Ministry of Health of Ukraine
Bogomolets National Medical University

GUIDELINES
to lectures

Educational discipline Standardization of medicines

Direction 22 Health care

Specialty 226 **“**Pharmacy, industrial pharmacy”

Specialization 226.01 “Pharmacy”

Form of study Full-time

The department of medicinal chemistry and toxicology

Approved at the department meeting on August 30, 2024, protocol No. 14

Head of the department of medicinal chemistry and toxicology,
DM, Professor **Nizhenkovska I.V.**

Considered and approved:
on the meeting of cycle methodical commission of specialty 226 "Pharmacy, industrial pharmacy" dated August 30, 2024, protocol No. 1

Topic N 1. The system of standardization of medicinal products in Ukraine and international principles of standardization of pharmaceutical products. State Pharmacopoeia of Ukraine. Analytical normative documentation for pharmaceutical products.

Type of lecture: traditional (informational)

Competencies:

Integral:

the ability to solve tasks of a research and/or innovative nature in the field of pharmacy and in the field of industrial production of medicines.

general:

GC01. Ability to abstract thinking, analysis and synthesis.

GC02. Knowledge and understanding of the subject area; understanding of professional activity.

GC03. Ability to communicate in the national language both orally and in writing.

GC05. Ability to evaluate and ensure the quality of the work performed.

GC06. Ability to work in a team.

GC09. Ability to use information and communication technologies

GC10. Ability to make decisions and act in accordance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

professionals:

PC02. Ability to collect, interpret and apply data necessary for professional activity, research and implementation of innovative projects in the field of pharmacy.

PC03. Ability to solve pharmacy problems in new or unfamiliar environments in the presence of incomplete or limited information, taking into account aspects of social and ethical responsibility.

PC04. Ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to people who are studying.

PC17. Ability to organize and carry out quality control of medicinal products of natural and synthetic origin in accordance with the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods (QCM), technological instructions, etc.; to prevent the distribution of low-quality, falsified and unregistered medicinal products.

PC18. Ability to develop and evaluate methods of quality control of medicinal products of natural and synthetic origin, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances using physical, chemical, physico-chemical, biological, microbiological and pharmaco-technological methods; carry out standardization of medicinal products in accordance with current requirements.

Purpose: to form systematized bases of scientific knowledge on the standardization of medicinal products; to reveal the status and prospects of progress in the field of standardization of medicinal products; to focus attention on the most complex and knotty issues regarding the system of standardization of medicinal products in Ukraine, international principles of standardization of pharmaceutical products, the role of the State Pharmacopoeia of Ukraine, analytical and normative documentation for pharmaceutical products; to provide an approximate basis for further assimilation of educational material in subsequent lectures and practical classes.

Lecture equipment: laptop, multimedia projector, blackboard.

Tasks of the lecture:

the student should know

the system of standardization of medicinal products in Ukraine, international principles of standardization of pharmaceutical products, main sections, articles and monographs of the State Pharmacopoeia of Ukraine, analytical and normative documentation for pharmaceutical products;

the student must be able to

analyze data from educational and special literature when solving tasks related to the standardization of medicinal products within the scope of quality control; use analytical and normative documentation that regulates the quality of medicinal products (State Pharmacopoeia of Ukraine, European Pharmacopoeia, USA Pharmacopoeia, British Pharmacopoeia, national and regional pharmacopoeias, AND, pharmacopoeial articles and monographs, GMP, GLP, GCP, orders and instructions, ISO documents); use industry standards, methodological guidelines when developing ADS for substances and medicinal products.

Lecture plan

The name the stage of the lecture	Content of the stage	Educational goal of the stage	Time
Introduction	Announcement of the topic of the lecture, of the lecture, definition of the purpose o lecture, a brief description of the problems proposed to be considered during lecture, a brief description of the literature.	Activation of the previo acquired scientific knowledg students from other discipl and laying the scientific basis assimilating the lecture materi	10 min
Main part	1.Discipline "Standardization medicines". The purpose and tasks of	To acquire knowledge about goals and objectives of	65 min

	discipline. Basic concepts. Purpose and tasks reveal the content, purpose and task the discipline. 2. The system of standardization medicines in Ukraine and internati principles of standardization pharmaceutical products: to re modern approaches, directions development of standardization accordance with state policy and requirements, criteria and moc requirements for the quality medicines, to familiarize with the n documents of the Ministry of Healt Ukraine, laws, standards. 3. SPU. Analytical norma documentation for pharmaceut products: emphasize the importance SPU, AND, MQC in pharmaceut analysis, familiarize yourself with structure and sections of the documer	discipline, basic concepts definitions. To acquire knowledge about system of standardization medicines in Ukraine international principles standardization of pharmaceut products. Familiarize yourself with structure, sections and conten the SPU, AND, MQC.	
Final part	Generalization in short formulations the main ideas of the lecture, logic concluding it as a complete w direction of further independent wor students; laying the scientific basis the following lectures.	Learning the actual materia the lecture, the main theoret provisions with the help logical nodes - the n questions of the lecture.	15 min

