FACULTY OF PHARMACY

STUDY PROGRAM 0916.1 PHARMACY

DEPARTMENT OF PHARMACEUTICAL AND TOXICOLOGICAL CHEMISTRY

APPROVED
at the meeting of the Commission for Quality Assurance and Evaluation of the Curriculum, Faculty of Pharmacy
Minutes No. 2 of 21.12.2017
Chairman PhD. associate professor
UNCU Livia

APPROVED
at the Council meeting of the Faculty of Pharmacy
Minutes No. 2 of 22.12.2017
Dean of Faculty PhD. associate professor
CIOBANU Nicolae

APPROVED
at the meeting of the chair of Pharmaceutical and Toxicological Chemistry.
Minutes No. 3 of 03.11.2017
Head of chair PhD. professor
VALICA Vladimir

SYLLABUS

DISCIPLINE **PHARMACEUTICAL CHEMISTRY**

Integrated studies

Type of course: **Compulsory**

Chisinau, 2017

I. INTRODUCTION

- **General presentation of the discipline: place and role of the discipline in the formation of the specific competences of the professional / specialty training program**

Pharmaceutical chemistry takes an important place in the professional studies of a future pharmacist, having at it's basis all the received notions from the fundamental disciplines for an exhaustive approach to the medicine.

The Pharmaceutical chemistry studies the obtaining methods of medical substances, their physical and chemical properties the and analysis methods; creates a methodology for acquiring and assessing the quality of the drug substances based on general and particular laws of ***Pharmaceutical chemistry***, as well as the correlation of the chemical structure - pharmacological activity for the fulfillment of the pharmacist's professional duties. Within each chemical and therapeutic class, drug substances are studied from the point of view of chemical structure and nomenclature, production possibilities, physico-chemical properties, essential biological properties, structure-activity relationships, pharmaceutical presentation. Another objective of the course of ***Pharmaceutical chemistry*** is to know the strategies applied to discover new bioactive molecules.

In the practical work is done the chemical identification of the drugs studied in the course, as well as the control of their purity.

Aim of the discipline the ***Pharmaceutical chemistry*** is focused on the complex study of pharmaceutical substances, from the point of view of the international common name, structural formula, chemical structure-pharmacological activity relationships, methods of production, physico-chemical properties, purity control, identification and dosing of pharmaceutical substances by classical chemical methods and modern instrumental methods (spectroscopic, chromatographic, etc.), but also in terms of requirements for preservation and transport conditions depending on physicochemical properties. Within the discipline, the development of self-training skills is expected to meet the professional exigencies of the future pharmacist.

- **Mission of the curriculum (aim) in professional training**

The ***Pharmaceutical chemistry*** discipline provides the necessary data to systematize the knowledge about the creation of drug substances from their production to the introduction into curative practice, the study of properties and the control of their quality.

- **Language (s) of the course:** Romanian; English.
- **Beneficiaries:** students of the III, IV year, faculty Pharmacy, specialty PHARMACY.

II. MANAGEMENT OF THE DISCIPLINE

Code of discipline		**S.05.O.054, S.06.O.063, S.07.O.071, S.08.O.077**	
Name of the discipline		**Pharmaceutical chemistry:** **Pharmaceutical chemistry-I and Pharmaceutical chemistry -II (y. III), Pharmaceutical chemistry -III (y. IV)**	
Person(s) in charge of the discipline		PhD in Pharmaceutical Sciences, professor **Vladimir Valica** – Pharmaceutical chemistry-III (y. IV). PhD in Pharmaceutical Sciences, associate professor **Livia Uncu** – Pharmaceutical chemistry-I and Pharmaceutical chemistry -II (y. III).	
Year	**III, IV**	Semesters	**5, 6, 7, 8**
Total number of hours, including:			**570**
Lectures	**136**	Practical/laboratory hours	**221**
Seminars		Self-training	**231**
Form of assessment	**CD, E, CD, E**	Number of credits	**4+5+5+5=19**

III. TRAINING AIMS WITHIN THE DISCIPLINE

At the end of the discipline study the student will be able to:

- ***at the level of knowledge and understanding:***
  - to determine the discipline's study objective;
  - to represent the organisation's objectives about the control of the substance's quality;
  - to describe the structure and content of the Analytical Documentation Normare (AND) of the quality of the drug substance

- to distinguish the theoretical basis and the essence of the quality determining methods

- ***at the application level:***
  - to organize and make the quality control of the drugs in conformity with the DAN requirements;
  - to apply modern instrumental methods of analysis;
  - to substantiate and possess the chemical classification of medicinal substances;
  - to use the principles for the identification of inorganic and organic substances;
  - to justify the methods for determining the purity of medicinal substances (common and specific impurities);
  - to justify the methods of dosing of medicinal substances and to calculate the active substance content.

