DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY
Department of Toxicological and Analytical Chemistry

APPROVED
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CURRICULUM ON THE OPTIONAL DISCIPLINE
MODERN ANALYTICAL LABORATORY PRACTICE

for students of the second year of the the Pharmacy Faculty

training of specialists of the second (master's) level of higher education
educational qualification «Master of Pharmacy»
education sector 22 «Public Healthcare»
Specialty 226 "Pharmacy, Industrial Pharmacy"

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INTRODUCTION

The curriculum of the optional discipline "**Modern analytical laboratory practice",**
is made in accordance the draft Standard of Higher Education of Ukraine for the training of specialists of *the second (master's) level*
education sector 22 " Public Healthcare"
specialty 226 " *Pharmacy, Industrial Pharmacy* "
educational program of *Master of Pharmacy*

DESCRIPTION OF THE DISCIPLINE (ABSTRACT)

The optional discipline "Modern Analytical Laboratory Practice" is designed to be studied by students of higher educational institutions of the pharmaceutical profile of Ukraine and is an integral part of the state standard of education.

According to the curriculum for the preparation of pharmacists at the educational and qualification level "Master", the study of the discipline is carried out in the 2nd year (full-time) which is allocated: 60 hours, the distribution of which is as follows: lectures -10 hours, practice -20 hours , individual students work - 60 hours.

The curriculum contains the necessary list of knowledge, skills and abilities, taking into account the international requirements for the credit transfer system, international regulations and standards governing the professional activities and training of masters of pharmacy.

Modern analytical laboratory practice is a training course that includes mastering a set of criteria that provide a basis for the correct assessment of results and conclusions obtained during laboratory research and management of laboratory research.

The structure of the discipline	**Number of credits, hours**				**Year of study / semester**	**Type of control**
	Total credits / hours	**Classroom hours**		**ISW**		
		Lectures (hours)	Practical classes (hours)			
Modern analytical laboratory practice 1 semantic module	**3.0 credits / 90 hours**	**10**	**20**	**60**	**2nd course (3-4 terms)**	**Credit**

The subject of study of the discipline are::
- organizational structure and staff of analytical control laboratories;
- system of receipt of samples for research and analysis;
- test system;
- evaluation of test results;
- rules of storage of samples;
- requirements for reagents and standard samples;
- tools and their calibration;
- safety issues in laboratories.

Interdisciplinary links:*:*
Modern analytical laboratory practice as a discipline::
a) is based on knowledge of mathematics, physics and inorganic chemistry;
b) lays the foundations for the study of analytical, pharmaceutical and toxicological chemistry and provides for the formation of skills in the application of acquired knowledge for the study of special disciplines and in professional activities.

1. The purpose and objectives of the discipline

1.1. The purpose of the discipline "Modern analytical laboratory practice" is to provide students with the necessary theoretical knowledge and practical skills to apply national and international standards relating to the organization of chemical analytical laboratories for quality control of medicines; assessing

the suitability of analysis methods, their reproducibility and establishing the limits of uncertainty of the obtained measurement results.

1.2. The main tasks of studying the discipline "Modern analytical laboratory practice" are to teach students the features of the system of production laboratory, knowledge of state and international standards, assessment of the suitability of methods of analysis; the ability to use national and international standards, conducting the necessary chemical and analytical studies, selecting the most appropriate methods of analysis, effectively determining the accuracy of the measurement results.

1.3. **Competences and learning outcomes**, the formation of which is facilitated by the discipline (relationship with the normative content of training of higher education, formulated in terms of learning outcomes in the Standard).