Recommended literature:

Basic

1.European Pharmacopoeia. Council of Europe: Strasbourg, 2019. 10-th edition. Vol. 1. p.1-135. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
2.European Pharmacopoeia. Council of Europe: Strasbourg, 2022. 11-th edition. Vol. 1. p. 1-205. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/

3. British Pharmacopoeia. 2009. Vol. 1 & 2. p. 1-59. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
6.Lecturer's material. The department of medicinal chemistry and toxicology of pharmaceutical faculty of Bogomolets National Medical University. https://www.youtube.com/@user-yj2fn5mz3x/

Auxiliary

1.European Commission Communication 'Towards an increased contribution from standardization to innovation in Europe' March 2008. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0133:FIN:en:PDF
2.Ali 'B. O. 'Fundamental principles of occupational health and safety', Geneva, International Labor Office, 2001, Retrieved 18 June 2012 at: http://www.ilo.org/wcmsp5/groups/public/@dgreports/@dcomm/@publ/documents/publication/wcms_093550.pdf
3.Saida E. & Taibi N. (2021). ISO 9001 Quality Approach and Performance Literature Review. European Scientific Journal, ESJ, 17(1), 128. https://doi.org/10.19044/esj.2021.v17n1p128
4. Robinson, J. The Pharmaceutical Journal. Falsified Medicines Directive (FMD): how it will work. 2018, https://pharmaceutical-journal.com/article/infographics/falsified-medicines-directive-fmd-how-it-will-work

Information resources

Website of the Department of Medicinal Chemistry and Toxicology of Bogomolets NMU
http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
Distance learning platform LIKAR_NMU https://likar.nmu.kiev.ua/
Official website of the Ministry of Health of Ukraine
https://moz.gov.ua/
State register of medicines.
URL: http://www.drlz.com.ua/ibp/ddsite.nsf/all/index?opendocument
Pharmaceutical encyclopedia
http://www.pharmencyclopedia.com.ua/
Pharmaceutical product certification system:
https://zakon.rada.gov.ua/laws/show/z2218-12#Text
pubmed.ncbi.nlm.nih.gov

Questions for student self-preparation for the lecture:

1. Describe the current international principles of standardization of the procedure of development, synthesis and analysis of pharmaceutical products.

2. Define WHO's strategy in the system of ensuring and guaranteeing the quality of medicinal products.

3. International Organization for Standardization ISO. The purpose, tasks and main functions of the ISO organization.

4. Characteristics of the modern ISO 9001 Product Quality Assurance Concept.

5. The purpose and objectives of international good practices in pharmacy GXP (GLP, GCP, GMP, GSP, GDP, GPP, GPSL).

6. Basic principles and rules of GMP EU, GMP WHO, GMP PIC.

7. European Medicines Agency (EMEA) – role in control and evaluation of medicinal products. EMEA priority areas of activity.

Questions for preparing for the FC, which reveals the lecture material:

1.The system of standardization of pharmaceutical products in Ukraine. Basic principles of drug standardization. Objects and subjects of drug standardization.

2.Bodies of the state system of drug standardization and their functions.

3.Normative and technical documentation that regulates requirements for the quality of medicinal products.

4.State Pharmacopoeia of Ukraine (SPU, SPhU): structure and content. General and separate articles of SPhU, monographs of the SPhU on substances and pharmaceutical preparations.

The methodical development was made by:

head of the department of medicinal chemistry and toxicology, DM, professor Nizhenkovska I.V., professor of department, doctor of pharm. sc. Welchinska O.V.

Topic N 2. The concepts of "falsified medicinal products" and "low-quality medicinal products". Types of drug falsification and factors contributing to drug falsification. International cooperation system of pharmaceutical inspections PIC/S.
Type of lecture: traditional (informational)
Competencies:
Integral:
the ability to solve tasks of a research and/or innovative nature in the field of pharmacy and in the field of industrial production of medicines.
general:
GC01. Ability to abstract thinking, analysis and synthesis.
GC02. Knowledge and understanding of the subject area; understanding of professional activity.
GC03. Ability to communicate in the national language both orally and in writing.
GC05. Ability to evaluate and ensure the quality of the work performed.
GC06. Ability to work in a team.
GC09. Ability to use information and communication technologies
GC10. Ability to make decisions and act in accordance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.
professionals:
PC02. Ability to collect, interpret and apply data necessary for professional activity, research and implementation of innovative projects in the field of pharmacy.
PC03. Ability to solve pharmacy problems in new or unfamiliar environments in the presence of incomplete or limited information, taking into account aspects of social and ethical responsibility.
PC04. Ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to people who are studying.
PC17. Ability to organize and carry out quality control of medicinal products of natural and synthetic origin in accordance with the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods (QCM), technological instructions, etc.; to prevent the distribution of low-quality, falsified and unregistered medicinal products.
PC18. Ability to develop and evaluate methods of quality control of medicinal products of natural and synthetic origin, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances using physical, chemical, physico-chemical, biological, microbiological and pharmaco-technological methods; carry out standardization of medicinal products in accordance with current requirements.