- ***at the integration level:***
  - to critically assess the quality of the drug according to the AND provisions;
  - to propose and carry out concrete and effective drug control actions;
  - to draw up the current documentation on quality control of medicinal substances.

IV. PROVISIONAL TERMS AND CONDITIONS

It is a multidisciplinary science that combines the knowledge of inorganic, organic, analytical chemistry, physico-colloidal chemistry, biological chemistry, physico-chemical analysis methods previously accumulated, and other specialized disciplines such as toxicological chemistry, pharmaceutical technology, pharmacology and pharmacognosis, medical chemistry.

V. THEMESAND ESTIMATEALLOCATION OF HOURS

Lectures, practical hours/ laboratory hours/seminars and self-training

No. d/o	THEME	Number of hours		
		Lectures	Practical hours	Self-training
Pharmaceutical chemistry-I				
1.	Introduction. Pharmaceutical chemistry, it's content. The place of pharmaceutical chemistry in the pharmaceutical science complex. The main stages of development of pharmaceutical chemistry. AND for medicines (European Pharmacopoeia, pharmacopoeial monographs). Pharmaceutical analysis: identifiying, purity determination, methods of quantitative determination.	4	3	-

No. d/o	THEME	Number of hours		
		Lectures	Practical hours	Self-training
2.	Inorganic drug substances. Preparations of oxygen, halides and their compounds with alkaline metals. Calcium, magnesium, boron, zinc, aluminum, silver, iron, carbonate preparations.	10	9	9
3.	Drugs with aliphatic and alicyclic structure. Halogen analysis in organic substances. Halogen derivatives of hydrocarbons. Derivatives of ethers and alcohols, aldehydes and carbohydrates. Carboxylic acid derivatives, unsaturated polyoxicarboxylic acids, acyclic urethanes and ureides, amino acids and terpenes. Derivatives of calciferols, cardenolides, male sex hormones (androgens), anabolic substances, derivatives of gestagens, estrogens, corticosteroids.	20	24	20
4.	*Control assessments.– 1, 2, 3.*	-	12	6
5.	*Differentiated colloquium.*	-	3	
	Total	**34**	**51**	**35**
Pharmaceutical chemistry-II				
6.	Drugs with aromatic structure. Phenol and quinone derivatives.	2	4	2
7.	Drugs with aromatic structure. Derivatives of p-aminophenols, aromatic and aminoaromatic acids. Jodular derivatives of aromatic and arylaliphatic amino acids. Radiopharmaceutical drugs.	6	16	10
8.	Antibacterial drugs. Characteristic, classification. The correlation between chemical structure and biological action. Drugs from the group of antibacterial benzenesulfonamides.	4	4	4
9.	Antibacterial drug substances with a heterocyclic structure. Derivatives of furan and 8-hydroxyquinoline.	2	4	4
10.	Antibiotics. Overall feature. Rational use of antibiotics; notions of bacterial resistance. Antibiotics from the group of nitrophenylalkylamine and tetracyclines.	4	4	4
11.	Antibiotics from the group of penicillins and natural and semisynthetic cephalosporins. Antibiotic aminoglycosides, polypeptides, lincosamine, macrolides. Antimycotics from the group of grains, pollen macrolides, synthetic antimycotics (derivatives of imidazole and 1,2,4-triazole). Antiviral, antimicrobial and antimalarial drug substances. Medicamente antineoplazice.	16	16	18
12.	*Control assessments – 1, 2, 3.*	-	12	6
13.	*Practical skills attestation.*	-	8	-
	Total	**34**	**68**	**48**
Pharmaceutical chemistry-III sem. VII				

