



MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
Faculty of pharmaceutical technology and management
Department of management and quality assurance in
pharmacy

METHODOLOGY AND LOGIC OF SCIENTIFIC RESEARCH

_____ (the name of educational component)

**WORK PROGRAM
of educational component**

training for _____ **Master** _____
(Higher Educational Level Name)
field of knowledge _____ **07 Management and administration** _____
(Code and Knowledge Field Name)
in specialty _____ **073 management** _____
(Code and Specialty Name)
of educational program _____ **Quality, standardization and certification** _____
(Educational Program Name)
specialization _____
(Specialization Name)

2023
year of creation

Work program of the educational component Methodology and logic of scientific research in specialty 073 management of educational program Quality, standardization and certification for applicants for higher education ___1___ year of study.


EDUCATIONAL COURSE TEAM: Litvinova O.V., professor of Department of management and quality assurance in pharmacy, Doctor of Pharmacy

(specify the LAST NAME, first name of the authors, their positions, scientific degrees and academic titles)

The work program has been considered and approved at the Meeting of Department of management and quality assurance in pharmacy

Record from « 01 » September 2023 № 1

Head of the Department



(signature)

Prof. Tatyana KRUTSKIKH
(surname and initials)

The work program has been approved at the meeting of the Methodical Commission of economic-managerial and social-humanitarian disciplines

Record from « 05 » September 2023 № 1

Head of Specialized Committee



(signature)

Prof. Alla NEMCHENKO
(surname and initials)

1. The Description of the educational component

The language of the study: English

Status of the educational component: compulsory subject.

Prerequisites for studying the educational component: The educational component “Methodology and logic of scientific research” is studied in combination with the study of such educational components as “Methodology, methods and tools of quality management”, “Information technology in quality management” and a number of others.

The subject of educational component study «Methodology and logic of scientific research» is theoretical, methodological, methodical bases of research activity, its technological, organizational, legal support.

Information volume of the educational component. _3_ECTS credit _90_hours are assigned to the study of the educational component.

2. Objectives and tasks of the educational component

The purpose of teaching the educational component «Methodology and logic of scientific research» is formation of knowledge on methodology, theory of method and process, psychology, methodological support of research activity, formation and improvement of such speech skills as English reading, speaking and writing, which will help improve the communicative competence of higher education students.

The **main tasks** of the educational component «Methodology and logic of scientific research» are a theoretical training on the issues: the essence of concepts and categories of scientific research methodology; organization of the process of scientific research; selection of objects of scientific research; application of theoretical and empirical research methods; research procedures, their content and development principles; planning of research works; development of stages and forms of the process of scientific research; mastering modern methods of research; registration of the results of scientific research and implementation of their medical and practice; information support of the process of scientific research; preparation of higher education applicants for effective communication in the professional environment, which will contribute to their competitiveness in the labor market.

3. Competence and planned educational outcomes

Educational component «Methodology and logic of scientific research» ensures the acquisition of applicants for higher education the following competences:

Integral competencies:

- the ability to solve complex specialized and practical problems characterized by the complexity and uncertainty of conditions in the field quality management, in the organizational and economic system of control, quality assurance, quality management, standardization, certification of products (goods, services) of the organization using theories and methods of social and behavioral sciences.

General competencies (GC):

GC 1. The ability to conduct research at the appropriate level;

GC 8. The ability to find, process and analyze information from various sources.

Professional competencies (PC):

PC 3. The ability for self-development, lifelong learning and effective self-management.

Integrative final program learning outcomes (PLO), the formation of which is facilitated by the educational component:

PLO 1. Critically comprehend, choose and use the necessary scientific, methodical and analytical tools for management in unpredictable conditions;

PLO 9. To be able to communicate in professional and scientific circles in state and foreign languages.

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

- principles of building science as an industry;
 - main categories of science;
 - regularities of science development;
 - methods and tools of scientific research organization;
 - methods of patent research;
 - types of intellectual property protection;
- be able to:*
- critically comprehend, choose and use the necessary scientific, methodical and analytical tools for management in unpredictable conditions;
 - be able to communicate in professional and scientific circles in state and foreign languages;
 - select objects and methods of scientific research;
 - search and analyze various sources of information;
 - conduct scientific research of systems and processes management;
 - apply modern techniques and methodological tools in scientific research;
 - plan and organize scientific experiments;
 - form questionnaires;
 - use automated information processing systems in scientific research;
 - compile reports on research work;
- have:*
- skills of analytical, statistical, computational, economic and mathematical methods;
 - skills of technologies for collecting the necessary information, statistical data processing, robot with databases.