Purpose: to form systematized bases of scientific knowledge on the standardization of medicinal products; to reveal the status and prospects of progress in the field of standardization of medicinal products; to focus attention on the most complex and

knotty issues regarding the concept of "falsified medicinal products" and "low-quality medicinal products", types of medicinal product falsification and factors contributing to the falsification of medicinal products, in relation to the international cooperation system of pharmaceutical inspections PIC/S; to provide an approximate basis for further assimilation of educational material in subsequent lectures and practical classes.

Lecture equipment: laptop, multimedia projector, blackboard.

Tasks of the lecture:

the student should know

the concepts of "falsified medicinal products" and "low-quality medicinal products", types of medicinal product falsification and factors contributing to medicinal product falsification; international cooperation system of pharmaceutical inspections PIC/S;

the student must be able to

analyze data from educational and special literature when solving tasks related to the standardization of medicinal products within the scope of quality control; use analytical and normative documentation that regulates the quality of medicinal products (State Pharmacopoeia of Ukraine, European Pharmacopoeia, USA Pharmacopoeia, British Pharmacopoeia, national and regional pharmacopoeias, AND, pharmacopoeial articles and monographs, GMP, GLP, GCP, orders and instructions, ISO documents) ; use industry standards, methodological guidelines when developing ADS for substances and medicinal products.

Lecture plan

The name the stage of the lecture	Content of the stage	Educational goal of the stage	Time
Introduction	Announcement of the topic of the lecture, of the lecture, definition of the purpose o lecture, a brief description of the problems proposed to be considered during lecture, a brief description of the literature.	Activation of the previo acquired scientific knowledg students from other discipl and laying the scientific basis assimilating the lecture materi	10 min
Main part	1.The concepts of "falsified medicinal products" and "low-qua medicinal products". The goal and t to reveal the main approaches to analysis of drugs, according to wh criteria drugs are classified as falsi	To acquire knowledge about goals and tasks of pharmaceut analysis, features of analysis falsified and low-quality drugs	65 min

	and low-quality. 2. Types of falsification of medic products and factors contributing falsification of medicinal produ reveal modern approaches, criteria modern requirements for the quality medicinal products, familiarize your with the main documents of the Mini of Health of Ukraine, laws, standards. 3. International cooperation system pharmaceutical inspections PIC/S: familiarize yourself with purpose, tasks and principles of activity.	To acquire knowledge about types of drug falsification factors contributing to c falsification. Get acquainted with the purp tasks and areas of work of PIC	
Final part	Generalization in short formulations the main ideas of the lecture, logic concluding it as a complete w direction of further independent wor students; laying the scientific basis the following lectures.	Learning the actual materia the lecture, the main theoret provisions with the help logical nodes - the n questions of the lecture.	15 min

Recommended literature:

Basic

1.European Pharmacopoeia. Council of Europe: Strasbourg, 2019. 10-th edition. Vol. 1. p.1-135. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
2.European Pharmacopoeia. Council of Europe: Strasbourg, 2022. 11-th edition. Vol. 1. p. 1-205. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
3. British Pharmacopoeia. 2009. Vol. 1 & 2. p. 1-59. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
6.Lecturer's material. The department of medicinal chemistry and toxicology of pharmaceutical faculty of Bogomolets National Medical University. https://www.youtube.com/@user-yj2fn5mz3x/

Auxiliary

1.European Commission Communication 'Towards an increased contribution from standardization to innovation in Europe' March 2008. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0133:FIN:en:PDF
2.Ali 'B. O. 'Fundamental principles of occupational health and safety', Geneva, International Labor Office, 2001, Retrieved 18 June 2012 at: http://www.ilo.org/wcmsp5/groups/public/@dgreports/@dcomm/@publ/documents/publication/wcms_093550.pdf
3.Saida E. & Taibi N. (2021). ISO 9001 Quality Approach and Performance Literature Review. European Scientific Journal, ESJ, 17(1), 128. https://doi.org/10.19044/esj.2021.v17n1p128
4. Robinson, J. The Pharmaceutical Journal. Falsified Medicines Directive (FMD): how it will work. 2018, https://pharmaceutical-journal.com/article/infographics/falsified-medicines-directive-fmd-how-it-will-work

Information resources

Website of the Department of Medicinal Chemistry and Toxicology of Bogomolets NMU
http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
Distance learning platform LIKAR_NMU https://likar.nmu.kiev.ua/
Official website of the Ministry of Health of Ukraine
https://moz.gov.ua/
State register of medicines.
URL: http://www.drlz.com.ua/ibp/ddsite.nsf/all/index?opendocument
Pharmaceutical encyclopedia
http://www.pharmencyclopedia.com.ua/
Pharmaceutical product certification system:
https://zakon.rada.gov.ua/laws/show/z2218-12#Text
pubmed.ncbi.nlm.nih.gov

Questions for student self-preparation for the lecture:

1. How is state management in the field of circulation of medicinal products carried out?

2. Define falsified medicinal products according to the Law of Ukraine "On Medicinal Products"

3. What is the essence of the concepts "falsified medicinal products" and "low-quality medicinal products"?

4. Are falsified medicinal products different from low-quality medicinal products?

5. Name the reasons and types of falsification of medicinal products. Give examples.

6. What liability is provided for the falsification of a medicinal product?

7. Give the characteristics of PIC/S.

Questions for preparing for the FC, which reveals the lecture material:

1.The Law of Ukraine «About Amendments to Certain Legislative Acts of Ukraine Regarding the Prevention of Drug Falsification».