No. d/o	THEME	Number of hours		
		Lectures	Practical hours	Self-training
14.	Drugs from the group of phenylalkylamines, arylhydroxypropanolamines. Drugs from the arylalkylamine group, oxyphenylalkylamine and their derivatives.	4	6	4
15.	General Characteristics and Classification of Heterocyclic Compounds. Drugs with diuretic and antidiabetic action.	4	6	6
16.	Drugs from the benzopyran, pyrrole and indole groups.	2	3	6
17.	Drugs from the imidazole and pyrazole groups.	2	3	6
18.	Drugs from the pyridine, piperazine and tropane group.	4	6	12
19.	Drugs from the quinoline, quinuclidine and isoquinoline group.	4	3	8
20.	Drugs from the group of pyrimidine and pyrimidino-thiazole, purine.	8	6	8
21.	Drugs from the pteridine and isoaloxazine group.	2	3	6
22.	Drugs with psychotropic action - neuroleptics.	4	3	3
23.	*Control assessments – 1, 2, 3.*	-	9	6
24.	*Differentiated colloquium.*	-	3	-
	Total	**34**	**51**	**65**
Pharmaceutical chemistry-III sem. VIII				
25.	Drugs with psychotropic action - anxiolytics, antidepressants.	2	3	4
26.	Drugs with antihystaminic action.	2	3	4
27.	Drugs with anti-inflammatory action.	2	3	6
28.	Metabolites and antimetabolites.	2	3	6
29.	Preconcentration and extraction methods in drug analysis. Separation of substances through state changes. Sublimation, lyophilization, distillation. Concentration by extraction. Types of extractions (simple extraction, repeated, synergic, countercurrent, ion pair extraction, solid phase, continuous flow).	4	6	6
30.	Biological methods of analysis.	4	3	6
31.	Chemical identification methods, purity and dosage determination of drug substances according to the requirements of the Pharmacopoeia.	18	15	27
32.	*Control assessments – 1, 2, 3*	-	9	6
33.	*Practical skills attestation.*	-	6	-
	Total	**34**	**51**	**65**
TOTAL		**136**	**221**	**213**

VI. REFERENCE OBJECTIVES OF CONTENT UNITS

Objectives	Content units
Theme (chapter) 1. Pharmaceutical chemistry – I.	
• To define the basic tasks of pharmaceutical chemistry; • To be aknowledged with the structure, properties, analysis methods-identification, purity and dosation identification as the primary steps of the drug substances quality control; • to demonstrate abilities to analyze and systematize the theoretical knowledge; • to apply the knowledge at other disciplines; • to be able to draw conclusions on the quality of the drug based on the results obtained in the analysis.	Pharmacopeal analysis methods - the basic methods of quality control of drug substances. Methodology of quality control of medicinal substances. The connection between the methods of analysis and the evaluation of the quality of the medicinal substances. Quality control of drug substances of inorganic, aliphatic and alicyclic nature. Control of drug substances according to quality parameters like "identification", "purity", "quantitative determination" as an important part of the pharmaceutical analysis.
Theme (chapter) 2. Chimie farmaceutică – II.	
• To know the connection between the structure and activity of the medicinal substances of the aromatic and antibacterian compounds group. • To know the international drug classification; • Demonstrate the application of modern methods of quality control of drug substances; • To apply the knowledges gained at another disciplines; • To integrate the knowledges about the drug's properties during the preserving, transporting and manufacturing pharmaceutical forms.	Classification of antibacterial drug substances. Mechanisms of action of different groups of drugs with antibacterial action. Quality control of drug substances in the group of aromatic and antibacterial compounds. Criteria for complex evaluation of the quality of medicinal substances.
Theme (chapter) 3. Chimie farmaceutică – III.	
• Define the main tasks of drug substances analysis; • Define the main approaches to quality control of drug substances; • To know the structure, properties, methods of analysis - identification, purity determination and dosing as the main stages in quality control of drug substances; • To perform the analysis and quality control of medicinal substances according to AND.	Classification of antidiabetic and diuretic drugs. Mechanism of action of antidiabetic, diuretic and psychotropic drugs as well as drug substances in the group of heterocyclic compounds. Quality control of drug substances with antidiabetic, diuretic and psychotropic action as well as heterocyclic compounds. Criteria for complex evaluation of the quality of medicinal substances.

