MINISTRY OF HEALTH OF UKRAINE

ODESA NATIONAL MEDICAL UNIVERSITY

Faculty of Pharmacy
Department of clinical and general pharmacology and pharmacognosy

CONFIRMED by

Acting vice-rector for scientific and pedagogical work

_____Eduard BURYACHKIVSKY

« ____» _____ 2023

METHODOLOGICAL DEVELOPMENT TO PRACTICAL LESSONS FROM THE EDUCATIONAL DISCIPLINE

Faculty, course _____Pharmaceutical_____II year_____

Educational discipline: "Theoretical foundations of the technology of dosage forms."

Approved:

Meeting of the department of general and clinical pharmacology and pharmacognosy

Odessa National Medical University

Protocol No._____ dated «_____» _____ 20_____

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Theme №1: Modern medicine and pharmacy in the countries of the world. Development trends of the world pharmaceutical market.

1. Relevance of the theme

The theme is of great importance for students of higher education and for familiarization with modern medicine and pharmacy in the countries of the world. The main importance today is the development trend of the world pharmaceutical market and the increase in the arsenal of medicines.

2. Educational goals:

As a result of independent study of this theme, students should:
- know:
- achievements in medicine at the present time
- modern achievements of pharmacy in the countries of the world
- the development trend of the world pharmaceutical market
- be able to:
- analyze the obtained results
- learn the trends in the development of the pharmaceutical market
- determine the place of the domestic market in comparison with other countries.

3. Materials for pre-audit preparation of students.

3.1. The main basic knowledge, skills, and abilities that are necessary for independent study and mastering of the topic and which are based on interdisciplinary connections:

№№ c.e.	Discipline	To know	Be able to
1	2	3	4
1.	Previous disciplines 1. General and inorganic chemistry 2. Ukrainian language by professional direction 3. Latin language	1.1. Basic laws and provisions of general chemistry. Characteristics of solutions. Methods of expressing the concentration of solutions. Concept of acid-base indicators. Conditions for precipitation of substances. The essence of redox reactions. 1.2. Classification of chemicals, their properties.	1.1. Identify macro- and microelements, physiological properties of macro- and microelements; write structural formulas 1.2. Make solutions 1.3. Conduct qualitative reactions 2.1. Correct use and spelling of botanical names of medicinal plants, medicinal plant raw materials 3.1. Correctly write etymological, Latin, botanical names of medicinal plants

		1.3. Qualitative reactions to different classes of substances 1.4. Gravimetric, titrimetric, chromatographic methods of analysis2.1. Business Ukrainian language 2.2. Medical terminology 3.1. Basics of grammar 3.2. Spelling of Latin names of medicinal plants, families and raw materials of plant origin	

3.2. Theme content.

the last decades of the 20th century. and the beginning of the new millennium, the world pharmaceutical industry and the world market of pharmaceutical products demonstrate dynamic development. compared to the low growth rates and even stagnation in the global economy in recent years, the pharmaceutical market continues to grow, remaining one of the most profitable and fast-growing sectors of the global economy: its growth rate is approximately 6-10% per year. Unlike other commodity markets and industries, where the net profit equals, on average, 5% of the total revenue, in the pharmaceutical industry this index reaches 18% per year.

According to American and expert data, in 2004, the European pharmaceutical market grew by 7% and reached a record $550 billion in sales. USA. Sales growth was noted in all major regions. At the same time, the maximum share of sales (45%) traditionally belongs to North America (USA and Canada), where the growth compared to 2003 was 8%. In the countries of the European Union, the market for pharmaceutical products grew by 6%, reaching approximately 26% of the world market (144 billion dollars).

In Eastern Europe and the countries of the former USSR, sales increased by 12% to $9 billion. The Japanese market grew the slowest - by only 2%, and the Chinese market developed the most dynamically, which increased by 28% and in terms of sales (9.5 billion dollars) exceeded the similar indicator of the Eastern European market. The pharmaceutical markets of Africa, some Arab countries and a number of Latin American countries are the least developed today.

Data on the rate of sales growth in the markets of individual countries in 2005 show that among the leading 12 countries, the highest rates are in Russia, where the market has grown over the last year by more than 38%, followed by Brazil - 38%, the People's Republic of China - 28%, Canada and Mexico – 15% each, Germany, Australia and New Zealand – 9% each.

The growth in sales of pharmaceuticals (phar.) was made possible by several factors. First, it is a global increase in morbidity due to the increased influence of man-made factors and the deterioration of the ecological situation, as well as the threat of

an epidemic of such diseases as atypical pneumonia, bird flu, etc. p. Thirdly, in China, India, Russia, the countries of Central and Eastern Europe, the growth of the population's income level at the beginning of the 21st century. basis for the use of more expensive and high-quality drugs.

The growth of the pharmaceutical market is also facilitated by the rapid development of such relatively new market areas as the segment of biologically active supplements (BADs) and the segment of generics - drugs whose patent protection has expired. Today, the share of generics in the markets of the USA, Great Britain, Canada and Germany has already reached 30% and, according to experts, it may continue to increase.

The key problem of the global pharmaceutical market is the growth of research costs. For example, as of 1987, the amount of costs required for the development of a new medicinal product (from the moment of discovery of a chemical substance to the moment of bringing a new medicinal product to the market) amounted to an average of 231 million dollars. USA. In the mid-1990s, a similar amount equaled, according to various estimates, from 3,507 to 500 million dollars. In 2010, the average price of the development of one new molecular compound and its subsequent introduction to the market as a medicinal product was 802 million dollars. Today, this amount is approximately 1 billion dollars on average.

The international "division of labor" in the field of the production of medicines and other pharmaceutical products is reflected in the following statistics: of the 50 largest pharmaceutical companies, which occupy more than 80% of the market, 20 companies are based in the USA (39.2% of the world pharmaceutical market), 18 companies – in Europe (33.3% of the market), 11 companies in Japan (7.8% of the market) and one in Israel 10%. As already mentioned above, the largest of the regional markets is the North American market and it is on it that the main sales are carried out by large American companies.

One of the most important features of the modern world market of pharmaceutical products is its development based on the interaction of global markets for goods, services, capital and intellectual property rights. Being, in its essence, a commodity, pharmaceutical products are at the same time very closely related to the provision of medical services, investment of capital in scientific preclinical research and new types of equipment, testing of medicinal products, their production, promotion to the market and sale, as well as to the protection and implementation of intellectual property rights for pharmaceutical products. Related services also play a very important role in the development of the world market of pharmaceutical products. On the one hand, these are services in the field of health care, without which the sale of medicinal products would practically not exist, on the other hand, these are business services related to marketing and promotion of products to the market. The total volume of the latter is about 19 billion dollars per year, only on the American market.

