ЛЬВІВСЬКИЙ НАЦІОНАЛЬНИЙ МЕДИЧНИЙ УНІВЕРСИТЕТ
ІМЕНІ ДАНИЛА ГАЛИЦЬКОГО

Кафедра організації і економіки фармації

ЗАТВЕРДЖУЮ
Перший проректор з
науково-педагогічної роботи
доц. І. І. Солонинко

“29” 06 2023 р.

НАВЧАЛЬНА ПРОГРАМА ДИСЦИПЛІНИ

Система якості у фармації
(назва навчальної дисципліни)

підготовки фахівців другого (магістерського) рівня вищої освіти
галузі знань 22 «Охорона здоров’я»
спеціальності 226 «Фармація, промислова фармація»
(очна денна і заочна форми навчання)
для студентів 5 курсу фармацевтичного факультету
ОК 26.3

Обговорено та ухвалено
на методичному засіданні кафедри
організації і економіки фармації
Протокол №11 від 23 червня 2023 р.
Завідувач кафедри ОЕФ
_____ проф. Громовик Б. П.

Затверджено
профільною методичною комісією
з хімічних та фармацевтичних
дисциплін
Протокол від 27 червня 2023 р.
Голова профільної методичної
комісії _____ проф. Білоус С.Б.

DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY

DEPARTMENT OF ORGANIZATION AND ECONOMICS OF PHARMACY

Approved by:
First Vice-Rector
for Research and Teaching
assoc. prof. Solonynko I.I. _____

"_____" _____ 2023 y.

CURRICULUM OF THE DISCIPLINE

"QUALITY SYSTEM IN PHARMACY"
(name of an academic discipline)

training of specialists of the second (master's) level of higher education
in the field of knowledge 22 "Health"
specialty 226 "Pharmacy, industrial pharmacy"
for 5th year students of the Faculty of Pharmacy

Discussed and approved at the methodical meeting of the department of organization and economics of pharmacy
June 23, 2023
Protocol No 11
Head of the department
_____ Prof. Hromovyk B.P.

Approved by the profile methodical commission on chemical and pharmaceutical disciplines
June 27, 2023
Protocol No 3
Head of the methodical commission
_____ Prof. S. B. Bilous

Lviv 2023

DEVELOPERS OF THE PROGRAM – personnel of the Department of Organization and Economics of Pharmacy: B.P. Hromovyk, Head of the Department (a Professor, a Doctor of Pharmaceutical Sciences), O.R. Levytska (an Associated Professor, a Doctor of Pharmaceutical Sciences), I.Ya. Horodetska (an Associated Professor, PhD), N.B. Yarko (an Associated Professor, PhD),

REVIEWER: Doctor of Pharmaceutical Sciences, Professor of the Department of Disaster Medicine and Military Medicine of Danylo Halytsky Lviv National Medical University P.V. Oliynyk.

INTRODUCTION

The program of study of the discipline **"Quality system in pharmacy"**

according to the Educational and professional program "Pharmacy, industrial pharmacy" of the second (master's) level of knowledge 22 "Health" specialty 226 "Pharmacy, industrial pharmacy" of Danylo Halytsky Lviv National Medical University named after.

The program of study of the discipline

Concluded in accordance with the Educational and Professional Program "Pharmacy, Industrial Pharmacy" of the second (master's) level of knowledge 22 "Health" specialty 226 "Pharmacy, Industrial Pharmacy".

Description of the discipline (abstract)

The discipline "Quality System in Pharmacy" is one of the disciplines in a set of elective courses that form masters of pharmacy. It enables the formation of applicants for higher pharmaceutical education a sufficient amount of theoretical knowledge and practical skills to plan and implement quality management of processes that affect the quality of pharmaceutical products at all stages of its life cycle: from development, research, registration and production to wholesale and retail implementation.