In accordance with the requirements of the standard, the discipline "**Modern analytical laboratory practice**" provides students with the acquisition of competencies:

integral:

- ability to solve typical and complex specialized problems and practical problems in the learning process, which involves research, innovation and is characterized by complexity and uncertainty of conditions and requirements;

general:

– the ability to apply knowledge in practical situations (GC-2);
– striving to preserve the environment (GC-3);
– the ability to abstract thinking, analysis and synthesis, the ability to learn and be modernly educated (GC-4);
– knowledge and understanding of the subject area and understanding of the profession (GC-6);
– ability to adapt and act in a new situation (GC-7);
– the ability to communicate in the state language both orally and in writing, the ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity (GC-8);
– the ability to choose a communication strategy, the ability to work in a team, interpersonal skills (GC-10);
– the ability to evaluate and ensure the quality of performed works (GC-11);
– the ability to conduct research at the appropriate level (GC-12);
- the ability to preserve and multiply the moral, cultural, scientific values and achievements of society based on an understanding of the history and patterns of development of the subject area, its place in the general system of knowledge about nature and society and in the development of society, techniques and technologies, to use different types and forms of motor activity for active recreation and leading a healthy lifestyle (GC-14).

special (professional, subject):

- the ability to consult on prescription and non-prescription drugs and other products of the pharmacy assortment; pharmaceutical care during the selection and sale of an over-the-counter medicinal product by assessing the risk/benefit ratio, compatibility, indications and contraindications guided by data on the health status of a specific patient, taking into account the biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical features of the medicinal product and other products of the pharmacy assortment (PC-2);
- the ability to ensure the rational use of prescription and non-prescription drugs and other products of the pharmacy assortment in accordance with the physicochemical, pharmacological characteristics, biochemical, pathophysiological features of a specific disease and pharmacotherapeutic schemes of its treatment (PC-4);
- the ability to monitor the effectiveness and safety of the use of medicinal products by the population according to the data on their clinical and pharmaceutical characteristics, as well as taking into account subjective signs and objective clinical, laboratory and instrumental criteria for the examination of the patient (PC-5);
– the ability to identify medicinal products, xenobiotics, toxins and their metabolites in biological fluids and tissues of the body, to conduct chemical and toxicological studies for the purpose of diagnosing acute poisoning, drug and alcohol intoxication (PC-6);
– the ability to ensure proper storage of medicines and other pharmacy products in accordance with their physical and chemical properties and the rules of Good Storage Practice (GSP) in health care institutions (PC-7);
- the ability to organize and participate in the production of medicinal products in the conditions of pharmaceutical enterprises, including the selection and justification of the technological process, equipment

in accordance with the requirements of Good Manufacturing Practice (GMP) with the appropriate development and execution of the necessary documentation. Determine the stability of medicinal products (PC-15);
- the ability to organize and carry out quality control of medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and proper practices in pharmacy, to determine sampling methods for the control of medicinal products and to carry out their standardization in accordance with current requirements, to prevent the distribution of falsified medicinal products (PC-19) ;
- the ability to develop methods of quality control of medicinal products, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances using physical, chemical, physico-chemical, biological, microbiological, pharmacotechnological and pharmaco-organoleptic control methods (PC-20).

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

Competence Matrix

№	Competence	Knowledge	Skills	Communication	Autonomy and responsibility
1	2	3	4	5	6
Integral competence					
Ability to solve typical and complex specialized problems and practical problems in professional activities in the field of health care, or in the learning process, which involves research and / or innovation and is characterized by complexity and uncertainty of conditions and requirements					
General competencies					
1	GC-2 Ability to apply knowledge in practical situations	Have specialized conceptual knowledge acquired in the learning process	To be able to solve complex tasks and problems that arise in professional activity.	Clear and unambiguous presentation of one's own conclusions, knowledge and explanations, which justify them to specialists and non-specialists	Be responsible for making decisions in difficult conditions
2	GC-3 Striving to preserve the environment	To know the problems of environmental preservation and the ways of its preservation	To be able to form requirements for oneself and others regarding the preservation of the environment	Make proposals to relevant bodies and institutions regarding measures to preserve and protect the environment	To be responsible for the implementation of environmental protection measures within the framework of one's competence
3	GC-4 Ability to abstract thinking, analysis and synthesis, ability to learn and be modernly educated	Know the methods of analysis, synthesis and further modern education	Be able to analyze information, make informed decisions, be able to acquire modern knowledge	Establish appropriate connections to achieve goals	Be responsible for timely acquisition of modern knowledge
4	GC-6 Knowledge and understanding of the subject area and	Have in-depth knowledge of the structure of	To be able to carry out professional	The ability to effectively form a communication	To be responsible for professional

