Danylo Halytsky Lviv National Medical University

Department of Pharmaceutical, Organic and Bioorganic Chemistry

APPROVED
First pro-rector
for the Academic Work
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Medical University
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_____
«__»__2021

WORKING EDUCATIONAL PROGRAM FOR "Standardization of drugs"

Second (master's) educational level
Field: 22 "Health"
Specialty: 226 "Pharmacy, industrial pharmacy"

Discussed and approved
Department of Pharmaceutical, Organic
and Bioorganic chemistry

Proceedings No 1
"31" August 2021.
Head of Department
prof. R.B. Lesyk

Approved
Methodical Commission
of pharmaceutical disciplines

Proceedings No 3
"31" August 2021.
Head of the methodical commission
asoc. prof. S.B. Bilous

Syllabus for “Standardization of drugs”
for 5nd year english medium students of pharmaceutical faculty
Specialty: 226 "Pharmacy, industrial pharmacy"
Authors: prof. Lesyk R, assoc prof. Sementsiv G., senior lect. Novikevych OT
on the basis of the sample program of the elective discipline modern methods of research of biological systems, approved by the State Institution "Central Methodical Cabinet for Higher Medical Education of the Ministry of Health of Ukraine" and the curriculum approved by the profile methodical commission (protocol №3 from 31.08.2021)

Changes and additions to the curriculum for the 2021-2022 academic year

#	The content of the changes made	Date and proceedings number of the department meeting	Notes

Head of Department of Pharmaceutical,
Organic and Bioorganic chemistry

prof. R.B. Lesyk

INTRODUCTION

The syllabus for "Standardization of drugs "

in accordance with the Standard of Higher Education of *the second (master's) level*

Field: 22 *"Health"*

Specialty: 226 "Pharmacy"

Master's Degree Programme in Pharmacy

Description of the discipline (abstract)

The discipline "Standardization of drugs " is devoted to the systematic study of the chemical behavior of drugs in relation to their structure and the formation of creative chemical thinking on this basis. It is necessary for the successful understanding of specialized disciplines, as well as for practical activity.

The main goal of Standardization of drugs as a fundamental discipline is to provide a scientific approach to solving such problems as pharmaceutical analysis, phytochemical and chemico-toxicological analysis, as well as synthesis, evaluation of quality and technology of medical preparations and their storage conditions.

Training of specialists who need knowledge of Standardization of drugs requires not only theoretical base but also the versatile practical skills for chemical experiments.

The tasks of Standardization of drugs are to determine the structure of drugs both natural and synthetic; studying and understanding of the chemical transformations of organic molecules based on the nature of functional groups; detection of relationships between molecular and electronic structure of compounds and their physiological and pharmacological effects, revealing the patterns of the chemical transformations; studying the aspects of obtaining, purification, and analysis of drugs.

The structure of the discipline	**The number of credits, hours**				**Year of study**	**Type of control**
	Total Credit hours	**Auditorium**		**Self-study**		
		Lectures	**Practical classes**			
	3.0 credits ECTS / 90 h	8	30	52	5nd year (9 semester)	credit
Per semester						
	3.0 credits ECTS / 90 h	8	30	52	9 semester	credit

The subject of the study of the discipline is

1. molecular structure of drugs;
2. physical and chemical properties of drugs;
3. types of chemical reactions;

4. reactivity of different classes of drugs;
5. biological activity of drugs;
6. relationship between the structure and properties of drugs, including metabolites and drugs;
7. methods of isolation, purification, identification and assay of drugs.

Interdisciplinary connections: - General and Inorganic chemistry; Analytical chemistry; Biophysics; Biology; Biological chemistry; Normal physiology; Pathological physiology; Pharmacology; Histology.

1. The objectives and tasks of the "Standardization of drugs" course

1.1. Objectives of teaching of the " Standardization of drugs " course are:

- mastering of regularity of chemical properties of drugs based on their structure; understanding of biochemical processes that occur in biological systems;
- be familiar with basic methods of drug synthesis as the basis for new biologically active substances creation;
- gaining practical skills that will be helpful to learn the standardization techniques and drug quality control.
- disclosure of organic chemistry practical aspects, methods and ways of usage of its achievements in the pharmaceutical practice.