According to the results of the rating compiled by the experts of "RIA Rating" based on the statistical data of the World Bank and the United Nations Commodity Trade Statistics Database, Germany is the leader in the export of pharmaceutical products.

The share of the export of pharmaceutical products of Germany is about 30% of the export of all chemical products of the country, but due to the diversified structures of foreign trade, this share in the total export of goods is small - only 4%. The

production of pharmaceutical products in Germany is developing according to the typical model of developed countries - great importance is attached to new research and development.

The second place in the ranking of countries for the export of pharmaceutical products is taken by Switzerland. Pharmaceuticals is the undisputed leader of the Swiss industry. Switzerland's positions are very strong in the production of antipyretic drugs, vitamins, anticancer interferon, and drugs for the treatment of AIDS. A high level of R&D spending is characteristic of the Swiss chemical industry. According to such an indicator as the percentage of R&D expenses to revenues, the Swiss HoffmannLa-Roche with 32% is the second pharmaceutical company in the world after the American Pfizer (35%), and in absolute values of research expenses, Swiss companies are definitely in the lead. Every fourth Swiss franc spent on research and development and innovation belongs to the pharmaceutical industry.

In third place in the ranking is Belgium, with the volume of exports of pharmaceutical products in the amount of 44 billion dollars. Such high positions of the country are explained by the fact that such large companies as Pfizer and GSK have completely transferred the production of vaccines to Belgium, which make up the majority of the country's pharmaceutical exports. In addition, Belgium's specialization can be called the re-export of pharmaceutical products, which includes both processing of initial products and sorting and repackaging. This is also confirmed by the large volume of import of pharmaceutical products.

The USA, ranked 4th, despite the large-scale transfer of production by American pharmaceutical giants to other countries, continues to play a rather important role in the world arena of pharmaceutical trade. At the moment, this country is the "legislator of fashion" in the field of production and trade of pharmaceutical products. It is possible to note the introduction of three stages of clinical trials, or the state stimulation of the production of drugs for rare diseases. Among the 50 largest pharmaceutical companies in the world, according to the Current Partnering agency, 18 are American.

The top five is rounded off by France, which, along with other developed European countries, develops and supplies a large number of medicines, cosmetics and other similar products to the world market, according to the export of pharmaceuticals in the amount of 34 billion dollars.

In general, it is not surprising that the top twenty of the rating includes mainly developed European countries. This is explained by the fact that the production of pharmaceuticals is associated with large costs for research and development of new medicines. In addition, the very process of manufacturing pharmaceutical products requires high costs for equipment, qualified personnel, etc.

3.3. Information necessary for the formation of knowledge - skills can be found in textbooks - the main ones:

1. Gladukh E.V. Theoretical foundations of pharmaceutical technology. Study guide for extracurricular independent work / E.V. Gladukh, I.V. Saiko, A.A. Sichkar, D.P. Soldatov. Kh.: NFaU, 2016. - 202 p.
2. Technology of drugs of industrial production (vol. 2 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2013. - 638 p.

3. Technology of drugs of industrial production (vol. 1 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2012. - 694 p.

Auxiliary:

1. Technological equipment of the pharmaceutical and biotechnological industry: tutorial. for university students education closing III-IV accreditation level / M.V. Stasevych and others; 2nd ed., revision. and added – Lviv: Novy svit-2000, 2018. – 410 p.
2. Yarnykh, T. G. Extemporaneous formulation (technology, analysis, application): method. rec. / T. G. Yarnykh, Fr. I. Tikhonov, I. S. Hryshchenko and others. - Kh., 2015. -379 p.
3. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2015. - Vol. 1. -1128 p.
4. Extraction of plant raw materials: training. Guide / Yu. I. Sidorov, I. I. Gubytska, R. T. Konechna, V. P. Novikov. – Lviv: View of the National Lviv Polytechnic University, 2018. - 336 p.
5. History of medicine and pharmacy: teaching. manual for pharmacy students. education closing and pharmacy Faculty of Higher Education of the Ministry of Health of Ukraine / A. A. Kotvitska, V. V. Gorbanev, O. O. Surikov and others. – Kharkiv: National Institute of Economics and Technology: Golden Pages, 2016. – 168 p.
6. Standard of the Ministry of Health of Ukraine "Requirements for the manufacture of non-sterile medicinal products in pharmacies" ST-N MOZU42 – 4.5: 2015 //Edited by Prof. O.I. Tikhonov and Prof. T.G. Jarnih - Kyiv, 2015. -109 p. (Approved by order of the Ministry of Health of Ukraine No. 398 dated 07/01/2015).

3.5. Material for self-control.

3.5.1. questions for self-control.

1. How has the global pharmaceutical market changed over the past 10 years? What is it connected with?
2. How have sales changed in different regions of the world?
3. In which countries are pharmaceutical markets the least developed?
4. What factors caused the increase in the sale of medicines.
5. How many products are generics in the developed countries of the world?
6. What is the key problem of the global pharmaceutical market?
7. Who is the leader in the export of pharmaceutical products?

Theme № 2: Pharmaceutical information as a component of scientific and technical information.

1. Relevance of the theme

The theme is of great importance for students when studying pharmaceutical information, which characterizes the pharmaceutical and medical side of the circulation of drugs that circulate in the pharmaceutical field, with a description of the pharmacological, chemical, biochemical, pharmacological and economic properties of drugs.

2. Educational goals:

As a result of independent study of this topic, students should:

- know:

- main sections of pharmaceutical information
- types of pharmaceutical information
- classification of pharmaceutical information by degree of management
- basic characteristics of scientific information

- be able to:

- analyze new pharmaceutical information
- use electronic sources of scientific information
- determine the impact of the received information on the pharmaceutical market and forecast the demand for a certain type of medicine.
- to determine normative reference and statistical information.

3. Materials for pre-audit preparation of students.

3.1. The main basic knowledge, skills, and abilities that are necessary for independent study and mastering of the topic and which are based on interdisciplinary connections:

№№ c.e.	Discipline	To know	Be able to
1	2	3	4
1.	Previous disciplines 1. General and inorganic chemistry 2. Ukrainian language by professional direction 3. Latin language	1.1. Basic laws and provisions of general chemistry. Characteristics of solutions. Methods of expressing the concentration of solutions. Concept of acid-base indicators. Conditions for precipitation of substances. The essence of redox reactions. 1.2. Classification of chemicals, their properties. 1.3. Qualitative reactions to different classes of substances	1.1. Identify macro- and microelements, physiological properties of macro- and microelements; write structural formulas 1.2. Make solutions 1.3. Conduct qualitative reactions 2.1. Correct use and spelling of botanical names of medicinal plants, medicinal plant raw materials 3.1. Correctly write etymological, Latin, botanical names of medicinal plants

		1.4. Gravimetric, titrimetric, chromatographic methods of analysis2.1. Business Ukrainian language 2.2. Medical terminology 3.1. Basics of grammar 3.2. Spelling of Latin names of medicinal plants, families and raw materials of plant origin	

3.2. Topic content.

Pharmaceutical information – information that characterizes the pharmaceutical and medical aspects of the circulation of medicinal products circulating in the pharmaceutical sphere, with a description of the pharmacological, chemical, biochemical, pharmacological and economic properties of medicinal products.

