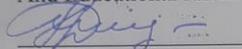


**“APROVE”**

Vice-rector of a Higher Education  
Institution from Scientific-Pedagogical  
And Educational Affairs

 Prof. of HEI

Oksana SEREBRENNIKOVA

“02” September 2022 year

**“AGREED”**

Head of the Pharmaceutical  
Chemistry Department

 Assoc. Prof. of HEI

Tetyana YUSHCHENKO

“02” September 2022 year

**SYLLABUS  
of academic discipline  
Pharmaceutical analysis**

Specialty	226 Pharmacy, Industrial Pharmacy
Educational level	The second (master's) level
Educational programme	<i>EPP "Pharmacy", 2022</i>
Academic year	2022-2023
Department	<i>Pharmaceutical Chemistry</i>
Lecturer (if lectures are given)	Assistant Liusine Ostretsova
Contact information	pharmchem@vnm.u.edu.ua Pirogov Street 56, tel. 55-39-54
Syllabus complier	Associated Professor of HEI candidate of Chemistry Science Tetyana YUSHCHENKO Assistant Liusine Ostretsova

## 1. Status and structure of the discipline

Discipline status	Selective
Discipline code in EPP/ discipline place in EPP	SC 49
Course / semester	5th years (IX semester)
The amount of discipline ( the total number of hours / number of credits ECTS)	90 hours / 3 credits ECTS
The structure of the discipline	Lectures 10 hours classes 30 hours Independent work 50 hours
Language of study	English
Form of study	Full - time , part-time ( <i>or remote by order</i> )

## 2. Description of the discipline

**Short annotation of the course, relevance.** According to the curriculum of specialty 226 "Pharmacy, industrial pharmacy" discipline "Pharmaceutical analysis of medicine" is studied during 9th semester of the fifth last year of study, it consists of 1 module. The total number of hours - 90 included lectures – 10 hours, practical classes

- 30, independent work - 50, ECTS credits -3. In the conditions of constant development of the pharmaceutical market and growth of requirements to quality of medicines, pharmaceutical chemistry, should provide to future experts both theoretical knowledge, and practical skills in the field of quality control of medicines.

Pharmaceutical analysis is an important component of the educational process, based on the theoretical knowledge and practical skills acquired in the university, transforming them into professional skills in the workplace: in pharmacies, in production, in laboratories for quality control of medicines and medical devices. ,.

**Prerequisites:** disciplines " Pharmaceutical analysis " is a knowledge base of "Analytical Chemistry", "Pharmaceutical Chemistry", "Organization and Economics of Pharmacy": acquired knowledge and skills in the discipline, understanding and possession of theoretical knowledge of qualitative and quantitative analysis, input and output quality control of medicines, etc. give the opportunity to be confident in their practical implementation, because it is necessary in professional activities.

**The purpose of the course and its significance for professional activities.** to consolidate and deepen the theoretical knowledge and practical skills acquired in the learning process and necessary for independent work in the performance of professional tasks of a pharmacist to control and ensure the quality of medicines.

Mastering the discipline will allow students to acquire, in addition to integral, the following competencies:

General (GC): GC 2, GC 4, GC 6, GC 11, GC 12.

Special (professional): PC 2, PC 6, PC 7, PC 14, PC 15, PC 18, PC 19, PC 20.

**Postrequisites.** disciplines "Industrial pharmaceutical practice by specialization: practice in pharmaceutical chemistry" , "Standardization of drugs" and already directly professional activity. Knowledge of the theoretical foundations is necessary for a deeper study of the above disciplines. Learning outcomes.