1.2. Tasks of the "Standardization of drugs" course are:

- to teach students the general principles of evaluation of the chemical properties of drugs, underlying the synthesis and analysis of pharmaceutical substances;
- to reveal of pharmaceutical chemistry practical aspects, the ways and methods of use its achievements in the pharmaceutical practice.

1.3. Competences and learning outcomes that are formed by this subject (the relationship with the normative content of the training of higher education graduates, formulated in terms of learning outcomes in the Standard of Higher Education)

In accordance with the requirements of the Standard of Higher Education, discipline ensures students' acquisition of **competences**:
-general: "КЗ.2"; "КЗ.3"; "КЗ.4"; "КЗ.6"; "КЗ.11", "КЗ.12".

Details of competences according to the descriptors are given in the form of "Matrix of competences".

Matrix of competences

No	Competence	Know ledge	Skills	Communi cation	Autonomy and responsibility
1	"КЗ.2" Ability to apply knowledge in practical situations	+	+		+
2	"КЗ.3" The striving to	+	+	+	+

	save the environment				
3	“КЗ.4” The ability to abstract thinking, analysis and synthesis; the ability to study and to be trained up-to date	+	+		+
4	“КЗ.6” Knowledge and understanding of the subject area and comprehension of the profession	+	+	+	+
5	“КЗ.11” Ability to assess and ensure the quality of performed work	+	+		+
6	“КЗ.12” Ability to perform research at the appropriate level	+	+		+

Learning outcomes:

Integrative final learning outcomes, the formation of which contributes to the discipline:
“ПРЗ 2”, “ПРЗ 3”, “ПРЗ 4”, “ПРЗ 6”, “ПРЗ 11”, “ПРЗ 12”

“ПРЗ 2” To apply knowledge of general and professional disciplines in professional activities;
“ПРЗ 3” to follow to the rules of sanitary-hygienic regime and safety requirements when carrying out professional activities;
“ПРЗ 4” to use the results of independent search, analysis and synthesis of information from various sources for solving typical tasks of professional activity;
“ПРЗ 6” to argue information for decision making, to be responsible for them in standard and non-standard professional situations; adhere to the principles of deontology and ethics in professional activities;
“ПРЗ 11” to follow the norms of communication in professional interaction with colleagues, management, consumers, to work efficiently in a team.
“ПРЗ 12” to use methods of performance indicators evaluation; to reveal reserves for improving of labor productivity.

As the result of the study of the " Standardization of drugs " course
***Student should know*:**

- basic principles of classification, nomenclature and structural isomerism of drugs;
- types of chemical bonds, conjugated systems, electronic effects, acidity and basicity of organic compounds as a basis of their reactivity;
- classification principles of identification reactions of drugs by the direction, the way of bond breaking and the their mechanisms;
- structure, nomenclature, isomerism, preparation methods and chemical properties of drugs;

- the names and the purposes of laboratory glassware and equipments;

be able to:

- use chemical and reference literature, work with tables and graphical material;
- to assemble a some laboratory apparatuses;
- master the methods of purification of liquid and solid organic compounds as well as to be able to determine their purity;
- determine the physical constants of organic compounds;
- carry out the elemental analysis;
- use laboratory methods of preparation of certain organic compounds;
- carry out specific reactions/ identification tests for basic functional groups;
- carry out the synthesis and analysis of drugs.

2. Information volume of subject matter

To study the academic discipline 3.0 credits ECTS, 90 hours are given.