Pharmaceutical information fully discloses such information as:

1) processes of production, distribution and dispensing of medicinal products;

2) management of information flows of financial processes;

3) resources of medical provision of the population;

4) information of the economic and information plan, which are exchanged between management systems**.**

Types of pharmaceutical information:

According to management functions, information is divided into: planning and accounting, normative and reference, reporting and statistical.

Planned (directive) information contains directive values of planned and controlled indicators of business planning for a certain period in the future (five-year, year, quarter, month, day).

For example, the production and sale of medicinal products in natural and value terms, the planned demand for these products and the profit from their sale, etc**.** **Accounting information** reflects the actual values of the planned indicators for a certain period of time. On the basis of this information, planned information can be adjusted, an analysis of the organization's activities can be carried out, and decisions can be made about more effective management, for example, of an information center, a clinic, a pharmaceutical enterprise, etc. Accounting information includes natural (operational) accounting, accounting, and financial accounting information.

For example, the accounting information is: the number of inquiries about medicinal products received at the center of information about medicinal products during the day (operational accounting), the salary of an employee for work (accounting), the actual cost price (accounting and financial accounting)**.**

Regulatory and reference information contains various reference and regulatory data related to the development, production, analysis, distribution of medicinal products. This is the largest and most diverse type of information.

Examples of normative reference information can be: State Pharmacopoeia; standards for manufacturing and quality control of medicinal products; cost standards (rates, tariffs); reference data for suppliers and consumers of pharmaceutical products; information about pharmaceutical products, etc.

Reporting and statistical information reflects the results of the actual activity of a pharmaceutical or medical enterprise. It is necessary for the management of the company, higher management bodies, state statistics bodies, insurance and tax authorities.

An example of this type of information can be information provided to state management bodies.

Classification of pharmaceutical information by management level:

Input information is information that comes to the enterprise (structural unit) from the outside and is used as primary information for the implementation of its functions.

Output information is information that flows from one control system to another. The same information can be input for one structural unit as its consumer, and output for the unit that produces it.

The form of presentation of pharmaceutical information can be in an alphanumeric context (in the form of combinations of alphabetic, numerical and special symbols) and in a graphic context (in the form of graphs, diagrams, drawings). Physical media of information can be paper, magnetic disk, image on the display screen, etc**.**

Characteristics of documentary and electronic sources of scientific information.

A source of scientific information is a conventional designation of a scientific document or publication that serves not only as the most important sources, but also as a means of transmitting scientific information in space and time. According to the form of presentation, sources of scientific information can be divided into documentary (book, journal, manuscript, etc.) and electronic (electronic versions of documentary sources, electronic databases, global information networks, etc.).

3.3. Information necessary for the formation of knowledge - skills can be found in textbooks - the main ones:

1. Gladukh E.V. Theoretical foundations of pharmaceutical technology. Study guide for extracurricular independent work / E.V. Gladukh, I.V. Saiko, A.A. Sichkar, D.P. Soldatov. Kh.: NFaU, 2016. - 202 p.
2. Technology of drugs of industrial production (vol. 2 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2013. - 638 p.
3. Technology of drugs of industrial production (vol. 1 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2012. - 694 p.

Auxiliary:

1. Technological equipment of the pharmaceutical and biotechnological industry: tutorial. for university students education closing III-IV accreditation level / M.V. Stasevych and others; 2nd ed., revision. and added – Lviv: Novy svit-2000, 2018. – 410 p.

2. Yarnykh, T. G. Extemporaneous formulation (technology, analysis, application): method. rec. / T. G. Yarnykh, Fr. I. Tikhonov, I. S. Hryshchenko and others. - Kh., 2015. -379 p.
3. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2015. - Vol. 1. -1128 p.
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6. Standard of the Ministry of Health of Ukraine "Requirements for the manufacture of non-sterile medicinal products in pharmacies" ST-N MOZU42 – 4.5: 2015 //Edited by Prof. O.I. Tikhonov and Prof. T.G. Jarnih - Kyiv, 2015. -109 p. (Approved by order of the Ministry of Health of Ukraine No. 398 dated 07/01/2015).

3.5. Materials for self-control.

3.5.1. Questions for self-control.

1. Define the term pharmaceutical information?
2. What sections does pharmaceutical information contain?
3. Name the types of pharmaceutical information?
4. What is planning and accounting information?
5. What is normative reference information?
6. What is reporting and statistical information?
7. Give examples of planning and accounting, regulatory and reference and reporting and statistical information?
8. Classification of pharmaceutical information by management level?
9. Main characteristics of documentary and electronic sources of scientific literature?

Theme №3: Normative and technical documentation for the industrial production of medicinal products.

1. Relevance of the topic.

This section of the topic is of great importance for students when studying the course "Theoretical foundations of the technology of dosage forms". Acquaintance with regulatory and technical documentation for the industrial production of medicinal products regulates the methods and indicators of the quality of auxiliary substances, materials, some types of raw materials and packaging materials in the manufacture of medicinal forms.

2. Educational goals:

As a result of independent study of this topic, students should:

- know:

- The main provisions of the production quality system documents
- Normative documents and their types.
- State standard of Ukraine.
- Industry standard of Ukraine.
- Standards of scientific, technical and engineering societies and unions of Ukraine.

- be able to:

- Apply the acquired knowledge to the quality system of the production of medicinal products
- Use regulatory documents
- Analyze the compliance of medicinal products with the State Standard of Ukraine and the industry standard of Ukraine.
- Establish requirements for medicinal substances, medicinal products, their packaging, conditions, shelf life and quality control methods, in accordance with analytical regulatory documentation.