	understanding of the profession	professional activity	activities that require updating and integration of knowledge	strategy in professional activities	development, the ability for further professional training with a high level of autonomy
5	GC-7 Ability to adapt and act in a new situation	Know ways of self-regulation, leading a healthy life and adaptation in a new situation	To be able to apply means of self-regulation, to be able to lead a healthy lifestyle and adapt to new situations of life and activity	Establish appropriate connections to achieve results	Be responsible for a healthy lifestyle and timely use of self-regulation methods
6	GC-8 The ability to communicate in the state language both orally and in writing, the ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity	Have perfect knowledge of the native language and basic knowledge of a foreign language	To be able to apply knowledge of the native language, both orally and in writing, to be able to communicate in a foreign language	Use your native language in professional and business communication and when preparing documents. Use a foreign language in professional activities	To be responsible for fluency in one's native language, for the development of professional knowledge
7	GC-10 Ability to choose a communication strategy; ability to work in a team; interpersonal skills	To know communication tactics and strategies, laws and methods of communicative behavior	Be able to choose methods and strategies of communication to ensure effective teamwork	Use communication strategies and interpersonal skills	To be responsible for the choice and tactics of the method of communicatio n
8	GC-11 Ability to evaluate and ensure the quality of the work performed	Know the methods of evaluating performance quality indicators	Be able to ensure quality performance of work	Establish connections to ensure quality performance of work	To be responsible for quality performance of works
9	GC-12 Ability to conduct research at the appropriate level	Know the responsibilities and ways of performing assigned tasks	To be able to determine the goal and task, to be persistent and conscientious in the performance of duties	Establish interpersonal relationships for effective performance of tasks and responsibilities	Be responsible for conducting research at the appropriate level
10	GC-14 Ability to preserve and multiply moral, cultural, scientific values and achievements of society based on understanding the history and patterns of	To know, preserve and multiply the moral, cultural, scientific values and achievements of society	To be able to use cultural, scientific values and achievements of society in professional	Use scientific, cultural, moral values in professional activities. Apply various types and forms of motor	To be responsible for the preservation and multiplication of moral,

	development of the subject area, its place in the general system of knowledge about nature and society and in the development of society, techniques and technologies, use different types and forms motor activity for active recreation and leading a healthy lifestyle		activities, to be able to use various forms of motor activity for active recreation and leading a healthy lifestyle	activity for active recreation and leading a healthy lifestyle	cultural, scientific values and achievements of society on the basis of understanding the history and patterns of development of the subject area, its place in the general system of knowledge about nature and society and in the development of society, engineering and technology. To be responsible for a healthy lifestyle.
Special (professional, subject) competencies					
1	PC-2 Ability to provide advice on prescription and non-prescription drugs and other products of the pharmacy assortment; pharmaceutical care during the selection and sale of an over-the-counter medicinal product by assessing the risk/benefit ratio, compatibility, indications and contraindications guided by data on the health status of a specific patient, taking into account the biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical features of the medicinal product and other products of the pharmacy assortment	To provide high-quality pharmaceutical care during the selection and sale of an over-the-counter medicinal product, to take into account the biopharmaceutical , physicochemical properties of the medicinal product	Be able to advise on prescription and non-prescription drugs. To be able to provide high-quality pharmaceutical care.	Use acquired skills for high-quality and professional provision of pharmaceutical care	To be responsible for the quality of the provided pharmaceutical care
2	PC-4 The ability to ensure the rational use of prescription and non-prescription drugs and	Know the rational use of prescription and non-prescription	Be able to use medicines rationally	Use acquired skills for rational use of medicines	To be responsible for making certain decisions