Structure of the discipline according to the content modules:

3. The structure of the discipline " Standardization of drugs "

Theme	Lectures	Practical classes	Self-study	Individual work
Topic 1. Law of Ukraine "On Medicinal Products"	1	2	4	-
Topic 2. Production of medicines. State quality control of medicines. Implementation of drugs	1	2	4	
Topic 3. Decree of the Cabinet of Ministers of Ukraine "On standardization and certification". Study of pharmaco-technological indicators, purity, identity and quantitative content of the medicinal substance "Angro" "Calcii gluconas pro injectionibus" and its compliance with the Pharmacopoeial article of SPU 1 ed.	0,5	2	4	
Topic 4. WHO strategy in the system of ensuring (guaranteeing) the quality of medicines. Principles and rules of GMP EU and GMP WHO and rules of GMP RIS and GMP WHO. Study of pharmaco-technological indicators, purity, identity and quantitative content of the drug substance "Angro" "Acidum ascorbinicum" and "Thiamini hydrobromidum aut hydrochloridum" and its compliance with the Pharmacopoeial article of the SPU 1 ed.	0,5	2	4	
Topic 5. Strategy of Ukraine in the system of quality assurance of medicines. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Analgini 0.5" and its compliance with the Pharmacopoeial article developed by the manufacturer	0,5	2	4	
Topic 6. State Pharmacopoeia of Ukraine. Terms. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Streptocidi 0.3" and its compliance with the Pharmacopoeial article developed by the manufacturer	0,5	2	4	
Topic 7. Requirements for quality management, principles of quality assurance, good manufacturing practice, quality control. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Furacilini 0.02 ad	0,5	2	4	

usum externum" and its compliance with analytical regulatory documentation (AND)				
Topic 8. Requirements for quality control: principles, general requirements. Study of pharmaco-technological parameters, purity, identity and quantitative content of the drug "Sol. Calcii chloridi 10% pro injectionibus ”and its compliance with the Pharmacopoeial article developed by the manufacturer	0,5	2	4	
Topic 9. Requirements for premises, equipment, personnel, documentation, sampling. Control of medicines in Ukraine in modern conditions. Study of pharmaco-technological parameters, purity, identity and quantitative content of drugs "Sol. Novocaini 0.5% per injection bus ”and“ Sol. Acidi nicotinici 1% pro injectionibus "and compliance with its analytical regulatory documentation (AND)	0,5	2	4	
Topic 10. Validation of analytical methods and tests. System of Pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine. Study of pharmaco-technological parameters, purity, identity and quantitative content of drugs "Sol. Euphylylini 2.4% per injection bus ”and“ Sol. Papaverini hydrochloridi 2% pro injectionibus ”and its temporary Pharmacopoeial article developed by the manufacturer	0,5	2	4	
Topic 11. Regulatory and technical documentation governing the quality of medicines. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions	0,5	2	4	
Topic 12. Documentation requirements. Principles, general requirements. Regulatory documentation for intermediate products, semi-finished products and Angro products. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions	0,5	2	4	
Topic 13. Production requirements: principles, general requirements. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in pharmacies according to doctors' prescriptions	0,5	2	2	
Topic 14. Validation. Requirements for	0,5	2	2	

finished products. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in pharmacies according to doctors' prescriptions				
Final assessment		2		
Total hours 90 / 3.0 ECTS credits	**8**	**30**	**52**	
				Credit