4. The educational component structure

Names of content modules and topics	The amount of hours											
	full time study						part time study					
	the whole amount	Including					the whole amount	including				
L		sem.	p.l.	lab.	self-study	L		sem.	p.l.	lab.	self-study	
<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>	<i>6</i>	<i>7</i>	<i>8</i>	<i>9</i>	<i>10</i>	<i>11</i>	<i>12</i>	<i>13</i>
Content module 1. Methodology and logic of scientific research												
Topic 1. The specifics of scientific knowledge. Dialectical and logical bases of scientific knowledge	8	2		2		4	9	1		1		7
Topic 2. The place of scientific research in the life cycle of pharmaceutical products	8	2		2		4	9	1		1		7
Topic 3. Legal and regulatory framework governing scientific research	8	2		2		4	8	1				7
Topic 4. Levels and methods of scientific research. The main stages and forms of the scientific research process	8	2		2		4	9	1		1		7
Topic 5. Intellectual property in scientific research	8	2		2		4	9	1		1		7

Topic 6. Organization of scientific research work	8	2		2		4	8	1		1		6
Topic 7. Information support of scientific research	7	2		1		4	9	2		1		6
Topic 8. Presentation of scientific research results <i>Final Control of Content module 1</i>	15	5		4		6	9	2		1		6
The whole amount of hours for the content module 1	70	19		17		34	70	10		7		53
Semester differential supervision	20			2		18	20			1		19
<i>The whole amount of hours for the course</i>	90	19		19		52	90	10		8		72

5. Contents of the educational component

Content module 1. Methodology and logic of scientific research

Topic 1. The specifics of scientific knowledge. Dialectical and logical bases of scientific knowledge.

Science as a result and a special kind of cognitive activity of people. The concept of science. Classification of sciences. Science as a system of knowledge. Different types of Knowledge. Scientific hypothesis: species, functions. Laws of dialectics in scientific research. Formal logic in scientific knowledge. Logic in scientific knowledge. Law of thought. Law of Non-Contradiction. Law of Identity. Law of Excluded Middle.

Topic 2. The place of scientific research in the life cycle of pharmaceutical products.

The role of knowledge and information in modern society. The role of innovation in development. Classification of innovations. Innovative process. Priority directions for the development of medicines for the health system. Features of the innovative process associated with the development and launch of medicines.

Topic 3. Legal and regulatory framework governing scientific research.

Law of Ukraine on scientific and scientific and technology activities. Law of Ukraine on innovation activity. Law of Ukraine about the special mode of innovative activities of technology parks. The Strategy of Innovative Development of Economy of Ukraine till 2030. Ukrainian and International protection of intellectual property

Topic 4. Levels and methods of scientific research. The main stages and forms of the scientific research process.

Theoretical research. Deduction & Induction. Analysis and synthesis. An analogy. Abstraction. Historical method. Types and methodologies of empirical research. Survey research. Experimental research. Correlational research. Bibliometric analysis. One-on-one interview. Focus groups. Heuristic technique. Brainstorming. Method of focal objects. The main stages and forms of the scientific research process. Criteria for a good research topic. Steps for conducting empirical research

Topic 5. Intellectual property in scientific research.

Necessity of legal protection of intellectual property objects. The concept of intellectual property rights. The concept of industrial property. Copyright and related rights. Academic integrity. Plagiarism. Non-property and property rights of intellectual property subjects. Objects of industrial property rights, their variety, characteristics and features. The main criteria for the patentability of the invention. Place of Intellectual property in pharmacy.

Topic 6. Organization of scientific research work.

Research Process. Formulation of Research Problem. Extensive Literature Survey. Development of Working Hypothesis. Preparing the Research Design. Collecting the Data. Execution of the Project. Analysis of Data. Hypothesis Testing. Generalizations and Interpretation. Plagiarism. The concept of scientific activity, its types. Forms of organization of research activities. Legal status of the subjects of scientific and scientific and technology activities. Rights and obligations of Manager of a Scientific Institution. Academic (scientific, science/technology) Council of Scientific Institution. Attestation of Scientific Institutions and Research Workers.

Topic 7. Information support of scientific research.