The structure of the discipline	Number of credits, hours, including				Year of study	Type of control
	Total	Classroom		Indep. Work, h.		
		Lectures, h.	Practical classes, h.			
Name of the discipline: **Quality system in pharmacy**	3 credits / 90 h.	8	30	52	5th year, autumn semester	Test

The subject of study of the discipline "Quality system in pharmacy" is the quality management system in pharmacy, approaches to its functioning, regulation of pharmaceutical organizations on quality.

Interdisciplinary links in the study of the discipline "Quality System in Pharmacy" are based on general knowledge of such disciplines as "Information Technology in Pharmacy", "Computer Modeling in Pharmacy", "Pharmaceutical Law and Legislation", "Organization and Economics pharmacy "," Pharmaceutical and medical commodity science "," Pharmaceutical management and marketing.

1. The purpose and objectives of the discipline

1.1.The purpose of teaching the discipline "Quality System in Pharmacy" is the acquisition by graduates of higher pharmaceutical education of systems thinking skills and integrated practical skills in planning and implementing work to control, ensure and manage the quality of processes affecting the quality of pharmaceutical products at all stages of its life cycle: from development, research, registration and production to wholesale and retail sales and medical applications.

1.2. The main task is the formation of system knowledge and practical skills in relation to quality management work carried out during the life cycle of the drug, the development of pharmaceutical quality systems and the preparation and conduct of their internal audits (self-inspections).

1.3 Competences and learning outcomes, the formation of which is facilitated by the discipline.

The discipline "Quality System in Pharmacy" provides the acquisition of higher education by **competencies:**

a) general competencies (GC):

GC4. Ability to use information and communication technologies and acquired knowledge in practical situations, to find, process and analyze information from various sources.

GC5. Ability to lead, lead a team, work in a team, communicate professionally with non-professionals in the field and constructively interact with other people, regardless of their background and cultural characteristics, and respect for diversity, even when dealing with complex issues.

GC6. Ability to identify, pose and solve problems, make informed decisions, evaluate and ensure the quality of work performed.

GC7. Ability to generate new ideas (creativity), develop and manage projects, plan and allocate time, work autonomously.

b) special (professional) competencies (SC):

SP1. Ability to understand the subject area in the direction and subject of pharmaceutical research and professional activities.

SC2. Ability to identify the need for additional knowledge in the field of pharmacy and in the field of scientific research, to generate scientific hypotheses.

SC3. Ability to apply the category-conceptual apparatus, the latest theories, concepts, technologies and methods needed to solve complex problems of the pharmaceutical sector of the healthcare sector.

SC4. Ability to formulate research questions, develop research projects.

Detailing of competencies according to NQF descriptors in the form of "Competence Matrix".

Competence Matrix

№	A competence	Knowledge	Skills	Communication	Autonomy and responsibility
GC4	Ability to use information and communication technologies and acquired knowledge in practical situations, to find, process and analyze information from various sources	Know modern information and communication technologies	Use information nor communication technologies, to find, process and analyze information from various sources	Ability to communicate results to stakeholders processing and analysis of information from various sources	Be responsible for the results processing and analysis of information from various sources
GC5	Ability to lead, manage team, work in a team, communicate professionally with non-professionals in the field and constructive interaction with other people, regardless of their background and cultural characteristics, and respect for diversity, even when solving complex issues	Know the features of leadership and leadership, professional communication with non-professionals	Be able to use professional knowledge to solve practical situations	Establish professional communication with non-professionals in the field and constructive interaction with other people, regardless of their background and cultural	Be responsible for the results of leadership and leadership and professional communication with non-professionals