	other products of the pharmacy assortment in accordance with the physico-chemical, pharmacological characteristics, biochemical, pathophysiological features of a specific disease and pharmacotherapeutic schemes of its treatment	drugs according to the specifics of a particular disease			about the use of medicines for a specific disease
3	PC-5 The ability to monitor the effectiveness and safety of the use of medicinal products by the population according to the data on their clinical and pharmaceutical characteristics, as well as taking into account subjective signs and objective clinical, laboratory and instrumental criteria for the examination of the patient	Monitor the effectiveness and safety of the use of medicinal products by the population	Be able to evaluate the effectiveness and safety of medicinal products in relation to their clinical and pharmaceutical characteristics	Reasonably evaluate the results of monitoring the effectiveness and safety of the use of medicinal products by the population	Be responsible for making certain decisions regarding the monitoring of the safety of medicinal products
4	PC-6 The ability to determine medicinal products, xenobiotics, toxins and their metabolites in biological fluids and body tissues, to conduct chemical and toxicological studies for the purpose of diagnosing acute poisoning, drug and alcohol intoxication	Qualitatively determine medicinal products, xenobiotics, toxins and their metabolites in biological fluids and body tissues for the purpose of diagnosing poisonings	To be able to carry out chemical and toxicological studies for the purpose of diagnosing acute poisoning	Reasonably evaluate the results of chemical and toxicological studies	To be responsible for conducting chemical and toxicological research
5	PC-7 Ability to ensure proper storage of medicines and other pharmacy products in accordance with their physico-chemical properties and the rules of Good Storage Practice (GSP) in healthcare facilities	Have specialized knowledge on the storage of medicinal products	To be able to properly store medicinal products according to their physical and chemical properties	Use acquired skills for rational storage of medicines	Be responsible for proper storage of medicines
6	PC-15 The ability to organize and participate in the production of medicinal products in the conditions of pharmaceutical	To participate in the production of medicinal products in the conditions of pharmaceutical	Be able to produce medicinal products, including the selection and	Use the acquired knowledge for the production of medicines	To be responsible for making decisions regarding the production of

	enterprises, including the selection and justification of the technological process, equipment in accordance with the requirements of Good Manufacturing Practice (GMP) with the appropriate development and preparation of the necessary documentation. Determine the stability of medicines	enterprises	justification of the technological process, equipment in accordance with the requirements of Good Manufacturing Practice. To be able to determine the stability of medicines		medicinal products
7	PC-19 Ability to organize and carry out quality control of medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and proper practices in pharmacy, to determine sampling methods for medicinal product control and to carry out their standardization in accordance with current requirements, to prevent the distribution of falsified medicinal products	Know the requirements of the State Pharmacopoeia of Ukraine and proper practices in pharmacy	Be able to control the quality of medicines	Use the acquired knowledge to control the quality of medicines	Be responsible for preventing the distribution of falsified medicinal products
8	PC-20 Ability to develop methods of quality control of medicinal products, including active pharmaceutical ingredients, medicinal plant raw materials and auxiliary substances using physical, chemical, physico-chemical, biological, microbiological, pharmacotechnological and pharmaco-organoleptic control methods	Know the methods of quality control of medicinal products	Be able to develop methods of quality control of medicinal products, medicinal plant raw materials, auxiliary substances	To substantiate the chosen methods of drug analysis in the conditions of a pharmacy and a pharmaceutical enterprise	To be responsible for the organization, provision and quality control of medicinal products in the conditions of a pharmacy and a pharmaceutical enterprise

Learning outcomes:
Integrative final program learning outcomes, the formation of which is facilitated by the educational discipline "Modern Analytical Laboratory Practice":
general and professional:
- to carry out professional activities in social interaction based on humanistic and ethical principles; identify future professional activities as socially significant for human health;