Patent documentation as a source of scientific information in the implementation of developments. Types of Patent Search. Databases of industrial property objects. Information support of scientific research: Academic databases: Scopus, Web of Science, PubMed, Food and drug administration website, etc.

Topic 8. Presentation of scientific research results.

Systematization of research results. Presentation of conclusions and recommendations in the form of a scientific article, abstracts of the report. Requirements for a scientific article and a scientific report. Structure of research article for journal publication. Types of articles. Types of journals: Open Access (OA) Publishing, Fully copyrighted journals, Hybrid journals. Predatory journals. Journal Impact Factor, h- index. Effective presentation skills.

Semester differential supervision

6. Names of lectures

№	Name of topic	The amount of hours	
		full time study	part time study
1	Topic 1. The specifics of scientific knowledge. Dialectical and logical bases of scientific knowledge	2	1
2	Topic 2. The place of scientific research in the life cycle of pharmaceutical products	2	1
3	Topic 3. Legal and regulatory framework governing scientific research	2	1
4	Topic 4. Levels and methods of scientific research. The main stages and forms of the scientific research process	2	1
5	Topic 5. Intellectual property in scientific research	2	1
6	Topic 6. Organization of scientific research work	2	1
7	Topic 7. Information support of scientific research	2	2
8	Topic 8. Presentation of scientific research results	5	2
The whole amount of hours		19	10

7. Topics of practical lessons

№	Name of topic	The amount of hours	
		full time study	part time study
1	Topic 1. The specifics of scientific knowledge. Dialectical and logical bases of scientific knowledge	2	1
2	Topic 2. The place of scientific research in the life cycle of pharmaceutical products	2	1
3	Topic 3. Legal and regulatory framework governing scientific research	2	
4	Topic 4. Levels and methods of scientific research. The main stages and forms of the scientific research process	2	1
5	Topic 5. Intellectual property in scientific research	2	1
6	Topic 6. Organization of scientific research work	2	1
7	Topic 7. Information support of scientific research	1	1
8	Topic 8. Presentation of scientific research results <i>Final Control of Content module 1</i>	4	1
9	Semester differential supervision	2	1
The whole amount of hours		19	8

8. Topics of laboratorial lessons

Not provided by the curriculum

9. Self-study work

№	Name of topic	The amount of hours	
		full time study	part time study
1	Topic 1. The specifics of scientific knowledge. Dialectical and logical bases of scientific knowledge	4	7
2	Topic 2. The place of scientific research in the life cycle of pharmaceutical products	4	7
3	Topic 3. Legal and regulatory framework governing scientific research	4	7
4	Topic 4. Levels and methods of scientific research. The main stages and forms of the scientific research process	4	7
5	Topic 5. Intellectual property in scientific research	4	7
6	Topic 6. Organization of scientific research work	4	6
7	Topic 7. Information support of scientific research	4	6
8	Topic 8. Presentation of scientific research results <i>Final Control of Content module 1</i>	6	6
9	Semester differential supervision	18	19
The whole amount of hours		52	72

Tasks for self-study work

1. Prepare an abstract on the topic: «Branches of science».
2. Prepare an essay on the topic: «Philosophy of science».
3. Prepare a presentation on the topic: «Research in the field of pharmacy and medicine».
4. Prepare an essay on the topic «The roles of patents and research in pharmaceutical innovation».
5. Prepare an essay on the topic: «Patent term extensions: issues, challenges and implications for pharmaceuticals».
6. Prepare a presentation on the topic: «The concept of empirical and theoretical levels of scientific research».
7. Prepare an essay on the topic: «The concept of heuristics. Heuristic methods».
8. Prepare a presentation on the topic: «Research university, institute, center».
9. Prepare an essay on the topic: «Search systems in scientific research».
10. Prepare a presentation on the topic: «Logic in scientific research».
11. Prepare an essay on the topic: «Scientific journal: Requirements, types, Impact Factor».
12. Prepare a presentation on the topic: «Relevance of the implementation of project management in scientific research».

10. Criteria and evaluation order of educational outcomes

The evaluation of the educational component is determined taking into account the results of the current educational activity of the student of higher education and evaluations of his assimilation of individual modules.

The success of each applicant of higher education is evaluated on a 100-point scale.

A applicant of higher education can receive 60 points for the current educational activity within the module. The maximum number of points that a student of higher education can score during the completion of the final control, taking into account the points for independent work, is 40 points.