2.The concepts of «falsified medicinal products» and «low-quality medicinal products». Types of drug falsification and factors contributing to drug falsification. Liability for falsification.

3.International cooperation system of pharmaceutical inspections PIC/S.

The methodical development was made by:

head of the department of medicinal chemistry and toxicology, DM, professor Nizhenkovska I.V., professor of department, doctor of pharm. sc. Welchinska O.V.

Topic N 3. The use of chemical methods of analysis in the development of quality standards of medicinal products according to the sections of the pharmacopoeias article "Identification", "Purity testing", "Quantitative determination".

Type of lecture: traditional (informational)

Competencies:

Integral:

the ability to solve tasks of a research and/or innovative nature in the field of pharmacy and in the field of industrial production of medicines.

general:

GC01. Ability to abstract thinking, analysis and synthesis.

GC02. Knowledge and understanding of the subject area; understanding of professional activity.

GC03. Ability to communicate in the national language both orally and in writing.

GC05. Ability to evaluate and ensure the quality of the work performed.

GC06. Ability to work in a team.

GC09. Ability to use information and communication technologies

GC10. Ability to make decisions and act in accordance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

professionals:

PC02. Ability to collect, interpret and apply data necessary for professional activity, research and implementation of innovative projects in the field of pharmacy.

PC03. Ability to solve pharmacy problems in new or unfamiliar environments in the presence of incomplete or limited information, taking into account aspects of social and ethical responsibility.

PC04. Ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to people who are studying.

PC17. Ability to organize and carry out quality control of medicinal products of natural and synthetic origin in accordance with the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods (QCM), technological instructions, etc.; to prevent the distribution of low-quality, falsified and unregistered medicinal products.

PC18. Ability to develop and evaluate methods of quality control of medicinal products of natural and synthetic origin, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances using physical, chemical, physico-chemical, biological, microbiological and pharmaco-technological methods; carry out standardization of medicinal products in accordance with current requirements.

Purpose: to form systematized bases of scientific knowledge on the standardization of medicinal products; to reveal the status and prospects of progress in the field of standardization of medicinal products; to concentrate attention on the most complex

and knotty questions regarding chemical methods of analysis in the development of quality standards of medicinal products according to the sections of the pharmacopoeial article "Identification", "Testing for purity", "Quantitative determination"; to provide an approximate basis for further assimilation of educational material in subsequent lectures and practical classes.

Lecture equipment: laptop, multimedia projector, blackboard.

Tasks of the lecture:

the student should know

chemical methods of analysis for the development of quality standards of medicinal products according to the sections of the pharmacopoeial article "Identification", "Testing for purity", "Quantitative determination";

the student must be able to

analyze data from educational and special literature when solving tasks related to the standardization of medicinal products within the scope of quality control; use analytical and normative documentation that regulates the quality of medicinal products (State Pharmacopoeia of Ukraine, European Pharmacopoeia, USA Pharmacopoeia, British Pharmacopoeia, national and regional pharmacopoeias, AND, pharmacopoeial articles and monographs, GMP, GLP, GCP, orders and instructions, ISO documents) ; use industry standards, methodological guidelines when developing ADS for substances and medicinal products.

Lecture plan

The name the stage of the lecture	Content of the stage	Educational goal of the stage	Time
Introduction	Announcement of the topic of the lecture, of the lecture, definition of the purpose o lecture, a brief description of the problems proposed to be considered during lecture, a brief description of the literature.	Activation of the previo acquired scientific knowledg students from other discipl and laying the scientific basis assimilating the lecture materi	10 min
Main part	1.The use of chemical methods analysis in the development of quality standards for medicinal products. Purpose and task: to reveal the main approaches to	To acquire knowledge about chemical methods pharmaceutical drug analysis their features.	65 min

	analysis of drugs using chemical methods. 2. Sections of the pharmacopoeial article "Identification" and "Testing purity": reveal the main approaches methods of drug analysis. 3. Section of the pharmacopoeial article "Quantitative determination" reveal the main approaches and meth of drug analysis.	To acquire knowledge about identification methods and drug purity tests. Get acquainted with methods of quantitative determination drugs.	
Final part	Generalization in short formulations the main ideas of the lecture, logic concluding it as a complete w direction of further independent wor students; laying the scientific basis the following lectures.	Learning the actual materia the lecture, the main theoret provisions with the help logical nodes - the n questions of the lecture.	15 min