- perform professional activities using creative methods and approaches;
- carry out professional communication in the state language, use oral communication skills in a foreign language, analyzing specialized texts and translating foreign language information sources;
- analyze information obtained as a result of scientific research, generalize, systematize and use it in professional activities;
- determine the advantages and disadvantages of drugs of various pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic and pharmacodynamic characteristics. Recommend to consumers over-the-counter medicinal products and other products of the pharmacy assortment with the provision of advisory assistance and pharmaceutical care;
- choose biological objects of analysis, determine xenobiotics and their metabolites in biological environments and evaluate the results obtained taking into account their distribution in the body;
- implement a complex of organizational and management measures to provide the population and health care institutions with medicines and other products of the pharmacy assortment. Carry out all types of accounting in pharmacies, administrative records, product analysis processes;
- promote health preservation, in particular disease prevention, rational prescription and use of medicines. To faithfully fulfill one's professional duties, to comply with the legislation on the promotion and advertising of medicinal products. Possess psychological communication skills to achieve trust and mutual understanding with colleagues, doctors, patients, consumers;
- justify the technology and organize the production of medicinal products at pharmaceutical enterprises and draw up technological documentation for the production of medicinal products at pharmaceutical enterprises;
- to ensure quality control of medicinal products and document its results. Manage quality risks at all stages of the life cycle of medicinal products;
- to determine the main organoleptic, physical, chemical, physicochemical and pharmacotechnological indicators of medicinal products, justify and choose methods of their standardization, carry out statistical processing of the results in accordance with the requirements of the current State Pharmacopoeia of Ukraine.

Learning outcomes for the discipline "Modern analytical laboratory practice"

To know:

- subject and tasks of modern analytical laboratory practice;
- organization of quality control of finished drugs and medicinal substances;
- methods of quality improvement and improvement of analysis methods;
- main validation characteristics of analytical control methods;
- features of unification of quality control methods.

To be able:

- work with regulations to ensure quality control of analytical laboratories;
- take and prepare samples for analysis;
- use standard compounds in the development of methods of analysis;
- to carry out validation of analytical methods.

2. Information volume of the discipline. 3 ECTS credit / 90 hours are allocated for the study of the academic discipline.

Content module 1. "Organization of quality of chemical-analytical measurements"

Topic 1. Basic principles of quality management system in laboratories.

The importance of quality management system; characteristics of the main elements of the quality management system; history of development of quality principles; the relationship of the quality management model with the requirements of international standards. Standards for laboratories, general provisions on standards (ISO 9001, ISO / IEC17025, ISO 15189, GLP). Provisions of the standard.

Topic 2. Preparation for analysis.

Factors to consider when choosing a method of analysis. Obtaining information about the acceptability of the method. Determining the cause of unsatisfactory results.

Topic 3. Validation of analytical methods.

Scheme of the validation process; determining the appropriate level of validation; selectivity; precision; offset (correctness); measurement range, detection limit (LOD) and limit of quantification (LOQ). Validation report and documentation.

Topic 4. Correctness of measurements.

Good laboratory practice: pre-analytical stage; analysis; after analysis. The importance of calibration in chemical analysis.

Topic 5 Rules for quality control.
Single samples; control samples; re-execution of tests; blind samples; chemical standards and additives. Laboratory environment: factors that affect quality; laboratory planning; equipment placement; change monitoring.

Topic 6. Data processing. Uncertainty of measurements.
Values of the main statistical parameters used to describe the data set. The terms "uncertainty", "error", "precision", "offset", "accuracy". Application of a systematic approach in estimating uncertainty. Measurement process; the concept of uncertainty; errors (random, systematic). Precision, offset and accuracy. Use of uncertainty.

Topic 7. Laboratory proficiency testing programs.
Organization of laboratory qualification assessment programs. Combination of z-indices. Interpretation of numerical estimates. Robust statistics. Benefits of participating in LT programs.