### 3. Learning outcomes.

- studying of international non-proprietary names of medicinal substances;
- studying of methods of obtaining medicinal substances;
- mastering the methods of qualitative and quantitative analysis of drugs, and their purity assesment;
- studying of the ways of drug metabolism;
- ability to determine the optimal conditions for storage of drugs;
- ability to use analytical documentation that regulates the quality of drugs (State Pharmacopoeia, International Pharmacopoeia, national and regional pharmacopoeias, MQC, relevant orders and instructions), methodical guidelines for the implementation of methods of quality control of substances and drugs;
- usage of chemical, physical, physico-chemical methods of quality control of drugs;
- ability to give a qualified assessment of the quality of drugs in accordance with the results of the analysis and the requirements of the MQC and regulations.
- theoretical bases of pharmaceutical analysis with their further realization in practical skills, including: organization of the State system of quality control of medicines of domestic and foreign production; regulatory framework governing the quality control of medicines (orders, instructions of the Ministry of Health, SPU, etc.); drug quality standards; quality certificates of medicines; the order of input control; the procedure for maintaining reporting documentation.

### 4. Content and logistic of the discipline

<p><b>"Industrial pharmaceutical practice by specialization : practice in pharmaceutical chemistry"</b></p>	<p>IX semester 90 hours /3,0 credits</p>	<p>Practical classes №№ 1-15 Topics for self- study: according to program of discipline</p>
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#### *The course includes 5 main topics*

1. The quality control system of medicinal products in Ukraine. The structure of the bodies of state control of the quality of medicinal products and the organization of its implementation.
2. Manufacturer's responsibility for the quality of medicinal products. Organization of the work of the quality control department in the production of pharmaceutical products.
3. Low-quality (substandard) and falsified medicinal products. Classification.  
Reasons for the distribution of falsified and substandard medicines  
means Methods of analytical detection of falsified medicinal products.
4. Program to combat the production and distribution of falsified medicinal products. Measures to remove falsified and low-quality (substandard) medicinal products from circulation. Orders of the Ministry of

Health of Ukraine dated 12.12.2001 No. 497 "On the approval of the Procedure for the prohibition (suspension) and removal from circulation of medicinal products in the territory of Ukraine", dated 07.08.2004 No. 349 "On the approval of the Rules for disposal and destruction low-quality medicines".

#### 5. Organization of the quality control system of medicinal products in Ukraine.

The student's independent work provides preparation for practical classes and intermediate tests, study of topics for independent extracurricular work, writing essays, preparation of presentations, tables. The control of mastering the topics of independent extracurricular work is carried out at the intermediate control classes and the final control of the discipline.

Individual work includes the study of scientific literature, preparation of reviews on the topics provided for presentation at the meetings of the student scientific circle, the implementation of scientific and practical researches, participation in specialized competitions, scientific and practical conferences and organization of students' research works.

Calendar plans of lectures, practical classes, thematic plan of independent extracurricular work, volume and directions of individual work are published on the website of the department.

The route for obtaining materials: Department of Pharmaceutical Chemistry / for students / Full-time education / (specialty 226 Pharmacy, Industrial Pharmacy) / 5<sup>th</sup> course / Educational materials / or through the link <https://www.vnmu.edu.ua/en/> department of Pharmaceutical Chemistry #.

Access to the materials is carried out through the student's corporate account [s000XXX@vnmu.edu.ua](mailto:s000XXX@vnmu.edu.ua).

#### 5. Forms and methods of monitoring academic performance

Current control in practical studies	Methods: <i>oral or written survey, testing, electronic survey, solving situational problems, conducting laboratory studies, interpreting them and evaluating their results (drawing up a daybook)</i>
Final control of the discipline - <i>differentiated credit</i>	Methods: <i>pre-examination testing, oral questioning</i> (according to the Regulation of the Academic process in National Pirogov Memorial Medical University, Vinnytsya (link <a href="https://www.vnmu.edu.ua/en/general-regulations">https://www.vnmu.edu.ua/en/general-regulations</a> ))
Learning success diagnostic tools	Theoretical questions, tests, practically-oriented situational tasks, practical tasks, practical skills demonstration

#### 5. Assessment criteria

Knowledge assessment is carried out in accordance with the Regulations of the Academic process in National Pirogov Memorial Medical University, Vinnytsya (link <https://www.vnmu.edu.ua/en/general-regulations>)