3. Materials for pre-audit preparation of students.

3.1. The main basic knowledge, skills, and abilities that are necessary for independent study and mastering of the topic and which are based on interdisciplinary connections:

№№ c.e.	Discipline	To know	Be able to
1	2	3	4
1.	Previous disciplines 1. General and inorganic chemistry 2. Ukrainian language by professional direction 3. Latin language	1.1. Basic laws and provisions of general chemistry. Characteristics of solutions. Methods of expressing the concentration of solutions. Concept of acid-base indicators. Conditions for	1.1. Identify macro- and microelements, physiological properties of macro- and microelements; write structural formulas 1.2. Make solutions 1.3. Conduct qualitative reactions

		precipitation of substances. The essence of redox reactions. 1.2. Classification of chemicals, their properties. 1.3. Qualitative reactions to different classes of substances 1.4. Gravimetric, titrimetric, chromatographic methods of analysis2.1. Business Ukrainian language 2.2. Medical terminology 3.1. Basics of grammar 3.2. Spelling of Latin names of medicinal plants, families and raw materials of plant origin	2.1. Correct use and spelling of botanical names of medicinal plants, medicinal plant raw materials 3.1. Correctly write etymological, Latin, botanical names of medicinal plants

3.2. Topic content.

All company documentation can be divided into quality system documents and those related to the production and quality control of specific products.

In accordance with the current Law of Ukraine "On Medicinal Products", the industrial production of medicinal products is carried out according to technological normative documents - regulations; requirements for the content, development, coordination and approval of technological documentation are defined by the Industry normative document - GND 09-001-98. This document provides for technical and technological regulations and a clearly defined amount of information when describing the technological process.

Resolution of the Cabinet of Ministers No. dated September 26, 2002 "Some issues of improving the quality of medicinal products" in Ukraine provides for certification of the production of medicinal products, as well as the creation of a national system of standardization of medicinal products harmonized with the requirements of the International Standardization System.

Guideline 42-01-2003 "Medical products. Technological process. Documentation" (Order of the Ministry of Health No. 117 of March 13, 2003) establishes rules for the preparation of documentation related to the technological process, namely: relevant documents of the quality system, production documentation and information, set out in the registration dossier.

Categories of regulatory and technological documentation

Enterprises must have a complete set of documentation, which consists of regulatory documents and production and technological regulatory documents**.**

Regulations Normative documentation (ND) - documents that establish rules, general principles or characteristics relating to various types of activities or their results.

Normative documents are divided into:

- State Standard of Ukraine (DSTU);
- industry standard of Ukraine (GSTU);

- standards of scientific, technical and engineering societies and unions of Ukraine (STTU);

- technical conditions of Ukraine (TUU);

- enterprise standards (STP).

A standard is a normative document, developed, as a rule, on the basis of the absence of contradictions on essential issues among the majority of interested parties and approved by a recognized body, in which rules, requirements, general principles or characteristics relating to various types of activities or their results to achieve the optimal degree of arrangement in the assigned area.

An international standard is a standard adopted by the states that have joined the Agreement on the implementation of a coordinated policy in the field of standardization, metrology and certification, which is applied directly by them.

A national standard is a standard adopted by a national standardization body of one country.

The State Standard of Ukraine is a national standard approved by the State Committee of Ukraine for Standardization, Metrology and Certification (State Standard of Ukraine).

Technical conditions (TU) - a regulatory document developed to establish requirements that regulate the relationship between the supplier (developer, manufacturer) and the consumer (customer) of products for which there are no state or industry standards. Technical conditions must meet the requirements of the state standard.

As a rule, DST, TU, GST regulate methods and indicators of the quality of auxiliary substances, materials, some types of raw materials and packaging materials.

Analytical regulatory documentation is a regulatory document that establishes requirements for medicinal substances, medicinal products, their packaging, conditions, shelf life, and quality control methods.

Analytical regulatory documentation (AND) – materials related to the methods of analyzing the quality of a medicinal product, as well as other documentation (pharmacopoeial articles) that make it possible to control its quality.

3.3. Information necessary for the formation of knowledge - skills can be found in textbooks - the main ones:

1. Gladukh E.V. Theoretical foundations of pharmaceutical technology. Study guide for extracurricular independent work / E.V. Gladukh, I.V. Saiko, A.A. Sichkar, D.P. Soldatov. Kh.: NFaU, 2016. - 202 p.
2. Technology of drugs of industrial production (vol. 2 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2013. - 638 p.
3. Technology of drugs of industrial production (vol. 1 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2012. - 694 p.

Auxiliary:

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2. Yarnykh, T. G. Extemporaneous formulation (technology, analysis, application): method. rec. / T. G. Yarnykh, Fr. I. Tikhonov, I. S. Hryshchenko and others. - Kh., 2015. -379 p.
3. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2015. - Vol. 1. -1128 p.
4. Extraction of plant raw materials: training. Guide / Yu. I. Sidorov, I. I. Gubytska, R. T. Konechna, V. P. Novikov. – Lviv: View of the National Lviv Polytechnic University, 2018. - 336 p.
5. History of medicine and pharmacy: teaching. manual for pharmacy students. education closing and pharmacy Faculty of Higher Education of the Ministry of Health of Ukraine / A. A. Kotvitska, V. V. Gorbanev, O. O. Surikov and others. – Kharkiv: National Institute of Economics and Technology: Golden Pages, 2016. – 168 p.
6. Standard of the Ministry of Health of Ukraine "Requirements for the manufacture of non-sterile medicinal products in pharmacies" ST-N MOZU42 – 4.5: 2015 //Edited by Prof. O.I. Tikhonov and Prof. T.G. Jarnih - Kyiv, 2015. -109 p. (Approved by order of the Ministry of Health of Ukraine No. 398 dated 07/01/2015).

3.5. Materials for self-control.

3.5.1. Questions for self-control.

1. The main characteristics of documents of the quality system for the production of medicinal products.
2. Law of Ukraine "On Medicinal Products".
3. Resolution of the Cabinet of Ministers No. 26 of September 26, 2002 on "Some issues of improving the quality of medicinal products."
4. Main categories of regulatory and technological documentation.
5. Normative documents and their types.
6. State Standard of Ukraine (DSTU).
7. Industry Standard of Ukraine (GSTU).
8. Standards of scientific, technical and engineering societies and unions of Ukraine (STTU).
9. Technical conditions of Ukraine (TUU).
10. Enterprise standards (STP).
11. International standard.
12. Analytical regulatory documentation (AND).

Theme 4: Theoretical foundations of grinding solid bodies. Theories of crushing of solid bodies.

1. Relevance of the topic

Grinding can be an auxiliary process to ensure dissolution, extraction, drying, etc., which proceed more quickly and completely, the greater the surface of the solids involved in them. In this case, the crushed material plays the role of a semi-finished product, as it is used by the enterprise to obtain various dosage forms. Therefore, this section of the topic is relevant and of great importance for students when studying the course "Theoretical foundations of the technology of dosage forms"**.**

2. Educational goals:

As a result of independent study of this topic, students should:

- know:

- Basic criteria and methods of crushing solid bodies
- Surface grinding theory (by P. Rittinger)
- Volume theory (V. Kirpichev)
- Classification of grinding machines
- The main groups and types of grinding machines used in the pharmaceutical industry.