Recommended literature:

Basic

1.European Pharmacopoeia. Council of Europe: Strasbourg, 2019. 10-th edition. Vol. 1. p.136-250. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
2.European Pharmacopoeia. Council of Europe: Strasbourg, 2022. 11-th edition. Vol. 1. p. 206-350. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
3. British Pharmacopoeia. 2009. Vol. 1 & 2. p. 60-120. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
6.Lecturer's material. The department of medicinal chemistry and toxicology of pharmaceutical faculty of Bogomolets National Medical University. https://www.youtube.com/@user-yj2fn5mz3x/

Auxiliary

1.European Commission Communication 'Towards an increased contribution from standardization to innovation in Europe' March 2008. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0133:FIN:en:PDF
2.Ali 'B. O. 'Fundamental principles of occupational health and safety', Geneva, International Labor Office, 2001, Retrieved 18 June 2012 at: http://www.ilo.org/wcmsp5/groups/public/@dgreports/@dcomm/@publ/documents/publication/wcms_093550.pdf

3.Saida E. & Taibi N. (2021). ISO 9001 Quality Approach and Performance Literature Review. European Scientific Journal, ESJ, 17(1), 128. https://doi.org/10.19044/esj.2021.v17n1p128
4. Robinson, J. The Pharmaceutical Journal. Falsified Medicines Directive (FMD): how it will work. 2018, https://pharmaceutical-journal.com/article/infographics/falsified-medicines-directive-fmd-how-it-will-work

Information resources

Website of the Department of Medicinal Chemistry and Toxicology of Bogomolets NMU
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Distance learning platform LIKAR_NMU https://likar.nmu.kiev.ua/
Official website of the Ministry of Health of Ukraine
https://moz.gov.ua/
State register of medicines.
URL: http://www.drlz.com.ua/ibp/ddsite.nsf/all/index?opendocument
Pharmaceutical encyclopedia
http://www.pharmencyclopedia.com.ua/
Pharmaceutical product certification system:
https://zakon.rada.gov.ua/laws/show/z2218-12#Text
pubmed.ncbi.nlm.nih.gov

Questions for student self-preparation for the lecture:

1. The use of chemical methods of analysis in the development of quality standards for medicinal products according to the section of the pharmacopoeial article "Identification". Give examples from DFU.

2. The use of chemical methods of analysis in the development of quality standards of medicinal products according to the section of the pharmacopoeial article "Testing for purity". Give examples from DFU.

3. The use of chemical methods of analysis in the development of quality standards of medicinal products according to the section of the pharmacopoeial article "Quantitative determination". Give examples from SPhU.

4. Purpose and tasks of international good practices in pharmacy GXP (GLP, GMP).

Questions for preparing for the FC, which reveals the lecture material:

1.Normative and technical documentation that regulates requirements for the quality of medicinal products.

2.State Pharmacopoeia of Ukraine (SPU, SPhU): structure and content. General and separate articles of SPhU, monographs of the SPhU on substances and pharmaceutical preparations.

3.State control of the quality of medicinal products. Research of pharmaco-technological indicators, purity, identification and quantitative content of medicinal products in the form of solutions for injections, eye drops, tablets, capsules, pessaries, ointments, aerosols, etc.

4.Standardized methods of medicinal products research. Physical, chemical, physical-chemical and biological test methods.

5.Requirements of the pharmacopoeia regarding the development of «Disintegration» and «Dissolution» tests for the standardization of tablets and capsules.

6.Qualitative reactions to cations and anions and their use in the standardization of medicinal products.

7.Qualitative reactions to functional groups and their use in the standardization of medicinal products.

The methodical development was made by:

head of the department of medicinal chemistry and toxicology, DM, professor Nizhenkovska I.V., professor of department, doctor of pharm. sc. Welchinska O.V.

Topic N 4. Standardized physical and physical-chemical methods of medicinal products research.

Type of lecture: traditional (informational)

Competencies:

Integral:

the ability to solve tasks of a research and/or innovative nature in the field of pharmacy and in the field of industrial production of medicines.

general:

GC01. Ability to abstract thinking, analysis and synthesis.

GC02. Knowledge and understanding of the subject area; understanding of professional activity.

GC03. Ability to communicate in the national language both orally and in writing.

GC05. Ability to evaluate and ensure the quality of the work performed.

GC06. Ability to work in a team.

GC09. Ability to use information and communication technologies

GC10. Ability to make decisions and act in accordance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

professionals:

PC02. Ability to collect, interpret and apply data necessary for professional activity, research and implementation of innovative projects in the field of pharmacy.

PC03. Ability to solve pharmacy problems in new or unfamiliar environments in the presence of incomplete or limited information, taking into account aspects of social and ethical responsibility.

PC04. Ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to people who are studying.

PC17. Ability to organize and carry out quality control of medicinal products of natural and synthetic origin in accordance with the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods (QCM), technological instructions, etc.; to prevent the distribution of low-quality, falsified and unregistered medicinal products.