4. Topics of lectures

№	Topic
1	Standardization of medicines. Decree of the Cabinet of Ministers of Ukraine "On standardization and certification". WHO strategy in the system of ensuring (guaranteeing) the quality of medicines. Compilation of mandatory principles, norms and rules, called "GMP" - "Good manufacturing practice". Quality certification system Medicines for International Trade developed by the World Health Organization (WHO) European Community (EU) Commission Directives of 1991. EU GMP and GMP WHO principles and rules and GMP RIS and GMP WHO rules EU Commission Directives 91/356 / EEC and 91/412 / EEC Functions performing GMP rules, Ukrainian quality assurance system for medicines, Law of Ukraine "On Medicinal Products" Competent management bodies in the field of creation, production, quality control and sale of medicines in Ukraine.
2	Strategy of Ukraine in the system of quality assurance of medicines. Guidelines "Manufacture of medicines. Appropriate rules and quality control" are developed in accordance with the legislation of Ukraine, the State Standardization System of Ukraine, the rules of GMP WHO and the EU, their characteristics, objectives, scope and significance. State Pharmacopoeia of Ukraine - concept, content, construction. The main principles on which the State Pharmacopoeia of Ukraine is based. Terms. Format of general and separate articles of the State Pharmacopoeia of Ukraine. Monographs of the State Pharmacopoeia of Ukraine on medicinal substances.
3	Requirements for quality management, principles of quality assurance, good manufacturing practice, quality control. Requirements for quality control: principles, general requirements. Good laboratory practice in quality control. Requirements for premises, equipment, personnel, documentation, sampling. Requirements for testing, control of raw materials, intermediates and materials, finished products. Control of medicines in Ukraine in modern conditions. Current state and prospects of development of biological methods of drug control.
4	Validation of analytical methods and tests. Standard samples. Basic provisions, procedure for development, certification, approval, registration and application. System of Pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine. Regulatory and technical documentation governing the quality of medicines. Temporary Pharmacopoeial Article (TFS), Pharmacopoeial Article (FS), their requirements for the quality of substances, injectable drugs, eye drops, tablet drugs, capsules, suppositories, ointments, aerosols, granules, oily solutions, tinctures and liquid extracts and sorbents. Requirements for documentation, principles, general requirements, required documentation. Specifications, specifications for raw materials and semi-finished products, for packaging materials. Regulatory documentation for intermediate products, semi-finished products and "angro" products. Specifications for finished products. Technological regulations, their categories. Contents of technological regulations. Production and technological instructions. Production requirements: principles, general requirements. Prevention of cross-contamination during production. Validation. Requirements for raw materials, for technological processes of manufacturing intermediate products, for packaging materials, for packaging and labeling processes. Requirements for finished products. Product complaints and recalls: principles, cases in which mandatory product recalls are required, procedure for recalling defective or potentially defective products.
Total	**8 hours**

5. Topics of practical classes

No	Theme	Hours
1.	Law of Ukraine "On Medicinal Products"	2
2.	Production of medicines. State quality control of medicines. Implementation of drugs	2
3.	Decree of the Cabinet of Ministers of Ukraine "On standardization and certification". Study of pharmaco-technological indicators, purity, identity and quantitative content of the medicinal substance "Angro" "Calcii gluconas pro injectionibus" and its compliance with the Pharmacopoeial article of SPU 1 ed.	2
4.	WHO strategy in the system of ensuring (guaranteeing) the quality of medicines. Principles and rules of GMP EU and GMP WHO and rules of GMP RIS and GMP WHO. Study of pharmaco-technological indicators, purity, identity and quantitative content of the drug substance "Angro" "Acidum ascorbinicum" and "Thiamini hydrobromidum aut hydrochloridum" and its compliance with the Pharmacopoeial article of the SPU 1 ed.	2
5.	Strategy of Ukraine in the system of quality assurance of medicines. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Analgini 0.5" and its compliance with the Pharmacopoeial article developed by the manufacturer	2
6.	State Pharmacopoeia of Ukraine. Terms. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Streptocidi 0.3" and its compliance with the Pharmacopoeial article developed by the manufacturer	2
7.	Requirements for quality management, principles of quality assurance, good manufacturing practice, quality control. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Furacilini 0.02 ad usum externum" and its compliance with analytical regulatory documentation (AND)	2
8.	Requirements for quality control: principles, general requirements. Study of pharmaco-technological parameters, purity, identity and quantitative content of the drug "Sol. Calcii chloridi 10% pro injectionibus ”and its compliance with the Pharmacopoeial article developed by the manufacturer	2
9.	Requirements for premises, equipment, personnel, documentation, sampling. Control of medicines in Ukraine in modern conditions. Study of pharmaco-technological parameters, purity, identity and quantitative content of drugs "Sol. Novocaini 0.5% per injection bus ”and“ Sol. Acidi nicotinici 1% pro injectionibus "and compliance with its analytical regulatory documentation (AND)	2
10	Validation of analytical methods and tests. System of Pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine. Study of pharmaco-technological parameters, purity, identity and quantitative content of drugs "Sol. Euphylylini 2.4% per injection bus ”and“ Sol. Papaverini hydrochloridi 2% pro injectionibus ”and its temporary Pharmacopoeial article developed by the manufacturer	2
11	Regulatory and technical documentation governing the quality of medicines. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions	2
12	Documentation requirements. Principles, general requirements. Regulatory documentation for intermediate products, semi-finished products and Angro products. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions	2
13	Production requirements: principles, general requirements. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in pharmacies according to doctors' prescriptions	2
14	Validation. Requirements for finished products. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in	2