- be able to:

- Apply certain types of grinding depending on the initial criteria
  Solid materials
- Use regulatory documents

3. Materials for pre-audit preparation of students.

3.1. The main basic knowledge, skills, and abilities that are necessary for independent study and mastering of the topic and which are based on interdisciplinary connections:

№№ c.e.	Discipline	To know	Be able to
1	2	3	4
1.	Previous disciplines 1. General and inorganic chemistry 2. Ukrainian language by professional direction 3. Latin language	1.1. Basic laws and provisions of general chemistry. Characteristics of solutions. Methods of expressing the concentration of solutions. Concept of acid-base indicators. Conditions for precipitation of substances. The essence of redox reactions. 1.2. Classification of chemicals, their properties. 1.3. Qualitative reactions to different classes of substances 1.4. Gravimetric, titrimetric, chromatographic methods of	1.1. Identify macro- and microelements, physiological properties of macro- and microelements; write structural formulas 1.2. Make solutions 1.3. Conduct qualitative reactions 2.1. Correct use and spelling of botanical names of medicinal plants, medicinal plant raw materials 3.1. Correctly write etymological, Latin, botanical names of medicinal plants

		analysis2.1. Business Ukrainian language 2.2. Medical terminology 3.1. Basics of grammar 3.2. Spelling of Latin names of medicinal plants, families and raw materials of plant origin	

3.2. Topic content.

Crushing is the destruction of material under the action of external forces that overcome the forces of adhesion between particles. Grinding is necessary in order to create a large specific surface of the material, then the chemical reactions proceed more intensively.

If as a result of grinding, finished products are obtained, the process is called final; if the crushed material will be processed in the future, the process is preparatory.

The choice of the method depends on the physical and mechanical properties of the material and the desired degree of grinding. Crushing and impact are effective for hard materials, splitting for brittle ones; for wet viscous materials — abrasion combined with crushing**.**

Grinding is a complex process that depends on a number of factors that are difficult to account for and mathematically describe. The main factors that affect the energy consumption per unit of production are the hardness of the material, its moisture, viscosity, surface condition, size and shape of pieces, placement of pieces between the working bodies of the machine, etc.

There is no single universal theory of grinding. Last century, the first attempts were made to theoretically substantiate the grinding processes. A significant contribution to the solution of this problem belongs to such domestic and foreign scientists and engineers as L. B. Levinson, V. L. Kirpichev, P. Rittinger, F. Kik, H. G. Yegorov, Z. V. Kantorovych, and others.

There are two theoretical approaches to determine the amount of energy required to grind a material: the surface theory of grinding, proposed in 1867 by P. Rittinger, and the bulk theory, proposed in 1874 by V. L. Kirpichov.

Surface theory. The theory is based on a hypothesis: the work spent on crushing the body is directly proportional to the area of the newly formed surfaces.

Bulk theory. The volumetric theory is based on the fact that external forces act on a piece of material being crushed, which cause a stress in the material equal to the strength limit during compression.

The surface theory is used to explain the process of cutting the body (for grinding corresponds to the process of abrasion), as well as the description of the processes of fine crushing and grinding, because it takes into account the relationship between the degree of grinding and energy consumption. The disadvantage is the difficulty of determining the specific work spent on the formation of a new surface.

Volumetric theory explains crushing and impact crushing processes, which are used mainly for coarse and medium crushing. It makes it possible to determine the work of destruction, but does not take into account the influence of the degree of grinding on energy consumption. The generalized theory, from an engineering point of

view, is unsuitable for solving specific problems, because it requires an accurate determination of the coefficients for each material. Formulas combining surface and volume theories have become widespread, in particular in the works of F. Bond, A. K. Rundkvist, and others.

When carrying out the grinding process, the requirements of the State Pharmacopoeia or DSTU are guided by the size of the crushed material. Grinding machines are selected based on the properties of the substance and the degree of its grinding

Grinding machines can be classified according to different characteristics:

According to the method of grinding the material (cutting, grinding, crushing, impact-centrifugal, impact, etc.).

According to the degree of crushing of the material (crushers for large, medium and fine crushing; mills for fine and colloidal crushing).

By the nature of the working tool (disc, ball, rotary, etc. machines).

According to the grinding method, the machines used in the pharmaceutical industry are divided into the following main groups:

- Cutters (grass cutters, root cutters, grass cutters).
- Crushing and grinding (rollers, runners, millstones).
- Impact-centrifugal (various disk mills).
- Impact (ball mills).
- Colloid grinders (friction and shock mills).

This classification is convenient because it is based on the nature of the operating forces, the main way in which the material is crushed.

The disadvantage of this classification is the lack of an indication of the method of crushing, which is the basis of the machine's operation. In addition, the shredder of the same type, depending on its size, can be assigned to machines of different grinding classes.

3.3. Information necessary for the formation of knowledge - skills can be found in textbooks - the main ones:

1. Gladukh E.V. Theoretical foundations of pharmaceutical technology. Study guide for extracurricular independent work / E.V. Gladukh, I.V. Saiko, A.A. Sichkar, D.P. Soldatov. Kh.: NFaU, 2016. - 202 p.
2. Technology of drugs of industrial production (vol. 2 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2013. - 638 p.
3. Technology of drugs of industrial production (vol. 1 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2012. - 694 p.

Auxiliary:

1. Technological equipment of the pharmaceutical and biotechnological industry: tutorial. for university students education closing III-IV accreditation level / M.V. Stasevych and others; 2nd ed., revision. and added – Lviv: Novy svit-2000, 2018. – 410 p.

2. Yarnykh, T. G. Extemporaneous formulation (technology, analysis, application): method. rec. / T. G. Yarnykh, Fr. I. Tikhonov, I. S. Hryshchenko and others. - Kh., 2015. -379 p.
3. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2015. - Vol. 1. -1128 p.
4. Extraction of plant raw materials: training. Guide / Yu. I. Sidorov, I. I. Gubytska, R. T. Konechna, V. P. Novikov. – Lviv: View of the National Lviv Polytechnic University, 2018. - 336 p.
5. History of medicine and pharmacy: teaching. manual for pharmacy students. education closing and pharmacy Faculty of Higher Education of the Ministry of Health of Ukraine / A. A. Kotvitska, V. V. Gorbanev, O. O. Surikov and others. – Kharkiv: National Institute of Economics and Technology: Golden Pages, 2016. – 168 p.
6. Standard of the Ministry of Health of Ukraine "Requirements for the manufacture of non-sterile medicinal products in pharmacies" ST-N MOZU42 – 4.5: 2015 //Edited by Prof. O.I. Tikhonov and Prof. T.G. Jarnih - Kyiv, 2015. -109 p. (Approved by order of the Ministry of Health of Ukraine No. 398 dated 07/01/2015).