3. The structure of the discipline

Topic	Number of hours			
	Lectures	Practice	ISW	ITasks
1	2	3	4	5
Content module 1. **"Organization of quality of chemical-analytical measurements"**				
Topic 1. Basic principles of quality management system in laboratories.	**2**	2	9	
Topic 2. Preparation for analysis	**2**	2	8	
Topic 3. Validation of analytical methods.	**2**	3	9	
Topic 4. Correctness of measurements.	1	2	8	
Topic 5. Rules of quality control.	1	2	9	
Topic 6. Data processing. Uncertainty of measurements.	1	2	8	
Topic 7. Laboratory proficiency testing programs.	1	3	9	
Final lesson of the practical course	-	2	-	
Enrollment of independent student work. Credit lesson	-	2	-	
Total	10	20	60	

4. Thematic plan of lectures

№	TOPIC	Number of hours
Content module 1. Organization of quality of chemical-analytical measurements		
1	Basic principles of quality management system in laboratories: the importance of the quality management system; characteristics of the main elements of the quality management system; history of development of principles	**2**

	quality; the relationship between the quality management model and the requirements international standards. Laboratory environment: factors that affect quality; laboratory planning; equipment placement; change monitoring.	
2	Sampling. The importance of sampling. Identification of sample types. The essence and significance of sampling plans. Regulatory and legal requirements. Types of sampling: probable sampling, non-random sampling, sampling bulk materials sampling of acceptance control.	**2**
3	Preparation for analysis. Factors to consider when choosing a method of analysis. Obtaining information about the acceptability of the method. Determining the cause of unsatisfactory results. Rules of quality control: blank samples; control samples; re-execution of tests; blind samples; chemical standards and additives.	**2**
4	Validation of analytical methods: scheme of validation process; determining the appropriate level of validation; selectivity; precision; bias (correctness); measurement range, detection limit (LOD) and limit of quantification (LOQ). Validation report and documentation.	**2**
5	Data Processing. The values of the basic statistical parameters used to describe the set in the data. The terms "uncertainty", "error", "precision", "offset", "accuracy". Application systematic approach in estimating uncertainty.	**2**
	Total	**10**

5. Thematic plan of seminars

№	**Topic**	**Number of hours**
Content module 1. Organization of quality of chemical-analytical measurements		
1.	Organization of the quality management system in the laboratory: the role of staff in the quality management system; development of a plan for checking the competence of staff; sequence of actions for assessing and maintaining the competence of staff; analysis of potential problems with customers; methods of measuring satisfaction. Responsibility of laboratory staff for quality: responsibility of management for quality; responsibilities of the quality manager; responsibilities of individuals employees.	4
2.	Number of samples and sample size: uncertainty of sampling, number of primary samples. Subsample selection: subsample selection technique. The importance of proper sample preparation and storage.	4
3.	Performance characteristics of the methods used for analysis. Performance characteristics of selected methods for determination of analytes: separation by thin layer chromatography; separation by gas or liquid chromatography. Causes of incorrect analytical results. Choice of appliances, glassware and equipment: suitability; equipment qualification; contamination cleaning and drying.	4
4	Carrying out metrological traceability: samples of comparison; chemical standards.	4
5	Application of statistical methods in laboratory proficiency testing programs. Target value: certified CRM value; set value; agreed value from expert laboratories; agreed value from participants' laboratories.	4
	Total	20

6. Thematic plan of independent work

№	**Topic**	**Number of hours**	**Type of control**

1	Responsibility of laboratory staff and management for the quality of experimental research	6	Current ccontrol at practi-cal classes
2	Laboratory equipment, its selection and qualification.	6	
3	Control of the purity class of chemical reagents and labeling in the analytical laboratory. Chemical standards, their choice.	6	
4	Good laboratory practice. The value of the pre-analytical stage of laboratory work.	6	
5.	The importance of sampling. What are the types of sample identification	6	
6.	Stages and stages of analytical laboratory work.	6	
7.	Rules for checking the linearity of quantitative methods. Research of stability of a technique of the analysis.	6	
8.	Application of statistical methods in laboratory proficiency testing programs (target range: set value; predicted value; results joint research).	6	
9.	Rules for checking the reproducibility of quantitative methods.	6	
10.	Validation of methods and determination of the required level of validation characteristics.	6	
	Total	**60**	