PC18. Ability to develop and evaluate methods of quality control of medicinal products of natural and synthetic origin, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances using physical, chemical, physico-chemical, biological, microbiological and pharmaco-technological methods; carry out standardization of medicinal products in accordance with current requirements.

Purpose: to form systematized bases of scientific knowledge on the standardization of medicinal products; to reveal the status and prospects of progress in the field of standardization of medicinal products; to concentrate attention on the most complex and knotty issues regarding standardized physical and physical-chemical methods of

drug research according to the sections of the pharmacopoeial articles of the Federal State University of Medicine; to provide an approximate basis for further assimilation of educational material in subsequent lectures and practical classes.

Lecture equipment: laptop, multimedia projector, blackboard.

Tasks of the lecture:

the student should know standardized physical and physico-chemical methods of drug research;

the student must be able to

analyze data from educational and special literature when solving tasks related to the standardization of medicinal products within the scope of quality control; use analytical and normative documentation that regulates the quality of medicinal products (State Pharmacopoeia of Ukraine, European Pharmacopoeia, USA Pharmacopoeia, British Pharmacopoeia, national and regional pharmacopoeias, AND, pharmacopoeial articles and monographs, GMP, GLP, GCP, orders and instructions, ISO documents) ; use industry standards, methodological guidelines when developing ADS for substances and medicinal products.

Lecture plan

The name the stage of the lecture	**Content of the stage**	**Educational goal of the stage**	**Time**
Introduction	Announcement of the topic of the lecture, of the lecture, definition of the purpose o lecture, a brief description of the problems proposed to be considered during lecture, a brief description of the literature.	Activation of the previo acquired scientific knowledg students from other discipl and laying the scientific basis assimilating the lecture materi	10 min
Main part	1.Use of standardized physical methods of drug analysis. Purpose and task: to reveal the n approaches to the analysis of drugs u physical methods. 2.Use of standardized chemical methods of drug analysis: reveal main approaches of chemical analysi drugs, chemical methods identification and quantification	To acquire knowledge about classification of physical meth of pharmaceutical drug analy their principles and features. To acquire knowledge about classification of chem methods of pharmaceutical c analysis, their principles features.	65 min

	(color reactions, precipitation reactions, microcrystallographic reactions, etc.). 3.Use of standardized physico-chemical methods of c analysis: reveal the main approaches of physico-chemical analysis of drugs, instrumental methods of identification quantification (chromatography, spectrosc electrophoresis, etc.).	To acquire knowledge about classification of physicochem methods of pharmaceutical c analysis, their principles features.	
Final part	Generalization in short formulation the main ideas of the lecture, logic concluding it as a complete w direction of further independent wor students; laying the scientific basis the following lectures.	Learning the actual materia the lecture, the main theoret provisions with the help logical nodes - the n questions of the lecture.	15 min

Recommended literature:

Basic

1.European Pharmacopoeia. Council of Europe: Strasbourg, 2019. 10-th edition. Vol. 1. p.255-300. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
2.European Pharmacopoeia. Council of Europe: Strasbourg, 2022. 11-th edition. Vol. 1. p. 357-450. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
3. British Pharmacopoeia. 2009. Vol. 1 & 2. p. 122-350. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
6.Lecturer's material. The department of medicinal chemistry and toxicology of pharmaceutical faculty of Bogomolets National Medical University. https://www.youtube.com/@user-yj2fn5mz3x/

Auxiliary

1.European Commission Communication 'Towards an increased contribution from standardization to innovation in Europe' March 2008. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0133:FIN:en:PDF
2.Ali 'B. O. 'Fundamental principles of occupational health and safety', Geneva, International Labor Office, 2001, Retrieved 18 June 2012

at: http://www.ilo.org/wcmsp5/groups/public/@dgreports/@dcomm/@publ/documents/publication/wcms_093550.pdf
3.Saida E. & Taibi N. (2021). ISO 9001 Quality Approach and Performance Literature Review. European Scientific Journal, ESJ, 17(1), 128. https://doi.org/10.19044/esj.2021.v17n1p128
4. Robinson, J. The Pharmaceutical Journal. Falsified Medicines Directive (FMD): how it will work. 2018, https://pharmaceutical-journal.com/article/infographics/falsified-medicines-directive-fmd-how-it-will-work

Information resources

Website of the Department of Medicinal Chemistry and Toxicology of Bogomolets NMU
http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
Distance learning platform LIKAR_NMU https://likar.nmu.kiev.ua/
Official website of the Ministry of Health of Ukraine
https://moz.gov.ua/
State register of medicines.
URL: http://www.drlz.com.ua/ibp/ddsite.nsf/all/index?opendocument
Pharmaceutical encyclopedia
http://www.pharmencyclopedia.com.ua/
Pharmaceutical product certification system:
https://zakon.rada.gov.ua/laws/show/z2218-12#Text
pubmed.ncbi.nlm.nih.gov

Questions for student self-preparation for the lecture:

1. Use of physical methods of analysis in the development of quality standards of medicinal products: determination of transparency and turbidity of liquids, degree of color of liquids, boiling point, melting point. Give examples from SPhU.