				characteristics, and respect for diversity, even when solving complex issues	
GC6	Ability to identify, pose and solve problems, make informed decisions, evaluate and ensure the quality of work performed	Know modern management approaches to justification of decisions	Be able to evaluate and ensure the quality of work performed	Identify, pose and solve problems, make informed decisions	Be responsible for the decisions made and the results of evaluation and quality assurance of work performed
GC7	Ability to generate new ideas (creativity), develop and manage projects, plan and allocate time, work autonomously	Know the features of generating new ideas, project management, planning and allocation of time, autonomous work	Be able to generate new ideas, develop and manage projects, plan and allocate time, work autonomously	Establish communicative connections in the context of a new professional situation	Be responsible for new ideas, project management results, planning and time allocation, results of autonomous work
SC1	Ability to understand the subject area in the direction and subject of pharmaceutical research and professional activities	Know the features of pharmaceutical science and practice	Be able to use the features of pharmaceutical science and practice	Be able to use the features of pharmaceutical science and practice	Be responsible for the results of understanding the subject area in the direction and subject of pharmaceutical research and professional activities
SC2	Ability to identify the need for additional knowledge in the field of pharmacy and in the field of scientific research, to generate scientific hypotheses	Know the features of identifying the need for additional knowledge in the field of pharmacy and research	Be able to identify the need for additional knowledge in the field of pharmacy and in the field of scientific research, generate scientific hypotheses	Establish communicative connections in the context of a new professional situation	To be responsible for the results of identifying the need for additional knowledge in the field of pharmacy and in the field of scientific research, as well as the generation of scientific hypotheses
SC3	Ability to apply the category-conceptual apparatus, the latest theories, concepts, technologies and methods needed to solve complex	Know the categorical apparatus, the latest theories, concepts, technologies	Be able to apply the categorical concept, the latest theories, concepts, technologies	Establish communicative connections in the context of a new professional	Be responsible for the proper application of the category-conceptual apparatus, the latest theories, concepts, technologies and

	problems of the pharmaceutical sector of health care	and methods needed to solve complex problems of pharmacy	and methods needed to solve complex problems of pharmacy	situation	methods necessary to solve complex problems of pharmacy
SC4	Ability to formulate research questions, develop research projects	Know the features of the formulation of research questions, development of research projects	Be able to formulate research questions, develop research projects	Establish communicative connections in the context of a new professional situation	Be responsible for the results of the formulation of research questions, development of research projects

Program learning outcomes (PLO):

- Use modern information sources of national and international level to assess the state of study of the object of research and the relevance of the scientific problem (PLO 4).
- Be able to analyze, systematize and interpret the results of scientific research, use methods of statistical data processing (PLO 8).
- Be able to interpret and analyze information using the latest information technologies (PLO 11).
- Coordinate the work of the research group, be able to organize collective work (graduates, colleagues, interdisciplinary team) (PLO 16).

Integrative final learning outcomes, the formation of which is facilitated by the discipline: the ability to solve typical and complex specialized problems and practical problems of managing a pharmaceutical organization in professional pharmaceutical activities, clearly and unambiguously communicate their conclusions and knowledge to professional and non-professional audience.

2. Information volume of the discipline

The study of the discipline is allocated 3 ECTS credits - 90 hours.

Topic 1. The evolution of the world development of science in quality management and its role in pharmacy.

Topic 2. Regulatory framework for quality management of medicines in the world and in Ukraine.

Topic 3. State quality assurance system of medicines. Certification and licensing of the pharmaceutical market of Ukraine.

Topic 4. Statistical methods of quality control.

Topic 5. Regulation and documentation of pharmaceutical quality system processes.

Topic 6. Risk assessment for the quality of the drug at the stages of its life cycle.

Topic 7. Organization of activities for validation of production processes and qualification of equipment and auxiliary systems in organizations - subjects of the pharmaceutical market.

Topic 8. Internal audits (self-inspections) of pharmaceutical quality systems.