	pharmacies according to doctors' prescriptions	
15	Final control	2
Total		**30**

6. Out-class works

№	Topic	Hours
1.	Law of Ukraine "On Medicinal Products"	**4**
2.	Production of medicines. State quality control of medicines. Implementation of drugs	**4**
3.	Decree of the Cabinet of Ministers of Ukraine "On standardization and certification".	**4**
4.	WHO strategy in the system of ensuring (guaranteeing) the quality of medicines. Principles and rules of GMP EU and GMP WHO and rules of GMP RIS and GMP WHO.	**4**
5.	Strategy of Ukraine in the system of quality assurance of medicines.	**4**
6.	State Pharmacopoeia of Ukraine. Terms.	**4**
7.	Requirements for quality management, principles of quality assurance, good manufacturing practice, quality control.	**4**
8.	Requirements for quality control: principles, general requirements.	**4**
9.	Requirements for premises, equipment, personnel, documentation, sampling. Control of medicines in Ukraine in modern conditions.	**4**
10.	Validation of analytical methods and tests. System of Pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine.	**4**
11.	Regulatory and technical documentation governing the quality of medicines. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions	**4**
12.	Documentation requirements. Principles, general requirements. Regulatory documentation for intermediate products, semi-finished products and Angro products. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions	**4**
13.	Production requirements: principles, general requirements. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in pharmacies according to doctors' prescriptions	**2**
14.	Validation. Requirements for finished products. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in pharmacies according to doctors' prescriptions	**2**
Total		**52**

7. Methods of studies

Explanatory-illustrative, problematic presentation, partially-exploratory.

Studying Standardization of drugs students use textbooks, lecture notes, methodological guidelines, chemical computer software, molecular models, laboratory devices and glassware necessary for performing experiments.

Methods for organization and accomplishment of studies are:
a) lectures
b) practical classes
c) students' independent study.

The topics of the lecture course cover the problematic issues of the appropriate sections of pharmaceutical chemistry.

Practical classes are organized as laboratory classes. These classes include: laboratory studies on production and detection of specific classes of drugs according to their functional groups, performing specific reactions of drugs and drug synthesis, its obtaining, purification and physicochemical constants determination.

Students are recommended to write short-term protocols of laboratory studies, indicating the purpose of the study and the conclusions.

The students also perform educational exercises and solve situational problems. ISIS Draw, Chemistry in motion, HyperChem computer programs, videos and models of molecules are used in practical classes.

The structure of practical classes includes:
- Discussion and explanation of the most complicated issues of the topic;
- Written test;
- Practical (laboratory) work.
- Filling in a practical lesson protocol.
- Summary of the lesson.

8. Methods of control

Types of control: initial, current and final.

Form of final control according to the curriculum: credit (9 semester). The initial control of theoretical training is carried out at the beginning of each class.

Current control is carried out at each class in accordance with specific objectives, as well as during the individual work of the teacher with the student for those topics that the student develops independently and they are not part of the structure of the practical lesson. A standardized form of control of theoretical and practical training of students is used. At each practical lesson the student answers test tasks, questions on the topic of practical lesson, 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 theme of laboratory class.

The test is performed individually according to the tasks of the lecturer and is evaluated by the appropriate assessment before the session.

Students' independent work is assessed 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. Assessment of practical training of students - as a result of the practical part - is made in the form of a protocol.

Criteria of assessment of current educational activity:

"Excellent" mark receives a student who actively participated in the discussion of the most difficult issues of the topic, gave at least 90% of correct answers to standardized tests, responded to written tasks without any mistake, performed practical work and filled in the protocol.

"Good" mark gets a student who participated in the discussion of the most difficult issues of the topic, gave at least 75% of correct answers to standardized tests, responded to written tasks with some insignificant mistakes, performed practical work and filled in the protocol.

"Satisfactory" mark receives a student who did not take part in the discussion of the most difficult issues of the topic, gave at least 60% of correct answers to standardized tests, responded to written tasks with a lot of mistakes, performed practical work and made the protocol.