Assessment of current educational activity (carried out during each lesson) - control of theoretical knowledge, practical skills and abilities. When mastering each topic of content modules for the current educational activity, points for all types of activities are assigned to the applicants, which are added up at the end of studying the content module. Depending on the number of points scored, the applicant can receive a maximum of 60 points or a minimum of 35 points for studying the module in practical classes.

The following scoring system is used for tasks:

Evaluation system, points	Evaluation criteria
3	mark is put to the student, who: <ul style="list-style-type: none"> showed comprehensive, systematized, in-depth knowledge of the program material when answering theoretical questions orally or in writing and knew how to correctly interpret the obtained results; demonstrate knowledge of the main and additional literature provided at the level of creative use.
2	mark is put to the student, who: <ul style="list-style-type: none"> demonstrated full knowledge of the program material when answering a theoretical question provided at the level of analogical reproduction, but made some minor mistakes.
1	mark is put to the student, who: <ul style="list-style-type: none"> showed insufficient deep knowledge of the main program material when answering a theoretical question in writing.

Individual tasks (theses)

5-6	Theses are completed in full, structured, using the given list of literature. The work uses scientific works of domestic and foreign scientists, statistical, practical material on one of the problems in the field of pharmacy. The main issues of the topic are correctly, deeply and comprehensively considered. The text of theses is edited, without grammatical errors.
3-4	Unclear and insufficiently complete presentation of the material of the topic, errors in the design of the work, violation of the logical sequence in the presentation of the material.
1-2	Significant errors in the presentation of information, insufficient volume of work, not structured according to the plan, use of an insufficient number of literary sources, spelling errors, typos

Tests

Test control for each topic consists of 5 test tasks for each topic and is estimated at 0.3 points. Points are awarded automatically for each correct answer.

Control of the content module is carried out in the form of credit based on approved tickets. The module is considered to be passed if the student of higher education scored at least the minimum score.

The following scoring system is used to control the content module, the student can score min - 25 points, max - 40 points.

- 15 tests, one correct answer to a question is worth 1 point; 15 x 2 points = 30 points.
- 1 practical task - the applicant of higher education is assigned from 0 to 10 points (table).

When developing evaluation criteria, the completeness and correctness of the task are taken as a basis. In addition, the ability of the student of higher education to differentiate, integrate and unify knowledge is taken into account.

Table

Assessment scale of the practical part

Rating, points	Evaluation criteria
9-10	The practical task was completed by the student independently without errors, he is able to competently justify the presented results, skillfully operates with terminology based on in-depth knowledge of the material
7-8	The practical task was completed by the student without errors, the results were obtained in the justification, the student of higher education demonstrated knowledge of the material from the discipline, but made some insignificant errors
5-6	The practical task is completed, but the student of higher education does not know how to correctly interpret the obtained results
1-4	The practical task was not completed in full, with significant errors
0	The student could not complete the practical task

11. Forms of progress and semester supervision of academic achievements

Current control and semester supervision are used for control forms. The current control is carried out for each practical activity according to the specific goals of the topic, during the individual work of the teacher

with the student for those topics that the student studies independently and they do not belong to the structure of the practical classes.

It is using the score scale for learning each practical lesson of the module for student current educational activity. At the end of the study of the content module, the score is summed up taking into account the individual independent work of the students.

Modular final control is carried out upon completion of module study. Students who completed all types of works provided for by the curriculum are admitted to the final control, and at the study of the module they have scored a score of not less than the minimum. The form of final control is standardized and includes the control of theoretical and practical training.

Semester control is carried out in the form of a semester differentiated credit.

12. Methodological support

1. Educational program of educational component.
2. Work program of educational component.
3. Silabus of educational components.
4. Calendar and thematic plans of lectures and practical classes.
5. Methodical materials of computer presentations of lectures.
6. Methodical recommendations for practical studies.
7. Methodological recommendations for independent work.
8. List of theoretical questions to the final module control.
9. Ticket package of content module check.
10. Test tasks.