3. The structure of the discipline

Topic	Lec-tures	Semi-nars	Individual work
1. Evolution of world science development on quality management and its role in pharmacy	2	4	8
2. Normative and legal base of quality management in the world and in Ukraine	-	4	8
3. State system of ensuring of medicines` quality. Certification and Licensing of subjects of the pharmaceutical market in Ukraine	2	4	6
4. Statistical methods of quality control	-	2	6
5. Regulation and documentation of processes of pharmaceutical system of quality	-	4	6
6. Risk assessment for quality of a drug on the stages of its life cycle	2	4	6
7. Organization of validation activity of production processes, qualification of equipment, and auxiliary systems in organizations – business entities of pharmaceutical market	2	4	6
8. Internal audit (self-inspection) of pharmaceutical quality systems	-	4	6
Total quantity of hours 60/2,0 credits ECTS	**8**	**30**	**52**
Final control	**Test**		

4. Thematic plan of lectures.

	Topic	Q. of hours
1.	Evolution of world science development on quality management and its role in pharmacy	2
2.	State system of ensuring of medicines` quality. Certification and Licensing of subjects of the pharmaceutical market in Ukraine	2
3.	Risk assessment for quality of a drug on the stages of its life cycle	2
4.	Internal audit (self-inspection) of pharmaceutical quality systems	2
	Total	8

5. Thematic plan of practical classes

№	Topic	Quant. of hours
1	Evolution of world science development on quality management and its role in pharmacy	4
2	Normative and legal base of quality management in the world and in Ukraine	4
3	State system of ensuring of medicines` quality. Certification and Licensing of subjects of the pharmaceutical market in Ukraine	4
4	Statistical methods of quality control	2
5	Regulation and documentation of processes of pharmaceutical system of quality	4
6	Risk assessment for quality of a drug on the stages of its life cycle	4
7	Organization of validation activity of production processes, qualification of equipment, and auxiliary systems in organizations – business entities of pharmaceutical market	4
8	Internal audit (self-inspection) of pharmaceutical quality systems	4
	Total	**30**

6. Thematic plan of independent work of students

№	Topic	Quant. of hours	Type of control
1.	Evolution of world science development on quality management and its role in pharmacy	8	Current control in practical classes
2.	Normative and legal base of quality management in the world and in Ukraine	8	
3.	State system of ensuring of medicines` quality. Certification and Licensing of subjects of the pharmaceutical market in Ukraine	6	
4.	Statistical methods of quality control	6	
5.	Regulation and documentation of processes of pharmaceutical system of quality	6	
6.	Risk assessment for quality of a drug on the stages of its life cycle	6	
7.	Organization of validation activity of production processes, qualification of equipment, and auxiliary systems in organizations – business entities of pharmaceutical market	6	
8.	Internal audit (self-inspection) of pharmaceutical quality systems	6	
	Total	**52**	

7. Teaching methods

In the process of studying the discipline "Quality System in Pharmacy" the following teaching methods are used:

- by type of cognitive activity: explanatory-illustrative; analytical, synthetic, inductive, deductive;
- according to the main stages of the process: formation of knowledge; application of knowledge; generalization; fixing; audit;
- according to the system approach: stimulation and motivation; control and self-control.
- by sources of knowledge: verbal - story, conversation; visual - demonstration, illustration.
- by the level of independent mental activity: problematic; partial search; research.

8. Methods of control:

• Types of control (current and final).

Current control of knowledge is carried out in order to identify the quality of the educational process and its results and is carried out during the practical classes provided by the curriculum of the discipline.

The current control of knowledge of applicants for higher education is assessed according to the following scheme:

№	Type of work	Maximum points	Score in points	Content of the work
1	Work during the class	5	A) 2,3,4,5 B) 2,3,4,5	A) active participation in practical classes: discussion of certain topics of the course; presentation of creative works, primary sources, etc .; B) express - control.
2	Independent work	5	2,3,4,5	Execution of one of the types of work: 1) elaboration and solution of certain situational tasks assigned to independent work; 2) preparation of the presentation and public speech.

Assessment of the work of higher education students in practical classes is based on the performances of higher education students in the classroom, which takes into account not only the level of problem solving, but also their activity in discussion, ability to oppose, ask questions, express their vision of the problem.