7. Individual tasks for full-time students are not provided.

Tasks for independent work

1. What are the requirements for documentation, staff of the control and analytical laboratory contains DSTU ISO 17025: 2006?
2. Explain the importance of sampling. What are the types of sampling? Give them a definition. Sampling plans.
3. The value of the number of samples and sample size on the quality of the results of analytical methods.
4. How is metrological traceability in the analytical laboratory?
5. Validation of methods and determination of the required level
6. Laboratory environment and factors that affect the quality of measurements.
7. Laboratory equipment, its selection and qualification.
8. What is a standard operating procedure? Specify the basic requirements for a proper SOP.
9. Control of the purity class of chemical reagents and labeling in the analytical laboratory.
10. Rules for quality control of reagents and methods of analysis.
11. The quality assurance program is necessary to improve the reliability, efficiency and use of laboratories to achieve the required technical quality of laboratory diagnostics.
12. Retrospective and perspective activity of laboratories

8. Teaching methods

In the process of studying the discipline "Modern analytical laboratory practice" the following teaching methods are used:

- explanatory-illustrative - (verbal and visual - lectures, theoretical part of the seminar);
- partial search method - preparation for a seminar, testing, monitoring the performance of independent work;
- research method - performing experimental work.

Preference is given to active and interactive methods and multimedia learning (multimedia lectures, educational films).

9. Control methods

Current control is carried out at each practical lesson in accordance with the specific objectives of the topic. All practical classes use objective control over the performance of independent work, theoretical training and the acquisition of practical skills.

The following means of diagnosing the level of preparation of students are used: testing, solving situational problems, conducting laboratory research, interpretation and evaluation of their results, control of practical skills.

At each practical lesson the student answers test tasks (on the topic of practical lesson, standardized questions, knowledge of which is necessary to understand the current topic, lecture course and independent work related to the current lesson; demonstrates knowledge and skills of practical skills according to the practical lesson). The following means of control of level of preparation of students are applied:

- oral examination and written assignments,
- solving situational problems,
- checking the ability to interpret and evaluate the results of various methods of quantitative determination of medicinal substances, control of practical skills.

10. ***Forms of current control:***

1. Theoretical knowledge - individual surveys, interviews;

2. Practical skills and abilities - solving typical and situational problems and control of practical actions.

Final control is carried out on the basis of control of theoretical knowledge, practical skills and abilities.

10.1 Evaluation of current educational activities. Current control during training is carried out by standardized control methods, including control of theoretical and practical training. At each practical lesson, the student answers 10 tests, 5 questions on the topic of the practical lesson, knowledge of which is necessary to understand the current topic, lecture course questions and independent work related to the current lesson.

At each lesson, the level of students' knowledge is assessed on a 4-point scale ("5", "4", "3", "2") in accordance with the criteria for assessing the current activities of the student. The obtained scores are converted into appropriate points.

Distribution of points received by students

Current control is carried out at each seminar. In each lesson, the student answers 10 tests and 5 questions on the topic of the seminar, the knowledge of which is necessary to understand the current topic, the issues of the lecture course and independent work related to the current lesson; demonstrates knowledge and skills of practical skills in accordance with the topic of practical training.

Evaluation criteria

Current control. At each lesson, the level of students' knowledge is assessed on a 4-point scale

Excellent ("5"). The student correctly, clearly, logically and fully answers the standardized questions of the current topic, including questions of independent work. Closely connects theory with practice and correctly demonstrates the performance (knowledge) of practical skills. Freely solves situational problems of increased complexity, is able to summarize the material.

Good ("4"). The student correctly and essentially answers the standardized questions of the current topic, independent work. Demonstrates performance (knowledge) of practical skills. Correctly uses theoretical knowledge in solving practical problems. Is able to solve easy and medium situational problems. Has the necessary practical skills and techniques to perform them in excess of the required minimum.

