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
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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

DISCIPLIN **INTRODUCTION TO GOOD PHARMACY PRACTICE**

Integrated studies

Type of course: **optional**

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**

  Introduction to Good Pharmacy Practice is a necessary discipline for pharmacy students, as it provides the basis for understanding the need for further specialized courses such as pharmaceutical chemistry, drug control, drug technology, pharmacology that will allow deeper integration of knowledge gained in these courses. Students will be able to integrate knowledge from pharmaceutical disciplines and to substantiate the necessary practical skills in specialized disciplines.

  The requirements for the formation of competencies in the pharmaceutical pharmacist's good practices are met within this interdisciplinary course. It is expected and recommended for the Pharmacy specialty.

  Introduction to Good pharmacy practice course is intended to help future pharmacists know the current GMP (Good Manufacturing Practice) and GLP (Good Laboratory Practice) requirements in drug technology, standardization and control, drug design and research, and to develop the practical skills needed to ensure the quality of drugs.

  Mission of the curriculum (aim) in professional training

  To provide students with knowledge of the principles of good pharmacy practice used in drug technology, drug standardization and control, drug research and development.

  Language (s) of the course: Romanian, Russian, English.

- **Beneficiaries:** students of the II year, faculty Pharmacy, specialty PHARMACY.

II. MANAGEMENT OF THE DISCIPLINE

Code of discipline		**S.06.A.066**	
Name of the discipline		**Introduction to Good Pharmacy Practice**	
Person(s) in charge of the discipline		PhD, D.Sc. in Pharmaceutical Sciences **Vladimir Valica**	
Year	**II**	Semester	**3**
Total number of hours, including:			**60**
Lectures	**17**	Practical/laboratory hours	
Seminars	**34**	Self-training	**9**
Form of assessment	**C**	Number of credits	**2**

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:***

- subject matter and objectives of the discipline;
- the basic notions and principles found in good pharmacy practice;
- particularities in good pharmacy practice;
- the specificity of the requirements of good pharmacy practice.

- ***at the application level:***

- theoretical knowledge in the practice of professional activity;
- practical skills in implementing good pharmacy practices;
- responsibility and persistence in pharmaceutical activity.

- ***at the integration level:***

- basic concepts of GMP;
- basic concepts of GLP;
- the ability to use good pharmacy practice to obtain qualitative, safe and harmless medicines.

IV. PROVISIONAL TERMS AND CONDITIONS

It is a multidisciplinary field that provides the basis for understanding the necessity of subsequent specialized courses such as pharmaceutical chemistry, drug control, drug

technology, pharmacology.

V. THEMES AND ESTIMATE ALLOCATION OF HOURS

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

No. d/o	THEME	Number of hours		
		Lectures	Seminars	Self-training
1.	Good pharmacy practices. General considerations. The importance of good pharmacy practice in obtaining safe and innocuous quality medicines. GMP Basic Criteria.	2	4	-
2.	GMP Basic Criteria. Guide to Good Practice in Manufacturing Medicines. The structure, the most important of the RBPFMs.	2	2	-
3.	Quality Management. Requirements for staff, premises and equipment.	-	2	-
4.	Production requirements and quality control described in the RBFM guide. The possibilities of the manufacturing and controlling contract. Importance of complaints and self-insight.	2	4	2
5.	Documentation in RBFM. Standard Operation Procedures. Practical work of totalization	2	2	3
6.	*Control assessments.*	-	2	-
7.	Guide to Laboratory Practices. Introduction and terminology. Definitions and deciphering of the most important terms used in preclinical studies. Moldovan and international legislation in the field of preclinical and animal studies.	2	2	-
8.	Particularities of preclinical studies in laboratory animals. Experiments in pharmacotoxicology. Modeling pathologies in preclinical studies.	-	2	2
9.	Organizing and conducting preclinical studies. Essential documents for a preclinical study. Requirements for personnel, room, equipment, test-systems, animals.	2	4	-
10.	Quality management in preclinical studies. Standard Operating Procedures in GLP: introduction, general data, design principles.	2	4	-
11.	Reporting the results of preclinical studies. Inspections and audit in the preclinical study. Principles for the preparation of the preclinical study finishing report. Reference documents. Types of audits and inspections. Audit report.Documentaţia în RBFM.	3	2	2
12.	*Control assessments.*		2	
13.	*Colloquium*.	-	2	-
Total		**17**	**34**	**9**