Independent work. Provides elaboration and solution of certain situational tasks, as well as preparation of a presentation and public speech. When preparing a presentation, it is necessary to assume that the plan, the clearly defined goals, the basic idea of the presentation, the conclusions and the list of sources used for its preparation are obligatory. At the same time, the applicant should not only prepare, but also briefly (for 5-7 minutes) to reveal to the audience the main problems discussed in the work. The main criteria for evaluating the presentation are:

1) compliance of the content of the presentation with the chosen topic;
2) the level of knowledge on the topic;
3) independence of the main content;
4) the ability to briefly and, at the same time, informatively reveal the content of the topic;
5) the ability to answer questions.

Preparation, design and presentation are evaluated at the seminar.

• Form of final control in accordance with the curriculum - credit.
• Evaluation criteria

Criteria for evaluating classes

Assessment of knowledge of the applicant for higher education during practical and seminar classes is carried out according to the following criteria:

• understanding, degree of mastering the theory and methodology of the problems under consideration;
• the degree of mastering the actual material of the discipline;
• familiarity with the main (mandatory) and additional literature, as well as with modern domestic and foreign literature on the issues under consideration;
• logic, structure, style of presentation of material in speeches in the audience, the ability to defend their position and to summarize the information obtained from the reports of others.

The level of knowledge of higher education students in practical classes is assessed on a four-point scale.

The applicant of higher education, who gave a reasoned and complete answer to all the questions posed in the tasks, deserves an "excellent" grade; fluent in program material, correctly reveals the essence of the concepts of the course, analyzes and comments on causal relationships, is able to logically formulate opinions, adhere to the sequence and accuracy of the material, make reasoned conclusions in accordance with the acquired knowledge and developed educational literature.

The higher education student deserves a grade of "good" if he / she answered all the questions correctly, showed mastery of the study material in the answers to the task, but made some shortcomings in the sequence of presentation, completeness of analysis or commenting on certain questions or conclusions and made minor factual errors.

The assessment of "satisfactory" is deserved by the applicant of higher education, who basically mastered the questions of the course, gave generally correct answers to at least two questions, but made mistakes in wording, made vague conclusions, presented the material insufficiently fully and consistently.

The assessment of "unsatisfactory" is received by the applicant who showed ignorance of the basic program material, stated it inconsistently and vaguely, did not answer any of the control questions offered in the task, made gross mistakes in defining concepts and analysing the facts, could not apply the acquired knowledge. in a specific situation.

9. Current control is carried out during laboratory classes and aims to verify the assimilation of higher education students of educational material. Current control includes verification of theoretical and practical training.

During the assessment of the mastery of each topic for the current educational activity, the applicant is given grades on a 4-point (national) scale. This takes into account all types of work provided by the discipline program. The higher education applicant must receive a grade from each topic for further conversion of grades into points on a multi-point (200-point) scale.

10. Forms of final control of learning success:

Semester test - a form of final control, which consists in assessing the mastering of higher education educational material solely on the basis of the results of certain types of work in seminars and during independent work. The semester test is held at the last lesson of the discipline. The test in the discipline is set according to the results of the current control and is expressed on a two-point scale: "credited" or "not credited". Applicants for higher education who have attended all the classes provided by the curriculum, performed all types of work provided by the program and received grades sufficient to convert to the minimum number of points are admitted to the final control.

11. Схема нарахування та розподіл балів, які отримують здобувачів вищої освіти:

Для дисциплін формою підсумкового контролю яких є залік:

Максимальна кількість балів, яку може набрати здобувач вищої освіти за поточну навчальну діяльність при вивченні дисципліни становить 200 балів.

Мінімальна кількість балів, яку повинен набрати здобувач вищої освіти за поточну навчальну діяльність для зарахування дисципліни становить 120 балів.

Розрахунок кількості балів проводиться на підставі отриманих здобувачем вищої освіти оцінок за 4-ри бальною (національною) шкалою під час вивчення дисципліни, шляхом обчислення середнього арифметичного (СА), округленого до двох знаків після коми. Отримана величина конвертується у бали за багатобальною шкалою таким чином:

11. Scheme of accrual and distribution of points received by applicants for higher education:

For disciplines the form of final control which is a test:

The maximum number of points that can be obtained by the applicant for higher education for the current educational activity in the study of the discipline is 200 points.