3.5. Materials for self-control.

3.5.1. Questions for self-control.

1. Define the concept of grinding.
2. The method of grinding depends on which criterion.
3. Surface grinding theory proposed in 1867 by P. Rittinger. 4. Volumetric theory, proposed in 1874 by V. L. Kirpichev.
5. Classification of grinding machines.
6. Classification according to the method of grinding the material (cutting, grinding, crushing, impact-centrifugal, impact, etc.).
7. Classification according to the degree of crushing of the material (crushers for large, medium and fine crushing; mills for fine and colloidal crushing).
8. Classification by the nature of the working tool (disk, ball, rotary, etc. machines).
9. The main groups of grinding machines used in the pharmaceutical industry.

Theme 5: Methods of determining the size of particles of solid bodies. Sifting and mixing of powdered materials. Theoretical foundations of pressing.

1. Relevance of the topic

This section of the topic is of great importance for students when studying the course "Theoretical foundations of the technology of dosage forms". Since medicinal and auxiliary substances must comply with regulatory and technical documentation, GOSTs and DSTU and enter the production after grinding in a sifted state and thoroughly mixed to achieve homogeneity, that is, the same ratio of constituent particles in any part of the resulting mixture.

2. Educational goals:

As a result of independent study of this topic, students should:

- know:

- familiarization with the auxiliary operations of sieving and mixing, which are used in the pharmaceutical industry
- mastering the methods of sieve analysis

- be able to:

- apply the acquired knowledge to the quality system of the production of medicinal products during sieving and mixing
- use regulatory documents
- distinguish the relationship between physico-chemical and technological properties of powdery substances
- determine the main stages of the pressing process

3. Materials for pre-audit preparation of students.

3.1. The main basic knowledge, skills, and abilities that are necessary for independent study and mastering of the topic and which are based on interdisciplinary connections:

№№ c.e.	Discipline	To know	Be able to
1	2	3	4
1.	Previous disciplines 1. General and inorganic chemistry 2. Ukrainian language by professional direction 3. Latin language	1.1. Basic laws and provisions of general chemistry. Characteristics of solutions. Methods of expressing the concentration of solutions. Concept of acid-base indicators. Conditions for precipitation of substances. The essence of redox reactions. 1.2. Classification of chemicals, their properties.	1.1. Identify macro- and microelements, physiological properties of macro- and microelements; write structural formulas 1.2. Make solutions 1.3. Conduct qualitative reactions 2.1. Correct use and spelling of botanical names of medicinal plants, medicinal plant raw materials 3.1. Correctly write etymological, Latin,

		1.3. Qualitative reactions to different classes of substances 1.4. Gravimetric, titrimetric, chromatographic methods of analysis2.1. Business Ukrainian language 2.2. Medical terminology 3.1. Basics of grammar 3.2. Spelling of Latin names of medicinal plants, families and raw materials of plant origin	botanical names of medicinal plants

3.2. Topic content.

Screening. Crushed medicinal products must be sifted through specified sieves. The purpose of this operation is to obtain a product with the same particle size, which is achieved by sieve analysis. Sifting is regulated by a special article of the DF XI "Definition of crushing powders and sieves".

Sieves are metal, made by stamping a metal sheet, and fabric, made of silk (DST 4403-77), kapron (OST 17-46-82)

and metal (DST 214-83) threads. There are open sieves, which are empty cylinders made of metal or wood, the bottom of which is tightened with a suitable fabric with a certain size of holes; and closed, consisting of the sieve itself, a receiver into which the sifted material enters, and a cover that protects it from spraying**.**

If used carelessly in sieves made of silk, the location of the threads can change, resulting in a powder with different particle sizes. The number of the silk sieve indicates how many holes are in 1 cm. The number of the metal wire sieve corresponds to the size of the sieve holes in millimeters. The number of punching sieves with round holes corresponds to the diameter of the hole in millimeters multiplied by 10. The number of the sieve with oblong holes corresponds to the width of the hole in millimeters multiplied by 10.

It is necessary to observe the conditions so that the crushed substances do not interact with the sieve material and do not change their composition.

The result of sieving directly depends on the pressure under which the powder passes, on the size of the sieve holes, as well as on the duration and force with which sieving is carried out. Therefore, during sieving, it is necessary to take into account the influence of these factors and to carry out this process not very quickly, thoroughly mixing the powder.

To obtain powders free from smaller particles, the method of "double sieving" is used, which consists in the fact that the smaller powder is freed by sieving through the next denser sieve.

When sieving, it is convenient to use a vibrating sieve. There are rotary, oscillating and vibrating sieves. Vibrating sieves are the most productive due to the vibrating movement of the grid and a higher frequency of oscillations.

As a result of simple sieving (through one sieve), the raw material is divided into two fractions:

1) sifted (bottom product) – material that has passed through a sieve;

2) residue (top product) – material that did not pass through the sieve and remained on top of the sieve.

Mixing is a process that results in homogeneity, that is, the same ratio of constituent particles in any part of the resulting mixture. The mixing process is the main operation in the manufacture of complex powders. If the ingredients are not thoroughly mixed, separate doses of the powder obtained during its next dosing may contain different amounts of medicinal substances. This can adversely affect the therapeutic effect of the medicinal product, and when using potent and poisonous medicinal substances - even lead to poisoning.

The method and order of mixing powders depends on the weight ratio of the prescribed ingredients and their physical and chemical properties (aggregate state, moisture absorption, etc.). Depending on the mentioned factors, very important practical provisions that should be followed when mixing powders are recommended.

The main ones are:

1. Medicinal substances of a complex powder, prescribed in equal or approximately equal amounts (the mass ratio does not exceed 1:5). In this case, two mixing options are possible:

- if the physicochemical properties of medicinal substances are approximately the same, then they are mixed taking into account the amount of losses during grinding.
- if the physical and chemical properties of medicinal substances are different, then mixing and grinding begin with a coarse-crystalline substance, and then fine-crystalline substances are added to it.

2. Amorphous substances (talc, magnesium oxide, starch, etc.) are mixed with the powder mass without additional grinding.

Pressing is a defining operation in the production of tablets. In modern industrial presses, powder is compressed bilaterally by upper and lower punches.

The entire pressing process is divided into three stages:

1) compaction (hydraulic pressing);

2) formation of a compact body;

3) volumetric compression of the resulting compact body.

In each stage, characteristic mechanical processes take place. At the beginning of compression, redistribution of particles occurs: small particles are placed in the gaps between large ones and are oriented in directions that provide maximum resistance to compression. Efforts applied in this case are insignificant, the sealing becomes noticeable already at minimal pressure. Energy is mainly spent on overcoming internal (between particles) and external (between particles and matrix walls) friction.