VII. PROFESSIONAL (SPECIFIC (SC)) AND TRANSVERSAL (TC) COMPETENCES AND STUDY OUTCOMES

✓ Professional (specific) (SC) competences

- PC1. Knowledge of the theoretical bases of the pharmaceutical chemistry discipline in the elaboration, analysis and standardization of the drug substances; knowledge of the pharmacist's rights and obligations; knowledge of the structure of analytical normative documents for medicinal substances, the structure of a pharmacopoeial monograph and the quality standards of the manufacturer.
- PC2. Performing various practical maneuvers related to the preparation, analysis and standardization of synthetic and vegetal medicinal substances; the knowledge of the medicinal substances based on the general laws of chemico-biological sciences, their specificity and the use of medicaments according to the particularities of the pharmaceutical chemistry, in order to fulfill the professional duties of the pharmacist.
- PC3. Designing practical activity in the analysis of drug substances; use and adaptation of theoretical knowledge in the analysis and control of drug substances; making professional work more efficient by introducing innovative pharmaceutical elements; application of the requirements of normative acts in the field of analysis and control of medicinal substances; owning the computer as a working tool in the theoretical and practical work; establishing the correlation between the components of the analyst activity process.
- PC4. Identification of the particularities of the analysis and control of the drug substances in the institutions of the pharmaceutical system, where the specialist is active; designing and coordinating the activity of analyzing and controlling drug substances in various institutions; actively engaging the specialist in the process of analyzing and controlling drug substances; demonstrating the ability to make decisions aimed at improving the methods of analyzing and controlling drug substances.
- PC5. Determining the criteria for evaluating the efficacy of the analysis and control of drug substances according to the actual conditions for their performance; identification of research issues in the analysis and control of drug substances; knowledge of the methodology of scientific research in the practical activity of analysis and control.
- PC6. Adoption of messages in various socio-cultural environments, including through multi-lingual communication; use of problem-solving capabilities in pharmaceutical activity through collaboration with physicians and patients; the use of information technology (and computer) in pharmaceutical activity.

✓ Transversal competences (TC)

- TC1. Promoting logical reasoning, practical applicability, assessment and self-

assessment in decision-making by solving tasks of professional activity, using information, bibliographic resources, medical-biological and pharmaceutical terminology, information and communication technologies; compliance with pharmaceutical ethics and deontology rules for analysis and control.

- TC2. Identification of the training needs according to the evolution of the pharmaceutical system; determining priorities in the continuing professional training of the analyst pharmacist; appreciation of changes in the system of analysis and control.
- TC3. Performing activities and exercising the roles specific to team work. Promoting the spirit of initiative, dialogue, cooperation, positive attitude and respect for others, empathy, altruism and continuous improvement of their own activity.

✓ **Study outcomes**

- To recognize the sources and obtaining methods of medicinal substances, their physical and chemical properties;
- To recognize the main laws of the connection between the chemical structure and the pharmacological properties as the basic material to be used for the synthesis of the drug substances to know their purity requirements and the storage conditions;
- To possess the general and specific methods for analyzing drug substances;
- To posess the pharmaceutical and pharmacopeeian methods of analysis;
- to respect ethical and deontological principles in relations with colleagues, medical workers and the public in professional activity.

Note. **Study outcomes** (are deduced from the professional competencies and formative valences of the informational content of the discipline).

VIII. STUDENT'S SELF-TRAINING

No.	Expected product	Implementation strategies	Assessment criteria	Implementation terms
1.	Working with lecture materials, methodical indication and DAN.	Work systematically in the library and media. Exploring the current electronic sources on the topic under discussion	1. Quality of formed judgments, logical thinking, flexibility. 2. The quality of systematization of the informational material obtained through its own activity.	During the semesters
2.	Reference.	Analysis of relevant sources on the topic of the paper.	1. The quality of systematization and	Semester VII or VIII

		Analysis, systematization and synthesis of information on the proposed theme. Compilation of the report in accordance with the requirements in force and presentation to the chair.	analysis of the informational material obtained through its own activity. 2. Concordance of the information with the proposed theme. 3. Quality of PPT presentation and answers to questions.	
3.	Case study analysis.	Choice and description of the case study Analysis of the causes of the issues raised in the case study. Prognosis of the investigated case. Deduction of the expected outcome of the case.	1. Analysis, synthesis, generalization of data obtained through own investigation. 2. Development of an algorithm of knowledge based on the obtained conclusions.	During the semesters
4.	Working with materials on-line.	Online self-assessment, study of online materials on the SITE Chair, expressing your own opinions through forum and chat.	Number and duration of SITE entries, self-evaluation results	During the semesters

IX. METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT

- ***Teaching and learning methods used***

At teaching the discipline ***"Pharmaceutical Chemistry"*** different methods and teaching methods are used, oriented towards the efficient acquisition and achievement of the objectives of the didactic process. In the theoretical lessons, along with traditional methods (lesson-exposure, lesson-conversation, synthesis lesson), modern methods (lesson-debate, lesson-conference) are also used. Practical forms of individual, frontal, group work. For the deeper learning of the material, different semiotic systems (scientific language, graphical language) and teaching materials (tables, schemes, photographs) are used. Within the lessons and extracurricular activities are used Information Communication Technologies - PowerPoint presentations.

- ***Applied teaching strategies / technologies*** *(specific to the discipline)*

Inductive, deductive strategies, teaching and learning takes place using models (analogue strategies), algorithmic strategies: explicative-demonstrative, intuitive, exponential, imitative and algorithmic ones; heuristic strategies - to develop knowledge through their own thinking effort, using problem-solving, discovery, modeling, hypothesis formulation, investigative experiment, which stimulates creativity.