The minimum number of points that must be obtained by the applicant for higher education for the current educational activity for enrollment in the discipline is 120 points.

The calculation of the number of points is based on the grades obtained by the higher education student on a 4-point (national) scale during the study of the discipline, by calculating the arithmetic mean (CA), rounded to two decimal places. The resulting value is converted into points on a multi-point scale as follows:

$$x = \frac{\text{CA} \times 200}{5}$$

Independent work is evaluated during the current control of the topic in the relevant lesson. Assimilation of topics that are submitted only for independent work is controlled during the final control.

12. Methodical support

Methodical materials for applicants for higher education:

1. Hromovyk B.P. Course "Quality system as quality": guidelines and a list of tasks for practical classes for students of the Faculty of Pharmacy full-time education. - Lviv, 2019. - 39 p.
2. Hromovyk B.P. Test work on the subject "Quality System as Quality": guidelines and a list of tasks for practical classes for students of the Faculty of Pharmacy by correspondence. - Lviv, 2019. - 21 p.

13. Extended plan of lectures, practical and seminar classes and independent work

Topic 1. The evolution of the world development of science in quality management and its role in pharmacy.

A systematic approach to the problem of product quality management. Models of quality management systems: model of A. Feigenbaum, model of J. Ettinger and J. Sittig, model of D. Juran, cyclic model of quality management of PDCA and its modification of PDSA. Principles of quality improvement: 14 principles of quality management by E. Deming, 14 principles by F. Crosby. The concept of annual quality improvement (AQI). Methods of G. Taguti. The sequence of development of methods and approaches to quality management in the world: individual quality control, quality control and testing; quality control (QC); quality assurance (QA) systems; quality management (QM); total quality management (TQM). The concept of quality management system of organizations - subjects of the pharmaceutical market (pharmaceutical quality systems). Integrated quality management system for medical care (KSUYALO). Drug life cycle. Implementation of the principles of quality assurance at the stages of the life cycle of medicines.

Topic 2. Regulatory framework for quality management of medicines in the world and in Ukraine.

Quality system in international standards ISO 9001 and ISO 13485 and industry guidelines ICH Q10 "Pharmaceutical quality system". Stages of building a pharmaceutical quality system. The concept of good pharmaceutical practices (GxP) and their role in quality assurance at all stages of the life cycle of medicines. Standards ISO 14001, OHSAS 18001, ISO 45001, SA 8000, ISO 26000, ISO 27001, ISO 22000. Integrated management systems for pharmaceutical organizations.

Topic 3. State quality assurance system of medicines. Certification and licensing of the pharmaceutical market of Ukraine.

The structure of the state system for regulating the circulation of medicines. Registration of medicines as a mechanism for admission of drugs to use. Procedure for state registration (re-registration) of medicines in Ukraine. Differences in the procedure for registration of drugs in Ukraine and the EU. Regulatory framework for pharmacovigilance. The structure of pharmacovigilance in Ukraine. Certification and licensing as components of the permitting system in the field of economic activity. The role of the State Pharmacopoeia in the system of standardization and quality control of medicines.

Topic 4. Statistical methods of quality control.

The essence of statistical methods of quality control. Seven quality control tools: checklist, histogram, scatter plot, stratification method, Pareto chart, Isikawa causal chart, Schuhart control chart. Principles of their construction and application.

Topic 5. Regulation and documentation of pharmaceutical quality system processes.

Development of Guidelines for quality, documented procedures for the implementation of pharmaceutical quality system processes and standard operating procedures (SOP). The role of records (protocols) of the pharmaceutical quality system in data registration. Checking the compliance of the document management system of the pharmaceutical quality system.

Topic 6. Risk assessment for the quality of the drug at the stages of its life cycle.