VI. REFERENCE OBJECTIVES OF CONTENT UNITS

Objectives	Content units
Theme (chapter) 1. Good pharmacy practices. General considerations of GMP, GDP, GLP.	
• Define the basic concepts of discipline; • know basic gmp criteria; • demonstrate abilities to analyze and systematize the theoretical knowledge; • apply the criteria for differentiating the methods used in good pharmacy practice; • integrate knowledge about good pharmacy practice into pharmaceutical activity.	Fundamental concepts of good manufacturing practice. Basic Criteria for Implementing Good Pharmaceutical Good Practices. Practical applications of the discipline. Examples
Theme (chapter) 2. Quality Management. Production requirements and quality control	
• Know the basic notions of quality management; • define quality management concepts; • demonstrate skills of knowledge of quality management; • apply the knowledge acquired for the use of RBPF; • integrate knowledge about quality management concepts into pharmaceutical practice.	Basic principles of quality management. The particularities of GMP compared to ISO.
Theme (chapter) 3. Documentation in RBFM. Standard Operation Procedures.	
• Define the concepts of documentation in RBFM; • demonstrate skills for the standard operating procedures used in GMP; • apply knowledge gained in working with documentation used in RBPF; • integrate knowledge about documentation into RBFM into pharmaceutical practice.	Basic principles for the development of Standard Operating Procedures. The main elements of the Standard Operating Procedures. Advantages of Using Standard Operation Procedures. Elaboration of standard operational procedures for various activities in GMP and GDP
Theme (chapter) 4. The Practice Guide to the Laboratory. Introduction and terminology. Definitions of the most important terms used in preclinical studies.	
• Define the concepts of Laboratory Practice Ways; • define the concepts of Good Laboratory Practice; • demonstrate the knowledge of the particularities of preclinical studies in laboratory animals; • apply the knowledge gained for critical analysis in organizing and conducting preclinical studies; • integrate acquired knowledge about GLP into pharmaceutical practice.	Particularities of preclinical studies in laboratory animals. Elaboration of standard operational procedures for various GLP activities.

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

✓ Professional (specific) (SC) competences

• PC1. Identification, knowledge and proper use of the basic principles of good pharmacy practice.

• PC2. Good knowledge, understanding and operation of theoretical knowledge and practical methods of good pharmacy practice.

• PC3. Professional possession of the principles of good pharmacy practice.

• PC4. Applying the theoretical and practical knowledge in solving complex situational problems of good pharmacy practice in pharmaceutical activity.

✓ Transversal competences (TC)

• TC1. Applying the basic principles of good pharmacy practice to the price of pharmaceutical activity.

• TC2. Ensure effective deployment and effective engagement in group activities. Identifying training needs according to the evolution of science in good pharmacy practice.

• TC3. Identifying opportunities for continuous training and efficient use of learning resources and techniques for their own development.

✓ Study outcomes

Upon completion of the course the student will be able to:

• know: the particularities of good pharmacy practice;

• be able to identify the main types of errors in the process of implementing good pharmacy practice.

• to formulate conclusions on the implementation of good pharmacy practice;

• apply the knowledge gained in studying good pharmacy practice to ensure the quality of medicines.