"Unsatisfactory" mark receives a student who did not take part in the discussion of the most difficult issues of the topic, gave less than 60% of correct answers to standardized tests, responded to written tasks with gross mistakes or did not give answer, didn't perform practical work and didn't make the protocol.

The final control is carried out upon completion of the study of the discipline in the form of a credit (3d semester) and the exam (4d semester).

Only those students who completed all types of works provided by syllabus and during study scored points not less than the minimum (3,0), and don't have any undone lectures and practical classes are allowed to put the exam. The standardized form of the exam includes control of theoretical and practical knowledge.

The exam includes: 50 tests (Form A), which are evaluated by 1 point (50 minutes), 6 "open" questions, which are evaluated by 5 points (40 minutes)

The maximum number of points a student can score for an exam is 80.

The minimum number of points during the examination - 50.

9. Scheme of accrual and distribution of scores received by students is as follows:

The maximum number of points that a student can get for current educational activity during study is 200 points.

The minimum number of points that a student score for the current academic activity to enroll in the discipline is 120 points.

Calculating the number of points is performed by the way of calculating the arithmetical average (AA) of student's received marks by traditional rate during the semester the discipline is studied, and rounded to two decimal places. The received value is converted into points by multi-point rate as follows:

$$xX = (AA \times 200)/5$$

For convenience, there is a table of conversion to 200-point rate:

Recalculation of the average mark for current activity into multi-point rate for disciplines, ending with exam.

4-point rate	200-point rate
5	120
4.95	119
4.91	118
4.87	117
4.83	116
4.79	115
4.75	114
4.7	113
4.66	112
4.62	111
4.58	110
4.54	109
4.5	108

4-point rate	200-point rate
4.45	107
4.41	106
4.37	105
4.33	104
4.29	103
4.25	102
4.2	101
4.16	100
4.12	99
4.08	98
4.04	97
3.99	96
3.95	95

4-point rate	200-point rate
3.91	94
3.87	93
3.83	92
3.79	91
3.74	90
3.7	89
3.66	88
3.62	87
3.58	86
3.54	85
3.49	84
3.45	83
3.41	82

4-point rate	200-point rate
3.37	81
3.33	80
3.29	79
3.25	78
3.2	77
3.16	76
3.12	75
3.08	74
3.04	73
3	72
Less then 3	Insuffi-cient

Students out-of classes works is assessed during the current verification of topic on the lesson.

A mark on a discipline is defined as the sum of points for the current educational activity (not less than 120).

Points from discipline are converted into ECTS rate, and 4-point (national) rate.

Points from ECTS rate can't be converted into 4-point rate and vice versa. Marks of students, who study in one specialty, and taking into account the number of points gained by him/her in the discipline are ranked by ECTS rate as follows:

ECTS Mark	Statistical index
A	Top 10% of students
B	Next 25% of students
C	Next 30% of students
D	Next 25% of students
E	Last 10% of students

A, B, C, D, E rankings are awarded to students of actual course, who study in one specialty and successfully completed the study of the discipline. Students who received FX, F ("2") ratings are not included in the list of ranked students. Students with an FX score after repassing the exam receive an "E" score automatically.

Score points for students who have successfully completed the program are converted to the traditional 4-point scale by the absolute criteria listed in the table below:

Points from discipline	Mark by 4-point rate
From 170 to 200 points	5

From 140 to 169 points	4
From 139 to the minimum number of points which student must get	3
Below the minimum number of points which student must get	2

Mark written by ECTS can't be converted into traditional scale because the ECTS scale and 4-point scale are independent (do not coincide).

Objectivity of assessment students` educational activities is checked by statistical methods (correlation coefficient between the ECTS mark and mark by national scale).

10. Methodical support

- plan of lectures,
- plans of practical classes,
- tasks for laboratory work, out-of class work,
- questions, tasks and test tasks for current and final control of knowledge and skills of students, after attestation monitoring of acquired knowledge and skills in the discipline.