Basic concepts and general scheme of risk management for quality. Goals and objectives of risk management The basic principles of risk management for the quality and types of risks of the pharmaceutical organization by the nature of the objects. The essence of the start of the risk management process for quality. The essence of general risk assessment. The essence of risk control. Risk information and risk review. Characteristics of the main methods and tools of risk analysis for the quality of pharmaceutical products.

Topic 7. Organization of activities for validation of production processes and qualification of equipment and auxiliary systems in organizations - subjects of the pharmaceutical market.

Basics of qualification and validation. Types of validation. Types of qualifications. Validation staffing. Validation documentation. Stages of qualification. Process validation. Validation of analytical methods. Validation of cleaning. Validation of computerized systems.

Topic 8. Internal audits (self-inspections) of pharmaceutical quality systems.

Basic components of modern models of quality management systems. The importance of audits in modern management systems. Classification of quality audits. Specifics of internal audits of quality management systems. Approaches to audit process management and program. Organization, documentary support, application of audit methods. Psychological and ethical aspects of audit. Corrective and preventive actions (SARA).

Questions for current and final control of students' knowledge and skills answer the questions of the extended plan of practical and seminar classes and independent work.

14. Recommended literature

Basic

1. Lecture material.
2. State Pharmacopoeia of Ukraine: in 3 volumes / State Enterprise "Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines". - 2nd type. - Kharkiv: State Enterprise "Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines", 2015.
3. SSU IEC / ISO 31010: 2013 Risk management. General risk assessment methods (IEC / ISO 31010: 2009, IDT). - [E-resource]. - Access mode: https://khoda.gov.ua/image/catalog/files/dstu %2031010.pdf.
4. Medicines. Process validation: ST-N MOZU 42-3.5: 2016 - [Effective from 2016-07-29]. - K.: МОЗ України, 2016. - 28 с. - (Instruction). - [E-resource]. - Access mode: http://old.moz.gov.ua/docfiles/dn_20160729_0802dod.pdf.
5. Medicines. Preclinical safety studies as a basis for human clinical trials and drug registration (ICH M3 (R2)): CT-H 42-6.0: 2014 - [Effective from 2014-09-19]. - K.: MHU, 2014. - 56 c. - (Instruction). - [E-resource]. - Access mode: https://dec.gov.ua//wp-content/uploads/attitude/n1.pdf
6. Medicines. Bioequivalence study: ST-N MOH 42-7.2: 2018 - [Valid from 2018-11-02]. - K.: МОЗ України, 2014. - 62 с. - (Instruction). - [E-resource]. - Access mode: https://dec.gov.ua//wp-content/uploads/attitude/1.pdf
7. Medicines. Good manufacturing practice: ST-N MOZU 42-4.0: 2016 - [Effective from 2016-07-01]. - K.: МОЗ України, 2016. - 332 с. - (Instruction). - [E-resource]. - Access mode: http://aipm.org.ua/wp-content/uploads/2016/08/GMP_42-4.0_2016.pdf
8. Medicines. Good distribution practice: ST-N MOZU 42-5.0: 2014 - [Effective from 2014-08-22]. - K.: МОЗ України, 2014. - 44 с. - (Instruction). - [E-resource]. - Access mode: http://bsc-gmp.com/uploads/files/news/60/gdp-anastanovaa-2014.pdf
9. Medicines. Good practice of promotion: ST-N MOZU 42-1.2: 2013 - [Effective from 2013-10-09]. - Kyiv: Ministry of Health of Ukraine, 2013. - 20 p. - (Instruction). - [E-resource]. - Access mode: https://zakon.rada.gov.ua/rada/show/v0870282-13/ed20131118
10. Medicines. Good regulatory practice: ST-N MOZU 42-1.1: 2013 - [Effective from 2015-05-21]. - K.: MHU, 2013. - 28 с. - (Instruction). - [E-resource]. - Access mode: https://gmpua.com/World/Ukraine/nastanova42112013.pdf
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