13. Reading suggestions

The main reading suggestions

1. Посилкіна О. В. Методологія наукових досліджень та інноваційний розвиток : навч. посіб. / О. В. Посилкіна, О. В. Літвінова, Ю. С. Братішко - Х. : НФаУ, 2020. – 220 с.
2. Prabhat Pandey, Meenu Mishra Pandey. Research methodology: tools and techniques. – Bridge Center, 2015. – 99 p.
3. Посилкіна, О. В. Управління інноваційною діяльністю : навч. посіб. для здобувачів вищої освіти, які навчаються за ОПП «Фармація» / О. В. Посилкіна, О. В. Літвінова, Ю. С. Братішко. - Х. : НФаУ, 2018. – 270 с.
4. Litvinova E.V., Posilkina O.V., Krutskikh T.V., Kovalenko S.M. Methodology and logic of scientific research : method. recommend. for practical studies for students of educational programs “Quality, standardization and certification”, “Healthcare management and pharmaceutical business”. – Kharkiv: NUPh, 2023. – 30 p.
5. Litvinova E.V., Posilkina O.V., Krutskikh T.V., Kovalenko S.M. Methodology and logic of scientific research : method. recommend. for seminars for students of educational programs “Quality, standardization and certification”, “Healthcare management and pharmaceutical business”. – Kharkiv: NUPh, 2023. – 18 p.
6. Litvinova E.V., Posilkina O.V., Krutskikh T.V., Kovalenko S.M. Methodology and logic of scientific research : method. recommend. for the individual work for students of educational programs “Quality, standardization and certification”, “Healthcare management and pharmaceutical business”, “Business economics”. – Kharkiv: NUPh, 2023. – 28 p.

Supplementary reading suggestions

1. Закон України «Про науку і науково-технічну діяльність» № 1977-ХІІ від 13.12.91 р. – [Електронний ресурс] – Режим доступу: <http://zakon.rada.gov.ua> - Заголовок з екрану.
2. Закон України «Про інноваційну діяльність» від 04.07.2002 р. № 40-ІV, із змінами та доповненнями [Електронний ресурс] – Режим доступу: <http://zakon.rada.gov.ua> - Заголовок з екрану.
3. Закон України «Про лікарські засоби» від 04.04.96 р. № 124-96 із змінами та доповненнями [Електронний ресурс] – Режим доступу: <http://zakon.rada.gov.ua> - Заголовок з екрану.

4. Закон України «Про охорону прав на винаходи і корисні моделі» від 15.12.93 р. № 3687-ХІІ, із змінами та доповненнями [Електронний ресурс] – Режим доступу: <http://zakon.rada.gov.ua> - Заголовок з екрану.
5. Agreement on trade-related aspects of intellectual property rights. URL: https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.
6. Posylkina O. V. Patent science. Manual (abstract of lectures) for foreign students in speciality 8.110201 «Pharmacy» / O.V. Posylkina, E.V. Litvinova. – Kharkiv: NUPh «Golden Pages», 2012. – 164 p.
7. Litvinova O, Klager E, Yeung AWK, Tzvetkov NT, Kimberger O, Kletecka-Pulker M, Willschke H and Atanasov AG (2023), Bibliometric analysis and evidence of clinical efficacy and safety of digital pills. Front. Pharmacol. 14:1023250. <https://doi.org/10.3389/fphar.2023.1023250>
8. Litvinova O, Klager E, Tzvetkov NT, Kimberger O, Kletecka-Pulker M, Willschke H, et al. Digital Pills with Ingestible Sensors: Patent Landscape Analysis. Pharmaceuticals (Basel). 2022 Aug 19;15(8):1025. <https://doi.org/10.3390/ph15081025>

14. Electronic resources, including the Internet

1. Офіційний сайт бібліотеки ім. Вернадського [Електронний ресурс]. – Режим доступу: <http://nbuv.gov.ua/>
2. Web of science [Електронний ресурс]. – Режим доступу: <https://mjl.clarivate.com/home?PC=MASTER&Full=Baltic%20Journal%20of%20Economic%20Studies>
3. Scopus[Електронний ресурс]. – Режим доступу: <https://www.elsevier.com/solutions/scopus/how-scopus-works/content>
4. PubMedCentral (PMC) <http://www.pubmedcentral.nih.gov/about/openftlist.html>
5. Центр дистанційних технологій навчання НФаУ [Електронний ресурс]. – Режим доступу: <http://www.pharmel.kharkiv.edu>
6. Офіційний сайт кафедри управління та забезпечення якості у фармації НФаУ [Електронний ресурс]. – Режим доступу: <https://quality.nuph.edu.ua/>
7. Офіційний сайт Наукової бібліотеки НФаУ [Електронний ресурс]. – Режим доступу: <http://lib.nuph.edu.ua/>