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	Work systematically in the library and mediate. Exploring the current electronic sources on the topic under discussion	1. Quality of formed judgments, logical thinking, flexibility. 2. The quality of the systematization of the informational material obtained through its own activity.	During the semester
2.	Report	Analysis of relevant sources on the topic of the paper. Analysis, systematization and synthesis of information on the proposed theme. Compilation of the paper according to the requirements in force and presentation to the chair.	1. The quality of systematization and analysis of the informational material obtained through its own activity. 2. Concordance of information with the proposed theme. 3. Quality of PPT presentation and answers to questions. During the semester	During the semester
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 case investigated. Deduction of the expected outcome of the case.	1. Ability to analyze, synthesize, generalize data obtained through its own investigation. 2. Formation of an algorithm of knowledge based on the obtained conclusions.	During the semester

IX. METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT

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

Exposure, interactive lecture, heuristic conversation, problem-solving, brainstorming, group work, individual study, work with textbook and text, debate, problem solving, role play, simulation, interactive listening**.**

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

Inductive, deductive, teaching and learning strategies are developed using models (analogue strategies), algorithmic strategies: explicative-demonstrative, intuitive, exponential, imitative and algorithmic; heuristic strategies - to develop knowledge through his or her own

thinking effort, using problem-solving, discovery, modeling, hypothesis formulation, heuristic dialogue, investigative experiment, assault of ideas, which stimulate creativity.

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

Current: front and / or individual control via:

(a) application of docimological tests;
(b) solving problems / exercises;
(c) analysis of case studies;
(d) playing role plays on the topics discussed;
(e) control assesments – 2;
(f) the current assessment of individual work at the end of the semester.

The average mark is calculated by average of the marks obtained at control assesments and the mark of self-training.

Final: Colloquy, the "pass" rating - oral test.

The final grade at the colloquium will be composed of the average score during the semester (50%), oral answer (50%).

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. Directiva 2003/94/CE a Comisiei Europene din octombrie 2003 de stabilire a principiilor şi orientărilor privind buna practică de fabricaţie cu privire la produsele medicamentoase de uz uman şi medicamentele experimentale de uz uman.
3. Handbook for Good Clinical Research Practice (GCP). Guidance for implementation. World Health Organization. 2002.
4. Handbook for Good Laboratory Practice (GLP). Quality practices for regulated non-clinical research and development. World Health Organization. 2009.
5. Hotărâre nr 63/2002 din 24/01/2002 privind aprobarea principiilor de Bună Practică de Laborator, precum și inspecția și verificarea respectării acestora în cazul testărilor efectuate asupra substanțelor chimice. Monitorul Oficial.Partea I, nr 102 din 06/02/2002. București. Romania.
6. Muntean D.L., Bojiţă M. Controlul medicamentelor (Metode spectrale, cromatografice şi electroforetice de analiză). – Cluj-Napoca: Editura Medicală Universitară „Iuliu Haţieganu”, 2004.
7. Ordinul AMDM nr. 24 din 04.04.2013 „Cu privire la aprobarea Ghidului privind buna practică de fabricaţie a medicamentelor (GMP) de uz uman”.
8. Regulile pentru buna practică în studiul clinic (ICH Guide For Good Clinical Practice). Buletinul INF (ediţie specială). Chişinău. 2002.
9. Methodical indications.

B. Additional:

1. Directive 2004/10/ec of the european parliament and of the council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version). Official Journal of the European Union. 20.2.2004. L50/44-L50/59
2. Directive 2004/9/ec of the european parliament and of the council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (Codified version) (Text with EEA relevance). Official Journal of the European Union. 20.2.2004. L50/28-L50/44
3. Directive 2010/63/eu of the european parliament and of the council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance). Official Journal of the European Union. 20.10.2010. L276/33-L276/79
4. Ghicavîi V., Bacinschi N., Guşuilă Gh. Farmacologia. (ediţia III) E.E.-P ”Tipografia Centrală”, Chişinău 2012, 996 p. ISBN 978-9975-53-068-2.
5. GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS. Eighth Edition Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Institute for Laboratory Animal Research Division on Earth and Life Studies. The national Academies Press. Wasington DC. 2010.
6. Legea privind protecția animalelor folosite în scopuri experimentale sau în alte scopuri științifice. Publicat : 27.10.2006 în Monitorul Oficial Nr. 168-169.
7. Каркищенко Н.Н., Грачева С.В. и соавт. Руководство по лабораторным животным и альтернативным моделям в биомедицинских исследованиях. Москва. 2010.
8. Хабриев Р.У. и соавт. Руководство по экспериментальному (доклиническому) изучению новых фармакологических веществ. Москва, 2005.