2. The use of physical-chemical methods of analysis in the development of quality standards for medicinal products: potentiometric determination of pH, relative density, refractive index, optical rotation. Give examples from SPhU.

3. Viscosity. Methods of viscometry. Give examples from SPhU.

4. Titration. Characteristics of titration methods. Give examples from SPhU.

5. Chromatographic methods of analysis (TLC, GC, HPLC).

6. Use of physical-chemical methods of analysis in the development of quality standards for medicinal products: atomic emission spectrometry, atomic absorption spectrometry, absorption spectrophotometry in the IR region, absorption spectrophotometry in the UV and visible spectrum regions. Give examples from SPU.

7. PMR spectrometry (NMR).

8. Mass spectrometry, mass spectrometry with inductively coupled plasma.

Questions for preparing for the FC, which reveals the lecture material:

1.Use of precipitation methods in the standardization of medicinal products.

2.Use of oxidation-reduction methods in the standardization of medicinal products.

3.The essence of gravimetry and its use in the development of quality standards for medicinal products.

4.Use of refractometry in the development of quality standards for medicinal products.

5.Methods of establishing the identity of inorganic and organic compounds depending on their structure. Use of titrimetric methods of drug analysis depending on their structure. Methods of determining the concentration depending on the method of analysis.

6.Use of modern instrumental methods to determine the identity, impurities and quantitative content of medicinal products. The use of instrumental methods for the analysis of drug mixtures. Methods of determination of concentrations.

7.Optical methods of analysis. Atomic and molecular spectra. Spectra of substances in the ultraviolet, visible and infrared regions of the spectrum. Types of photometric analysis. Photocolorimetry, spectrophotometry and their use in quality control of medicinal products. Methods of determining concentrations in photocolorimetry and spectrophotometry, refractometry and polarimetry. Use of NMR spectroscopy, mass spectroscopy, X-ray spectral method in the analysis of medicinal products.

8.Chromatographic methods of analysis. The use of thin-layer, gas-liquid and high-performance liquid chromatography to confirm the identity, determine the concomitant impurities and the quantitative content of medicinal products.

The methodical development was made by:

head of the department of medicinal chemistry and toxicology, DM, professor Nizhenkovska I.V., professor of department, doctor of pharm. sc. Welchinska O.V.

Topic N 5. Use of chromatographic and spectral methods for identification, purity testing and quantification in the standardization of medicinal products.

Type of lecture: traditional (informational)
Competencies:
Integral:
the ability to solve tasks of a research and/or innovative nature in the field of pharmacy and in the field of industrial production of medicines.
general:
GC01. Ability to abstract thinking, analysis and synthesis.
GC02. Knowledge and understanding of the subject area; understanding of professional activity.
GC03. Ability to communicate in the national language both orally and in writing.
GC05. Ability to evaluate and ensure the quality of the work performed.
GC06. Ability to work in a team.
GC09. Ability to use information and communication technologies
GC10. Ability to make decisions and act in accordance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.
professionals:
PC02. Ability to collect, interpret and apply data necessary for professional activity, research and implementation of innovative projects in the field of pharmacy.
PC03. Ability to solve pharmacy problems in new or unfamiliar environments in the presence of incomplete or limited information, taking into account aspects of social and ethical responsibility.
PC04. Ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to people who are studying.
PC17. Ability to organize and carry out quality control of medicinal products of natural and synthetic origin in accordance with the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods (QCM), technological instructions, etc.; to prevent the distribution of low-quality, falsified and unregistered medicinal products.
PC18. Ability to develop and evaluate methods of quality control of medicinal products of natural and synthetic origin, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances using physical, chemical, physico-chemical, biological, microbiological and pharmaco-technological methods; carry out standardization of medicinal products in accordance with current requirements.

Purpose: to form systematized bases of scientific knowledge on the standardization of medicinal products; to reveal the status and prospects of progress in the field of standardization of medicinal products; to focus attention on the most complex and

knotty issues regarding standardized chromatographic and spectral methods for identification, purity tests and quantitative determination in the standardization of medicinal products according to the sections of the pharmacopoeial articles of the Federal Drug Administration; to provide an approximate basis for further assimilation of educational material in subsequent lectures and practical classes.

Lecture equipment: laptop, multimedia projector, blackboard.

Tasks of the lecture:

the student should know standardized physical and physical-chemical methods of drug research;

the student must be able to analyze data from educational and special literature when solving tasks related to the standardization of medicinal products within the scope of quality control; use analytical and normative documentation that regulates the quality of medicinal products (State Pharmacopoeia of Ukraine, European Pharmacopoeia, USA Pharmacopoeia, British Pharmacopoeia, national and regional pharmacopoeias, AND, pharmacopoeial articles and monographs, GMP, GLP, GCP, orders and instructions, ISO documents) ; use industry standards, methodological guidelines when developing ADS for substances and medicinal products.