Continuous assessment	On a five point system of traditional assessments: 5 «excellent», 4 «good», 3 «satisfactory», 2 «unsatisfactory»
Midpoint separation assessment	On a five-point system of traditional assessments
Control of practical skills	According to the five-point system of traditional assessments

Final control of the discipline	<p><i>Sum of points for pre-examination testing (12-20points) and oral questioning (38-60 points) (for disciplines included in Step 1,2)</i></p> <p>Exam grade:  71-80 points - "excellent"  61-70 points - "good"  50-60 points - "satisfactory"  Less than 50 points - "unsatisfactory" / did not pass</p>
Discipline assessments:	<p>Current academic assessment - from 72 to 120 points (conversion of the average traditional assessment of practical class on a 120-point scale): 60% of the grade for the discipline</p> <p>Final control - from 50 to 80 points: 40% of the grade for the discipline</p> <p>Individual work - from 6 to 12 points</p> <p>From 122 to 200 points in total.</p>

### Discipline Score Scale: National and ECTS

The sum of grades		Score on a national scale	
for all types of educational activities	Score ECTS	For exam, course project (work), practice	for credit test
180-200	<b>A</b>	excellent	credited
170-179,99	<b>B</b>	good	
160-169,99	<b>C</b>		
141-159,99	<b>D</b>	satisfactory	
122-140,99	<b>E</b>	satisfactory	
0-121,99	<b>FX</b>	unsatisfactory with the possibility of reassembly	is not credited with the possibility of reassembling
	<b>F</b>	unsatisfactory with a mandatory reexamination of discipline	is not credited with mandatory reexamination of discipline

## **5. Policy of discipline / course**

The student has the right to receive high-quality educational services, access to contemporary scientific and educational information, qualified advisory assistance during the study of discipline and mastering practical skills. The policy of the department during the providing of educational services is a student-centered, based on normative documents of the Ministry of Education and the Ministry of Health of Ukraine, the Statute of the University and the Procedure for the Providing of Educational Services regulated by the main principles of the organization of the educational process in National Pirogov Memorial Medical University, Vinnytsya and the principles of academic integrity ( link <https://www.vnmu.edu.ua/en/general-regulations> ).

### **Adherence to the rules of VNMU, safety techniques during practical classes.**

**Requirements for preparation for practical classes.** Student should be present at the practical lesson on time, theoretically prepared according to the topic, adhere to the necessary for work in the laboratory form of clothing (medical gown, if necessary - hat, gloves, etc.). When performing a laboratory work, it is necessary to strictly follow the rules and safety precautions, experiments are possible only in the presence of a teacher or laboratory assistant in the classroom. Show tolerance, courtesy, tact and respect to other participants during the discussion.

**Usage of mobile phones and other electronic devices.** The use of electronic devices is allowed, but limited to individual cases. It is allowed to use these devices for testing on the Microsoft Teams platform, for mathematical calculations ("Calculator" function), for processing literary sources in electronic form (agreement with teacher is required). It is forbidden to use electronic devices during classes for photo, audio and video recording without the consent of all participants of the educational process, for entertainment purposes, as well as during an oral survey.

**Academic integrity.** When studying the discipline, the student must be guided by the Code of Academic Integrity and Corporate Ethics of National Pirogov Memorial Medical University, Vinnytsya (link: <https://www.vnmu.edu.ua/en/general-regulations/> Code of Academic Integrity). In case of violation of the norms of academic integrity during the current and final controls student receives a grade of "2" and must work it out to his teacher in the prescribed manner within two weeks after receiving an unsatisfactory assessment).

**Missed classes.** Missed classes are working out in the manner prescribed by Regulations of the Academic process in National Pirogov Memorial Medical University, Vinnytsya (link <https://www.vnmu.edu.ua/en/general-regulations>) at the time of work out schedule (published on the website of the department <https://www.vnmu.edu.ua/> department of Pharmaceutical Chemistry#) to the teacher on duty. To work out missed lesson student must provide permission from the dean's office, pass multiple choice questions (MCQ) on a missed topic and recitation, work out laboratory work (if the latter is in a particular topic), draw up a laboratory report and defend it to the teacher on duty.