11. List of practical skills

- Be able to use chemical and reference literatures, work with the tables and graphic material.
- To know the names of chemical glassware and laboratory equipment and their use.
- Be able to compile individual laboratory installations.
- Be able to use methods of purification liquid and crystalline organic compounds and determinate their purity.
- Be able to determine the physical constants of drugs (melting point, boiling temperature, optical activity, etc.).
- To know laboratory methods of the assay of drugs.
- To know specific reactions/identification tests of functional groups of drugs.
- To carry out synthesis and analysis of the drugs.

12. List of theoretical and general question

1. The structure of the State Pharmacopoeia of Ukraine. Drug quality assessment system.
2. The structure of the monograph. The difference between pharmacopoeial requirements from the norms and methods of analysis for chemical and others. products manufactured in accordance with State Standards (DSTU) and technical conditions (TU).
3. Peculiarities of pharmaceutical analysis are related to the purpose of the drug and the professional responsibility of the pharmacist. Relativity of requirements and methods of quality assessment depending on the pharmacological action of the drug

(purpose, dosage, method of administration), method of production, the presence of excipients and related substances in the dosage form.
4. Unification and standardization of similar tests in groups of medicinal substances. General provisions, general articles and monographs of the Pharmacopoeia, their relationship.
5. Analysis of physicochemical properties of drugs as one of the elements of drug quality assessment. Organoleptic analysis, evaluation of drug solubility as a general approximate characteristic of the test substance. Use of physical constants (relative density, viscosity, boiling / melting point, solidification) in drug trials.
6. Analysis of physicochemical properties of drugs as one of the elements of their quality assessment. The use of physical constants such as refractive index, optical rotation in drug testing.
7. The use of spectroscopic and chromatographic methods in the identification of drugs; features of use of standard samples of medicinal substances and standard spectra. IR, UV spectrophotometry, NMR spectroscopy.
8. The use of spectroscopic and chromatographic methods in the identification of drugs; features of use of standard samples of medicinal substances and standard spectra. Mass spectrometry (MS); high performance liquid chromatography; thin layer chromatography.
9. Identification of medicinal substances of inorganic nature. Reactions for the identification of cations of aluminum, ammonium, potassium, sodium, calcium, magnesium, zinc and iron (II, III).
10. Identification of medicinal substances of inorganic nature. Reactions for the identification of cations of antimony, bismuth, mercury, silver, arsenic, lead.
11. Identification of medicinal substances of inorganic nature. Reactions for identification of chlorine, bromine, iodine anions.
12. Identification of medicinal substances of inorganic nature. Reactions for the identification of sulfates, sulfites, nitrates, nitrites, phosphates, carbonates, hydrocarbons.
13. Identification of drugs of organic nature by functional groups (functional analysis). Reactions for the identification of primary alcohols, polyhydric alcohols, secondary alcohols, phenols.
14. Identification of drugs of organic nature by functional groups (functional analysis). Reactions for the identification of aldehydes, ketones, carboxylic acids, amides.
15. Identification of drugs of organic nature by functional groups (functional analysis). Identification reactions of double bonds, covalently bonded halogen atoms, ethers, esters.
16. Identification of medicinal substances of organic nature by functional groups (functional analysis). Reactions for the identification of primary, secondary and tertiary aromatic amines.
17. Identification of medicinal substances of organic nature by functional groups (functional analysis). Identification reactions of primary, secondary and tertiary aliphatic amines and primary, secondary aliphatic nitro compounds. Reactions for the identification of aromatic nitro compounds.
18. Causes that cause changes in the structure of the drug (exposure to light, moisture, temperature and other factors provided by the conditions and terms of