When the pressure increases, intensive compaction of the material takes place due to the filling of voids and elastic deformation of the particles, which contributes to a more compact packing of the particles. At this stage of pressing, a compact porous body with sufficient mechanical strength is formed from the loose material.

After the particles are tightly compressed at the points of contact, plastic deformation is observed. At this stage, at high pressure values, when the mechanical strength of the tablets changes slightly, volume compression of powder particles and granules occurs without increasing the contact surfaces.

3.3. Information necessary for the formation of knowledge - skills can be found in textbooks - the main ones:

1. Gladukh E.V. Theoretical foundations of pharmaceutical technology. Study guide for extracurricular independent work / E.V. Gladukh, I.V. Saiko, A.A. Sichkar, D.P. Soldatov. Kh.: NFaU, 2016. - 202 p.
2. Technology of drugs of industrial production (vol. 2 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2013. - 638 p.
3. Technology of drugs of industrial production (vol. 1 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2012. - 694 p.

Auxiliary:

1. Technological equipment of the pharmaceutical and biotechnological industry: tutorial. for university students education closing III-IV accreditation level / M.V. Stasevych and others; 2nd ed., revision. and added – Lviv: Novy svit-2000, 2018. – 410 p.
2. Yarnykh, T. G. Extemporaneous formulation (technology, analysis, application): method. rec. / T. G. Yarnykh, Fr. I. Tikhonov, I. S. Hryshchenko and others. - Kh., 2015. -379 p.
3. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2015. - Vol. 1. -1128 p.
4. Extraction of plant raw materials: training. Guide / Yu. I. Sidorov, I. I. Gubytska, R. T. Konechna, V. P. Novikov. – Lviv: View of the National Lviv Polytechnic University, 2018. - 336 p.
5. History of medicine and pharmacy: teaching. manual for pharmacy students. education closing and pharmacy Faculty of Higher Education of the Ministry of Health of Ukraine / A. A. Kotvitska, V. V. Gorbanev, O. O. Surikov and others. – Kharkiv: National Institute of Economics and Technology: Golden Pages, 2016. – 168 p.
6. Standard of the Ministry of Health of Ukraine "Requirements for the manufacture of non-sterile medicinal products in pharmacies" ST-N MOZU42 – 4.5: 2015 //Edited by Prof. O.I. Tikhonov and Prof. T.G. Jarnih - Kyiv, 2015. -109 p. (Approved by order of the Ministry of Health of Ukraine No. 398 dated 07/01/2015).

3.5. Materials for self-control.

3.5.1. Questions for self-control.

1. List the classification of grinding machines and types of grinding depending on the degree of grinding of the product.
2. What is the difference between grinding material on rolls with the same and different rotation speeds?

3. What materials are crushed on rollers?
4. Give examples of the influence of the degree of grinding of a medicinal substance on its therapeutic activity.
5. What safety and occupational health and safety measures must be observed during the technological operations of grinding and sifting powders?
6. Describe the main physical and chemical properties of powdered substances.
7. What is the relationship between the physicochemical and technological properties of powdery substances?
8. How do the technological properties of powders affect the quality of granules and tablets?
9. What indicators are used to control the quality of powdered substances?
10. The main stages of the pressing process?

Theme 6: Criteria and methods of evaluation of South Africa.

1. Relevance of the topic

This section of the topic is of great importance for students when studying the discipline, since surface-active substances are actively used for the manufacture of various dosage forms. Therefore, knowledge of the criteria and methods of evaluating surfactants will contribute to the in-depth study of drug manufacturing technology in the future.

2. Educational goals:

As a result of independent study of this topic, students should:

- know:

- Classes of surfactants according to the III International Congress
- Evaluation criteria of surfactants
- Anionic surfactants
- Cationic surfactants
- Amphoteric surfactants

- be able to:

- Apply the acquired knowledge to the quality system of the production of medicinal products
- Use regulatory documents
- Distinguish between different classes of surfactants.

3. Materials for pre-audit preparation of students.

3.1. The main basic knowledge, skills, and abilities that are necessary for independent study and mastering of the topic and which are based on interdisciplinary connections:

№№ c.e.	Discipline	To know	Be able to
1	2	3	4
1.	Previous disciplines 1. General and inorganic chemistry 2. Ukrainian language by professional direction 3. Latin language	1.1. Basic laws and provisions of general chemistry. Characteristics of solutions. Methods of expressing the concentration of solutions. Concept of acid-base indicators. Conditions for precipitation of	1.1. Identify macro- and microelements, physiological properties of macro- and microelements; write structural formulas 1.2. Make solutions 1.3. Conduct qualitative reactions 2.1. Correct use and spelling of botanical names of medicinal

		substances. The essence of redox reactions. 1.2. Classification of chemicals, their properties. 1.3. Qualitative reactions to different classes of substances 1.4. Gravimetric, titrimetric, chromatographic methods of analysis2.1. Business Ukrainian language 2.2. Medical terminology 3.1. Basics of grammar 3.2. Spelling of Latin names of medicinal plants, families and raw materials of plant origin	plants, medicinal plant raw materials 3.1. Correctly write etymological, Latin, botanical names of medicinal plants

3.2. Topic content.

Surfactants are chemicals that reduce the surface tension of a liquid, facilitating spreading and reducing the surface tension at the interface between two liquids. These are substances whose molecules or ions are concentrated under the action of molecular forces (adsorbed) near the interface of phases and reduce the surface energy.

Surface-active substances are usually amphiphilic organic compounds (the term amphiphilic means that they contain both hydrophilic groups ("tails") and hydrophobic groups ("heads"). Due to this structure, they dissolve both in non-polar fats and organic solvents, and and in polar environments (water).

According to the structure of the molecule, at the III International Congress on South Africa in 1960, it was accepted to divide surface-active substances into the following classes:

1. Ionogenic surfactants
- Anionic surfactants
- Cationic surfactants
- Amphoteric surfactants
2. Nonionic surfactants
- Alkylpolyglucosides
- Alkylpolyethoxylates

Anionically active surfactants contain polar groups in the molecule, which dissociate in aqueous solutions to form negatively charged ions with a long hydrophobic chain. During adsorption, anionic surface-active substances give the surface a negative charge. The hydrophobic part of the molecule is usually saturated or unsaturated aliphatic or arylaliphatic chains. The most common representatives are

alkyl sulfates and alkyl aryl sulfonates, as well as derivatives of saturated and some unsaturated carboxylic acids (soaps).