*Note.* To ensure the completion of the laboratory works, it is necessary to apply in advance to the laboratory assistant of pharmaceutical chemistry department and indicate the topic and specific date of rework to prepare the necessary reagents, laboratory utensils, etc.

The reworks of missed lectures are carried out to the lecturer of the subject, with the permission of the dean, the abstract of the lecture, a short recitation on the topic of the lecture is possible.

**The procedure for admission to the discipline final control** is given in the Regulations of the Academic process in National Pirogov Memorial Medical University, Vinnytsya (link <https://www.vnmdu.edu.ua/en/general-regulations>). To the final control allowed students who do not have missed practical classes and lectures and received an average traditional grade of at least "3".

**Additional points.** Individual points in the discipline (from 6 to 12) that student can receive for individual work, the amount of which is published on the website of the department in the educational methodical materials of the discipline, the number of points is determined by the results of IRS according to Regulation of the Academic process in National Pirogov Memorial Medical University, Vinnytsya (link <https://www.vnmdu.edu.ua/en/general-regulations>).

**Conflict resolution.** In case of misunderstandings and complaints to the teacher because of the quality of educational services, knowledge assessment and other conflict situations, students should submit his / her claims to the teacher. If the issue is not resolved, the student has the right to apply to the head of the department according to Complaints Consideration Procedure in VNMU named after M.I. Pirogov (link <https://www.vnmdu.edu.ua/en/general-regulations>.)

**Politics in terms of remote learning.** Distance learning regulated by the Regulations of the elements of remote learning in National Pirogov Memorial Medical University, Vinnytsya (<https://www.vnmdu.edu.ua/> General information). The main training platforms for studying are Microsoft Team and Google Meets. Practical classes and lectures, exercises and consultations during distance learning is published on the website of the department ([https://www.vnmdu.edu.ua/en/ Department of Pharmaceutical Chemistry / to Students](https://www.vnmdu.edu.ua/en/Department%20of%20Pharmaceutical%20Chemistry%20for%20Students) or [https://www.vnmdu.edu.ua/en/Department of Pharmaceutical Chemistry / News](https://www.vnmdu.edu.ua/en/Department%20of%20Pharmaceutical%20Chemistry%20News)).

Feedback from teachers is via messengers (Viber, Telegram, WhatsApp) or e-mail (at the teacher's choice) during working hours.

### **1. Educational resources.**

Educational and methodological support of the discipline is published on the website of the department ([https://www.vnmdu.edu.ua/en/ department of Pharmaceutical Chemistry](https://www.vnmdu.edu.ua/en/department%20of%20Pharmaceutical%20Chemistry)

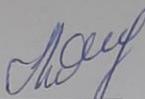
/ for students). Consultations are held twice a week according to the schedule.

**2. The timetable and distribution of groups** with assigned teachers are published on the web page of the department ([https://www.vnmdu.edu.ua /en/ department of Pharmaceutical Chemistry / for students](https://www.vnmdu.edu.ua/en/department%20of%20Pharmaceutical%20Chemistry%20for%20Students)).

**3. Questions to the intermediate and final semester control (credit) of the discipline** are published on the web page of the department ([https://www.vnmdu.edu.ua / en/ department of Pharmaceutical Chemistry / for students](https://www.vnmdu.edu.ua/en/department%20of%20Pharmaceutical%20Chemistry%20for%20Students)).

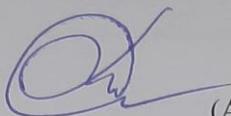
The syllabus of discipline "Pharmaceutical analysis" was discussed and approved at the meeting of the department of Pharmaceutical Chemistry (record №1, dated "01" September 2022)

Responsible for the academic year

  
(signature)

(Assistant Liusine Ostretsova)

Head of the department

  
(signature)

(Assoc.Prof.of HEI Tetyana YUSHCHENKO)