Satisfactory ("3"). The student incompletely, with the help of additional questions, answers the standardized questions of the current topic, lecture course and independent work. Cannot build a clear, logical answer on their own. During the answer and demonstration of practical skills the student makes mistakes. The student solves only the easiest problems, has only a mandatory minimum of research methods.

Unsatisfactory ("2"). The student does not know the material of the current topic, can not build a logical answer, does not answer additional questions, does not understand the content of the material. Makes significant, gross mistakes when answering and demonstrating practical skills.

11. The form of final control of academic performance in the study of the optional discipline is a credit. The final control consists of a written answer to the test tasks of format A (blank). The student answers 40 test tasks of format A on each topic of the module and is evaluated with 2 points for each correct answer.

The credit score is determined by the sum of points for answers to test tasks. The maximum number of points in the test is 80. The minimum number of points is 50.

12. Scheme of accrual and distribution of points received by students:

The maximum number of points that a student can receive for the current activity is 200 points.

The minimum number of points that a student can score for the current activity for the test is 120 points.

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

$$x = \text{CA} \times 120 / 5.$$

Recalculation of the average score for current activities in a multi-point scale is based on the table:

Recalculation of the average score on "Modern analytical laboratory practice" for the current activity into a multi-scale scale:

4-point rate	**5**	**4.97**	**4.95**	**4.92**	**4.9**	**4.87**	**4.85**	**4.82**	**4.8**	**4.77**	**4.75**	**4.72**	**4.7**
200-point rate	200	199	198	197	196	195	194	193	192	191	190	189	188
4-point rate	**4.67**	**4.65**	**4.62**	**4.6**	**4.57**	**4.52**	**4.47**	**4.45**	**4.42**	**4.4**	**4.37**	**4.35**	**4.32**
200-point rate	187	186	185	184	183	181	180	178	177	176	175	174	173
4-point rate	**4.3**	**4.27**	**4.24**	**4.22**	**4.19**	**4.17**	**4.14**	**4.12**	**4.09**	**4.07**	**4.04**	**4.02**	**3.99**
200-point rate	172	171	170	169	168	167	166	165	164	163	162	161	160
4-point rate	**3.97**	**3.94**	**3.92**	**3.89**	**3.87**	**3.84**	**3.82**	**3.79**	**3.77**	**3.74**	3.**72**	3.**7**	3.**67**
200-point rate	159	158	157	156	155	154	153	152	151	150	149	148	147
4-point rate	**3.65**	**3.62**	**3.57**	**3.55**	**3.52**	**3.5**	**3.47**	**3.45**	**3.42**	**3.4**	3.**37**	3.**35**	3.**32**
200-point rate	146	145	143	142	141	140	139	138	137	136	135	134	133
4-point rate	**3.3**	**3.27**	**3.25**	**3.22**	**3.2**	**3.17**	**3.15**	**3.12**	**3.1**	**3.07**	3.**02**	3	**Less than 3**
200-point rate	132	131	130	129	128	127	126	125	124	123	121	120	Not enough

The student's independent work is assessed during the current control of the topic in the relevant classroom. Assessment of topics that are submitted for self-study and are not included in the topics of classroom training, are controlled during the final tests.

The form of **final control** of study in the discipline "Modern Analytical Laboratory Practice" - is a **credit** that is given to a student who has completed all types of work provided by the curriculum, completed all classes and scored no less than the minimum.

13. Methodical support

- Multimedia texts of lectures

- Computers
- A set of situational tasks for classes.
- Recommended Books.

14. References

Basic

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15. Information resources

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3. http://www.oecd.org/env/ehs/testing/glp-frequently-asked-questions.htm
4. http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:31995L0046
5. www.moz.gov.ua/ua/portal/Pro_20090514_0.html
6. https://newiso9001.files.wordpress.com/2016/12/clause_by_clause_explanation_of_iso_9001_2015_en.pdf