Cationic surfactants, unlike anionic surfactants, dissociate in aqueous solution to form a positively charged surfactant ion with a long hydrophobic chain and a negatively charged ion, usually a halide, sometimes an anion of sulfate or orthophosphoric acid. When adsorbed on the surface, cationic surfactants give it a positive charge. Nitrogen-containing compounds predominate among cationic ionogenic surfactants. The most important industrial importance among them are compounds of pyridine, quinoline, phthalazine, benzimidazole, benzothiazole, etc.

Nonionic surfactants are surface-active substances whose molecules in aqueous solutions are not capable of dissociation into ions. The molecules of such substances also have a diphilic nature: they consist of a long hydrocarbon chain with hydrophilic ether and hydroxyl groups, which determine the solubility of such substances in water. Nonionic surfactants are obtained by the interaction of ethylene oxide and alcohols, carboxylic acids, alkylphenols and alkylnaphthols, amines, amides, imidazoles, sulfamides, and mercaptans. The advantage of ionogenic surfactants is the ability to adjust their hydrophilicity. Also a positive feature is that the hardness of the water does not affect their solubility, as well as the fact that they can be used with cationic and anionic surfactants, which is the reason for their frequent use in detergents.

According to the mechanism of action on the surface properties of solutions, surfactants are divided into four groups.

The second group includes substances that show surface activity at the interface of two immiscible liquids, but do not form colloidal structures. Such substances, being adsorbed on interfaces, reduce the free surface energy of a liquid or a solid body and thereby facilitate the process of formation of a new surface, in particular, in the process of dispersion. Therefore, surfactants of the second group are called dispersants. They are used when spraying liquids, emulsifying, dispersing solids, etc. Dispersants can be any surfactants that are adsorbed on the surface of particles of the dispersion medium and stabilize a highly dispersed suspension. Therefore, hydrophilizing surfactants, usually surface-active polymers, serve as dispersants in aqueous media.

The third group consists of surfactants that create a gel-like structure in the adsorption layer and in the solution. Such substances prevent coagulation of particles, stabilize the dispersed phase in the dispersion medium, therefore they are called stabilizers. The mechanism of action of the stabilizers is that, in addition to creating a structural-mechanical barrier for particle convergence, the outer surface of the formed surfactant shell is hydrophilic, and aggregation cannot occur due to the collision of external surfaces. Examples of surfactant stabilizers are glycosides (saponin), polysaccharides, and high-molecular substances such as proteins. Stabilizers not only prevent the aggregation of particles, but also prevent the development of coagulation structures, blocking by adsorption the points of attachment of particles and thereby preventing their convergence. Therefore, suspension stabilizers are also adsorption plasticizers. The latter are widely used in hydraulic construction, ceramic production, in the construction of asphalt roads, in engineering geology, and in agriculture with the aim of improving the soil structure.

The fourth group of surfactants consists of washing substances, or detergents, which occupy the first place in terms of practical application. Their purpose is to remove various types of pollution from the surface by transferring the pollutants into a

state of stabilized emulsion or suspension. These surface-active substances must possess the entire set of properties characteristic of the three previous groups, that is, the ability to strongly reduce surface tension, exhibit a wetting, hydrophilizing effect, and be not only dispersants, but also strong stabilizers of emulsions and suspensions.

In addition to the considered classifications, all surface-active substances can be divided according to the colloid structure into substances that are in real solution, and therefore do not have a washing effect, and detergents that create micellar or even gel-like structures. Washing substances, or detergents, can be substances of any of three chemical classes, i.e., anionic, cationic, and nonionic. At the same time, a mandatory condition should be high polarity (hydrophilicity) of the polar group and at the same time a sufficient length of the hydrocarbon chain. That is why higher homologues of alcohols and carboxylic acids are not detergents. When passing from acids to their salts of alkali metals, the polarity and, therefore, the hydrophilicity of the groups increases, which determines the soap-like properties of these substances. The introduction of an even more hydrophilic sulfo group increases the colloidal solubility in water not only of alkaline alkylsulfonates, but also of the acids themselves, which is largely the basis of the action of modern synthetic detergents.

3.3. Information necessary for the formation of knowledge - skills can be found in textbooks - the main ones:

1. Gladukh E.V. Theoretical foundations of pharmaceutical technology. Study guide for extracurricular independent work / E.V. Gladukh, I.V. Saiko, A.A. Sichkar, D.P. Soldatov. Kh.: NFaU, 2016. - 202 p.
2. Technology of drugs of industrial production (vol. 2 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2013. - 638 p.
3. Technology of drugs of industrial production (vol. 1 of 2). Chuyeshov V. I., Gladukh E. V., Saiko I. V., Lyapunova O. O., Sichkar A. A., Krutskikh T. V., Ruban O. A. Kh.: National University of Applied Sciences; Golden Pages, 2012. - 694 p.

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1. Technological equipment of the pharmaceutical and biotechnological industry: tutorial. for university students education closing III-IV accreditation level / M.V. Stasevych and others; 2nd ed., revision. and added – Lviv: Novy svit-2000, 2018. – 410 p.
2. Yarnykh, T. G. Extemporaneous formulation (technology, analysis, application): method. rec. / T. G. Yarnykh, Fr. I. Tikhonov, I. S. Hryshchenko and others. - Kh., 2015. -379 p.
3. State Pharmacopoeia of Ukraine / State enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products" - 2nd edition. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicinal Products", 2015. - Vol. 1. -1128 p.
4. Extraction of plant raw materials: training. Guide / Yu. I. Sidorov, I. I. Gubytska, R. T. Konechna, V. P. Novikov. – Lviv: View of the National Lviv Polytechnic University, 2018. - 336 p.

5. History of medicine and pharmacy: teaching. manual for pharmacy students. education closing and pharmacy Faculty of Higher Education of the Ministry of Health of Ukraine / A. A. Kotvitska, V. V. Gorbanev, O. O. Surikov and others. – Kharkiv: National Institute of Economics and Technology: Golden Pages, 2016. – 168 p.
6. Standard of the Ministry of Health of Ukraine "Requirements for the manufacture of non-sterile medicinal products in pharmacies" ST-N MOZU42 – 4.5: 2015 //Edited by Prof. O.I. Tikhonov and Prof. T.G. Jarnih - Kyiv, 2015. -109 p. (Approved by order of the Ministry of Health of Ukraine No. 398 dated 07/01/2015).

3.5. Materials for self-control.

3.5.1. Questions for self-control.

1. Define the term surface-active substances.
2. Classes of surfactants according to the III International Congress (1960).
3. Anionic surfactants.
4. Cationic surfactants.
5. Amphoteric surfactants.
6. Alkyl polyglucosides and their characteristics.
7. Alkyl polyethoxylates and their characteristics.
8. Classification of surface-active substances according to the mechanism of action.
9. Classification of surfactants according to colloidal structural characteristics.