- ***Methods of assessment*** *(including the method of final mark calculation)*

Current: frontal or/and individual control via:

(a) application of docimological tests;
(b) solving problems / exercises;
(c) analysis of case studies;
(d) control assesments - 12 (3 at Pharmaceutical chemistry-I; 3 at Pharmaceutical chemistry -II; 6 at Pharmaceutical chemistry -III);
(e) the current assessment of self-training: Pharmaceutical chemistry-I, and Pharmaceutical chemistry-II and Pharmaceutical chemistry-III (sem. VII, sem. VIII) at the semester ending.

The average annual score will show the average score between the scores obtained in totals and the note for self-training.

Final: Differentiated colloquium (Pharmaceutical chemistr-I and Pharmaceutical chemistry-III sem. VII); examination (Pharmaceutical chemistry-II and Pharmaceutical chemistry-III sem.VIII).

Differentiated colloquium –test-control and oral answer.

The final mark of the ***differentiated colloquium*** will be made up of the average grade during the semester (50%), test-control (20%), oral answer (30%).

Examination - practical skills, test-editor and oral answer.

The final mark of the ***examination*** will be made up of the annual average mark (30%), practical skills (20%), test-control ((Pharmaceutical chemistry-I and (Pharmaceutical chemistry-III sem. VII) or test-editor ((Pharmaceutical chemistry-III sem. VIII) (20%) and oral answer (30%).

Method of mark rounding at different assessment stages

Intermediate marks scale (annual average, marks from the examination stages)	National Assessment System	ECTSEquivalent
1,00-3,00	**2**	**F**
3,01-4,99	**4**	**FX**
5,00	**5**	**E**
5,01-5,50	**5,5**	
5,51-6,0	**6**	
6,01-6,50	**6,5**	**D**
6,51-7,00	**7**	
7,01-7,50	**7,5**	**C**
7,51-8,00	**8**	
8,01-8,50	**8,5**	**B**
8,51-8,00	**9**	
9,01-9,50	**9,5**	**A**
9,51-10,0	**10**	

The average annual mark and the scores of all the final examination (computer assisted, test, oral) - all will be expressed in numbers according to the scoring scale (according to the table), and the final grade obtained will be expressed in two decimal digits will be transferred to the notes book.

Absence on examination without good reason is recorded as "absent" and is equivalent to 0 (zero). The student has the right to have two re-examinations.

X. RECOMMENDED LITERATURE:

A. Compulsory:

1. Course support.
2. Melentyeva G., Antonova L. Pharmaceutical Chemistry. English translation. Moscow: Mir Publihers, 1988.
3. European Pharmacopoeia - 8th edition. Council of Europe, 67075 Strasbourg Cedex, France - 2013.
4. Methodical indications.

B. Additional:

1. Babilev F.V. Chimie farmaceutică, Chişinău: Universitas, 1994.
2. Bojiţă M., Roman L., Săndulescu R., Oprean R. Analiza şi Controlul medicamentelor.Vol. I. - Cluj-Napoca: Editura Intelcredo, 2003.
3. Bojiţă M., Roman L., Săndulescu R., Oprean R. Analiza şi Controlul medicamentelor.Vol. II. - Cluj-Napoca: Editura Intelcredo, 2003.
4. European Pharmacopoeia - 7th edition. Council of Europe, 67075 Strasbourg Cedex, France - 2010. (electronic version)
5. Farmacopea Română. Ediţia X-a –Bucureşti: Editura medicală, 1993.
6. Haţieganu E., Stecoza C. Chimie terapeutica. Vol. II. – Bucureşti: Editura Medicala, 2006-2008.
7. Lista medicamentelor esenţiale. Ordinul MS RM Nr. 162 din 23.04.07.
8. Matcovschi C., Safta V. Ghid farmacoterapeutic (medicamente omologate în Rep. Moldova). – Ch.: „Vector V-N" SRL, 2010 (F.E.-P. „Tipor. Centrală"). .
9. Беликов В.Г. Фармацевтическая химия.- М.: МЕДпресс-информ, 2007.
10. Вартанян Р.С. Синтез основных лекарственных средств. – М.:МИА, 2004.
11. Руководство к лабораторным занятиям по фармацевтической химии. Под ред. Арзамасцева А.П. – М.: Медицина, 2001.
12. Фармацевтическая химия. Под ред. Арзамасцева А.П. – М.: ГЭОТАР-Медиа, 2006.