storage). The effect of impurities on the qualitative and quantitative composition of the drug and the possibility of changing its pharmacological activity (specific and general impurities).
19. Nature and nature of impurities, methods of their detection. Production impurities, intermediates, raw materials. Unification of tests.
20. General provisions for determining the content of impurities on the indicators of "transparency, turbidity" and "color" of the solution, etc. Approaches to setting the limits of permissible impurities based on the degree of sensitivity of chemical reactions. Reference solutions.
21. Tests for impurities of inorganic ions. Conditions and chemistry of ammonium and arsenic ion detection reactions.
22. Tests for impurities of inorganic ions. Conditions and chemistry of reactions for the detection of potassium, calcium and magnesium ions.
23. Tests for impurities of inorganic ions. Conditions and chemistry of detection reactions of iron, aluminum, zinc and heavy metals.
24. Tests for impurities of inorganic ions. Conditions and chemistry of reactions for the detection of chlorides, fluorides, sulfates, phosphates.
25. Production and properties, purity research, conditions and terms of storage of purified water, highly purified water and water for injections.
26. Methods of quantitative analysis of the content of drugs. The choice of method that allows you to assess the content of the drug by functional groups that characterize its properties. Features of quantitative determination of individual substances and dosage forms. Validation of analytical methods.
27. Methods of quantitative analysis of the content of drugs. Relative specificity, sensitivity, correctness (accuracy) and reproducibility of the method. Comparative evaluation of the suitability of modern chemical and physicochemical methods for the quantitative determination of the active substance.
28. Methods of quantitative analysis of the content of drugs. The influence of polyfunctionality of drugs on the choice of quantitative method. Weight analysis (gravimetry).
29. Methods of quantitative analysis of the content of drugs. The influence of polyfunctionality of drugs on the choice of quantification method. Determination of nitrogen in organic compounds after mineralization (Kjeldahl method).
30. Titrimetric methods of analysis. Acid-base titration method in aqueous and non-aqueous media.
31. Titrimetric methods of analysis. Argentometry, complexometry.
32. Titrimetric methods of analysis. Mercurimetry, permanganatometry, bromatometry.
33. Titrimetric methods of analysis. Iodometry, iodometry, cerimetry.
34. Titrimetric methods of analysis. Dichromatometry, nitritometry. Potentiometric titration.
35. Optical methods in quantitative analysis. Refractometry, polarimetry.
36. Optical methods in quantitative analysis. UV and IR spectrophotometry, photometry in the visible region of the spectrum.
37. Chromatographic methods: gas-liquid chromatography (GC) and high performance liquid chromatography (HPLC), electrophoresis.
38. Methods based on thermodynamic properties of substances: thermographic

methods, phase solubility method. Combination of extraction, chromatographic and optical methods in the analysis of dosage forms.

39. Express analysis of drugs. Current trends in the development of pharmaceutical analysis.

13. Literature/textbooks

1. Ahuja, S., & Scypinski, S. (Eds.). (2001). Handbook of modern pharmaceutical analysis (Vol. 3). Academic press.
2. Schirmer, R. E. (1990). Modern methods of pharmaceutical analysis (Vol. 2). CRC press.
3. Siddiqui, M. R., AlOthman, Z. A., & Rahman, N. (2017). Analytical techniques in pharmaceutical analysis: A review. Arabian Journal of chemistry, 10, S1409-S1421.
4. Vankeirsbilck, T., Vercauteren, A., Baeyens, W., Van der Weken, G., Verpoort, F., Vergote, G., & Remon, J. P. (2002). Applications of Raman spectroscopy in pharmaceutical analysis. TrAC trends in analytical chemistry, 21(12), 869-877.
5. Ermer, J., & Miller, J. H. M. (Eds.). (2006). Method validation in pharmaceutical analysis: A guide to best practice. John Wiley & Sons.
6. Lim, C. K., & Lord, G. (2002). Current developments in LC-MS for pharmaceutical analysis. Biological and Pharmaceutical Bulletin, 25(5), 547-557.
7. David C. Eaton. Laboratory investigation in Organic Chemistry. – McGRAW-HILL BOOK COMPANY. – New York – Toronto. – 893 p.

14. Information resources

1. www.ncbi.nlm.nih.gov/PubMed – free access to the database of scientific research in the field of biomedical sciences.
2. https://pubchem.ncbi.nlm.nih.gov/ free access to the database of scientific data in the field of biomedical sciences.
3. http://www.orgsyn.org - has provided the chemistry community with detailed, reliable, and carefully checked procedures for the synthesis of organic compounds.
4. http://www.organic-chemistry.org - offers an overview of recent topics, interesting reactions, and information on important chemicals for organic chemists.