Lecture plan

The name the stage of the lecture	**Content of the stage**	**Educational goal of the stage**	**Time**
Introduction	Announcement of the topic of the lecture, of the lecture, definition of the purpose o lecture, a brief description of the problems proposed to be considered during lecture, a brief description of the literature.	Activation of the previo acquired scientific knowledg students from other discipl and laying the scientific basis assimilating the lecture materi	10 min
Main part	1.Use of standardized chromatogra and spectral methods for identificatio medicinal products. Purpose and task reveal the main approaches to identification using chromatographic spectral methods. 2. The use of standard chromatographic and spectral meth for drug purity tests: to reveal the n	To acquire knowledge about use of instrumental meth (chromatography spectroscopy) during identification. To acquire knowledge about use of instrumental meth	65 min

	approaches to drug purity tests u chromatographic and spectral method 3. The use of standard chromatographic and spectral meth for the quantitative determination medicinal products: to reveal the n approaches to the quantita determination of drugs u chromatographic and spectral method	(chromatography spectroscopy) during drug pu tests. To acquire knowledge about use of instrumental meth (chromatography spectroscopy) during quantitative determination drugs.	
Final part	Generalization in short formulation the main ideas of the lecture, logic concluding it as a complete w direction of further independent wor students; laying the scientific basis the following lectures.	Learning the actual materia the lecture, the main theoret provisions with the help logical nodes - the n questions of the lecture.	15 min

Recommended literature:

Basic

1.European Pharmacopoeia. Council of Europe: Strasbourg, 2019. 10-th edition. Vol. 1. p. 320-450. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
2.European Pharmacopoeia. Council of Europe: Strasbourg, 2022. 11-th edition. Vol. 1. p. 550-720. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
3. British Pharmacopoeia. 2009. Vol. 1 & 2. p. 356-770. http://nmu.ua/zagalni-vidomosti/kafedri/kafedra-farmatsevtycheskoj-byologycheskoj-y-toksykologycheskoj-hymyy/
6.Lecturer's material. The department of medicinal chemistry and toxicology of pharmaceutical faculty of Bogomolets National Medical University. https://www.youtube.com/@user-yj2fn5mz3x/

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1.European Commission Communication 'Towards an increased contribution from standardization to innovation in Europe' March 2008. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0133:FIN:en:PDF
2.Ali 'B. O. 'Fundamental principles of occupational health and safety', Geneva, International Labor Office, 2001, Retrieved 18 June 2012

at: http://www.ilo.org/wcmsp5/groups/public/@dgreports/@dcomm/@publ/documents/publication/wcms_093550.pdf
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Distance learning platform LIKAR_NMU https://likar.nmu.kiev.ua/
Official website of the Ministry of Health of Ukraine
https://moz.gov.ua/
State register of medicines.
URL: http://www.drlz.com.ua/ibp/ddsite.nsf/all/index?opendocument
Pharmaceutical encyclopedia
http://www.pharmencyclopedia.com.ua/
Pharmaceutical product certification system:
https://zakon.rada.gov.ua/laws/show/z2218-12#Text
pubmed.ncbi.nlm.nih.gov

Questions for student self-preparation for the lecture:

1. Use of chromatographic methods of analysis in the development of quality standards of medicinal products for identification, purity tests and quantitative determination: TLC, GC, HPLC. Give examples from SPhU.

2. Chromatographic methods of analysis (TLC, GC, HPLC). Describe the methods. Give examples of their use during the analysis of the quality of medicinal products.

3. PMR spectrometry (NMR). Describe the methods. Give examples of their use during the analysis of the quality of medicinal products.

4. Mass spectrometry, mass spectrometry with inductively coupled plasma. Describe the methods. Give examples of their use during the analysis of the quality of medicinal products.

Questions for preparing for the FC, which reveals the lecture material:

1.Use of refractometry in the development of quality standards for medicinal products.

2.Methods of establishing the identity of inorganic and organic compounds depending on their structure. Use of titrimetric methods of drug analysis depending on their structure. Methods of determining the concentration depending on the method of analysis.

3.Use of modern instrumental methods to determine the identity, impurities and quantitative content of medicinal products. The use of instrumental methods for the analysis of drug mixtures. Methods of determination of concentrations.

4.Optical methods of analysis. Atomic and molecular spectra. Spectra of substances in the ultraviolet, visible and infrared regions of the spectrum. Types of photometric analysis. Photocolorimetry, spectrophotometry and their use in quality control of medicinal products. Methods of determining concentrations in photocolorimetry and spectrophotometry, refractometry and polarimetry. Use of NMR spectroscopy, mass spectroscopy, X-ray spectral method in the analysis of medicinal products.

5.Chromatographic methods of analysis. The use of thin-layer, gas-liquid and high-performance liquid chromatography to confirm the identity, determine the concomitant impurities and the quantitative content of medicinal products.

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