more than 70 countries. In our country, the publication of this book "Homeopathic Medicines" was published in 1967 under the editorship of VI Rybak.

The arsenal of homeopathic medicines includes about 2,000 items.

However, the nomenclature of homeopathic medicines described in the manual and approved by the order of the Ministry of Health of the USSR from $03.08.89 \ \text{N}_{\text{\tiny 2}}\ 165$ includes more than 500 items, of which fixed assets - 378 items, additional - 136 items:

- Plant origin (over 68%) 349 items;
- Mineral origin (about 25%) 128 items;
- Animal origin (about 7%) 34 names.

Of all the raw materials used for the preparation of homeopathic medicines, some substances are specific and are used only in homeopathy (hemlock, graphite, frog, cactus, amanita, sepia, thuja, etc.).

Questions for self-control

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- 1. The concept of homeopathy. Basic principles of homeopathy, the difference between homeopathy and allopathy.
- 2. Homeopathy as a science. History of homeopathy. The main periods of development of homeopathy.
- 3. Doganemanovsky period of development of homeopathy
- 4. Samuel Hahnemann. The main works.
- 5. State regulation of production of homeopathic medicines. The right to prepare homeopathic remedies. Stages of creation of homeopathic medicines
- 6. Stages of registration of domestic homeopathic medicines and issuance of permits for their use and introduction into production.
- 7. Classification of homeopathic medicines.

Approximate tasks for the study of theoretical material

- 1. Make a dictionary of basic concepts on the topic
- 2. Fill in the orientation card for independent preparation of the student with the use of literature on the topic (the need to include in the guidelines of the orientation card is decided by the staff of the department):

Basic and tasks	In the fairy tale	Answers
and		
1	2	3
Explore:		
Potency	Define the term.	
-		
Dynamization	Define the term.	
Homeopathic	Define the term. Drug	
medicine	cycles.	

II. Practical work (tasks) that will be performed in class:

Formation of professional skills:

- 1.1. content of tasks
- 1. Characteristics of homeopathic matrix tinctures.
- 2. Technology of production of homeopathic matrix tinctures according to SPU.

To prepare a matrix tincture of fresh vegetable raw materials according to the SPU, you first need to determine?

- 3. Quality control of homeopathic matrix tinctures .
- 4. Participating homeopathic medicines remedies are represented by both new substances and new homeopathic remedies. Make a scheme "Homeopathic medicines".
 - 1.2. recommendations (instructions) for performing tasks (professional algorithms, orientation maps for the formation of practical skills, etc.);

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Complete an individual task set by the teacher:

Describe the best technology.

Fill in the front of the homeopathic matrix tincture written control passport.

- 1) Characteristics of raw materials-
- 2) Technology-
- 3) Registration of matrix tincture -
- 1.3. requirements for the results of work, including before registration;

According to the course of the practical lesson to design an individual task in a workbook.

- 1) Characteristics of raw materials-
- 2) Technology
- 3) Registration of matrix tincture -

III. Test tasks for self-control

Test tasks on this topic:

- 1. Homeopathy from the Greek language (ὅμοιος μ πάθος) is translated as:
- A * similar to the disease
- B similar and healing
- B the same and cure
- G the art of healing
- D medical art
- 2. Homeopathy is:
- A * individual regulatory therapy, the purpose of which is to influence the processes of self-regulation of the body with drugs selected strictly individually, taking into account the reactivity of the patient
- B part of alternative medicine, which includes knowledge about diseases, methods and treatments that are passed down from generation to generation
- C a system of scientific knowledge and practical activities that combine to identify, treat and prevent disease, preserve and strengthen the health and efficiency of people, prolong life
- D the direction of traditional Chinese medicine, in which the impact on the body is carried out by special needles through special points on the body by inserting them into these points and manipulating them
- E a type of unconventional (alternative, alternative) medicine, which involves the impact on humans through known or unknown to modern science (including esoteric) types of energy for the diagnosis, treatment and prevention of various diseases
- 3. The founders of homeopathy are:
- A * Samuel Hahnemann
- B Constantine Goering
- C Wilmar Schwabe
- D. James Kent
- E Friedrich Stromeyer
- 4. What tree Hahnemann studied, which later proved that "Like is treated like":

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- A. * hina
- B fir
- C eucalyptus
- D cypress
- E yew
- 5. In what year were the results of Hahnemann's work "Organ of Medicinal Art" published:
- A * 1810
- B 1910
- C 1710
- D 1850
- E 1950
- 6. Symptoms that occur in a healthy person when taking homeopathic medicines, S. Hahnemann called:
- A * medicinal pathogenesis
- B drug infection
- C artificial symptoms
- D unnatural infection
- E medical disease
- 7. As in homeopathy are called doses:
- A * dilution
- B stirring
- C reproduction
- D rarefaction
- E breeding
- 8. Specify the first basic principle of homeopathy:
- A * principle of similarity
- B the principle of mixing
- C the principle of relief of symptoms
- D the principle of using large doses
- E the principle of similarity of symptoms

IV. Individual tasks for students on the topic of the lesson - to present in the form of presentations or IWS.

- 1. The concept of homeopathy and its basic principles.
- 2. State regulation of production of homeopathic medicines.
- 3. Features of prescribing homeopathic recipes.
- 4. Nomenclature of homeopathic medicines.

Recommended literature

Main:

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- 2. Modern aspects of extemporaneous allopathic, homeopathic and cosmetic medicines creation: collection of scientific works. Issue 6. Kharkiv: NUPh publishing house, 2021. 109 p.
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- 8. Методичні рекомендації з підготовки до підсумкового модульного контролю з технології гомеопатичних лікарських засобів для здобувачів вищої освіти / Л. І. Вишневська, Н. П. Половко, С. В. Олійник, І. С. Коноваленко. Х.: Вид-во НФаУ, 2018. 27 с.
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