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

DISCIPLINE **DRUG DEVELOPMENT AND PHARMACEUTICAL RESEARCH**

Integrated studies

Type of course: **Compulsory discipline**

Chisinau, 2017

I. INTRODUCTION

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

Drug development and pharmaceutical research is a discipline aimed to develop skills for the research activities by pharmacist students in accordance with contemporary requirements and modern standards of drug research. ***Drug development and pharmaceutical research*** is a necessary course due to the results of the pharmaceutical scientific researches, which have a great contribution to the development of the society and to the technical and scientific progress. Discipline ***Drug development and pharmaceutical research*** is an instrument of investigation, communication and organization of the experiments and their results and works with specific concepts to be learned and applied effectively in research.

In order to prepare highly qualified specialists in the field of pharmaceutical research, the course is designed and recommended for the pharmacy specialty.

Being an integration discipline, it correlates with all disciplines in the pharmaceutical field and allows the integration of gained knowledge and application for a high-quality pharmaceutical scientific research.

The knowledge gained from the course ***Drug development and pharmaceutical research*** could be applied by the students for the license thesis, thus contributing to the improvement of the quality of the students' scientific works.

- **Mission of the curriculum (aim) in professionaltraining**

Discipline ***Drug development and pharmaceutical research*** provides the data needed to guide the student pharmacist in the face of a new experiment or research project in the field of medical and pharmaceutical.

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

II. MANAGEMENT OF THE DISCIPLINE

Code of discipline		**S.08.O.080**	
Name of the discipline		**Drug development and pharmaceutical research**	
Person(s) in charge of the discipline		PhD in pharmaceutical sciences, associate professor **Livia Uncu**	
Year	**IV**	Semester/Semesters	**8**
Total number of hours, including:			**90**
Lectures	**17**	Practical/laboratory hours	**51**
Seminars		Self-training	**22**
Form of assessment	**CD**	Number of credits	**3**

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:***

– the object of study of the discipline;
– the objectives of the discipline;
– the fundamental notions and concepts of pharmaceutical research.

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

– the knowledge of a specialized bibliographic study;
– the objectives of the discipline;
– the requirements for the elaboration of a review for a specialized scientific article;
– the requirements for the elaboration of a specialized scientific article;
– the principles to edit a specialized scientific article;
– collection of data for the development of pharmaceutical dossier;
– the knowledge of perfecting of pharmaceutical dossier.

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

– fundamental notions of research methodology;
– basic concepts in statistics;
– views in support of new ideas;
– ability to use contemporary methods in the field of pharmaceutical research;
– validation principles.

IV. PROVISIONAL TERMS AND CONDITIONS

The knowledge in the field of mathematics and fundamental and applied pharmaceutical disciplines are required in order to acquire a more efficient understanding of the subject of the course ***Drug development and pharmaceutical research***. Also, the knowledge of the computer is an indispensable requirement.

V. THEMESAND ESTIMATEALLOCATION OF HOURS

Lectures, practical hours/ laboratory hours/seminarsand self-training

No.	THEME		Number of hours		
			Lectures	Practical hours	Self - training
1.	**Pharmaceutical scientific research. Planning and design of a research study on drug development.**	Fundamental notions of research methodology and instruments of pharmaceutical research.	1	3	-
		Planning and design of a research study.	1	-	-
		Methodology of pharmaceutical research. Stages of elaboration of a medicine.	2	-	-
2.	**Critical and specialized bibliographical study.**	Literature study.	1	3	2
		Organization, documentation via the Internet (search engines, international scientific databases), drafting of their bibliographic records (classical or electronic system).	-	3	2
		Critical bibliographical study. Revision of a specialized scientific article.	1	3	2
3.	**Processing and analysis of experimental results.**	Processing of experimental results.	1	3	2
		Basic notions in analysis of the experimental results.	1	3	2
		Basic notions in statistics. Statistical tests of significance.	1	3	2
		Regression and calibration.	-	3	2
4.	**Validation in pharmaceutical research.**	Validation principles. Validation of analytical methods.	2	3	2
		Quality control and validation of experimental results.	1	-	-
		Preparation of the validation report.	-	3	2
		Dissemination of research results. Intelectual property.	1	-	
5.	**Stability studies of drugs.**	Stability studies in drug research.	2	6	2
		Basic notions of a pharmaceutical dossier.	1	3	
		Creating of a work plan of license thesis; preparation of a research report.	1	3	2

No.	THEME	Number of hours		
		Lectures	Practical hours	Self - training
	Control assessments – 1, 2.	-	6	
6.	***Differentiated colloquium.***	-	3	
Total		**17**	**51**	**22**

VI. REFERENCE OBJECTIVES OF CONTENT UNITS

Objectives	Contents units
Chapter 1. Pharmaceutical scientific research. Planning and design of a research study.	
• to define the fundamental notions of a scientific research; • to know the stages of a scientific research and the way in which a concrete research is carried out; • to know the specific aspects of a pharmaceutical research; • to know the ethical considerations of a pharmaceutical research; • to elaborate a research protocol.	The fundamental notions of a scientific research. Stages of scientific research. Particularities of a pharmaceutical research. Null, alternative, directional, non-directional hypotheses. Dependent and independent, categorical and continuous, quantitative and qualitative variables of a research. Ethical considerations of a pharmaceutical research. Research protocol: compartments and content.
Chapter 2. Critical and specialized bibliographical study.	
• to apply internet and library documentation on a topic of pharmaceutical research or on the topic of license thesis; • to know the requirements of the elaboration and editing of a scientific article; • to know the requirements of writing and editing of a review of a scientific article; • to apply the knowledge gained in the practice of pharmaceutical research.	Documentation via the Internet: search engines, international scientific databases. Bibliographical style reference guides (classic or electronic system). Scientific article: compartments and requirements of its elaboration. The review of a scientific article: compartments and content.
Chapter 3. Processing and analysis of experimental results.	
• to define the basic notions in statistics; • to represent the experimental data by mathematical equations; • to represent experimental data using tables and charts; • to apply correctly the statistical significance of tests t (Student), F (Fisher), C (Cochran), Q of	Basic concepts in statistic: true value, accuracy, accuracy, R domain, relative standard deviation, population, sample. Tables - types and rules of construction. Charts - types and rules of construction. Significance tests: t (Student), F (Fisher), C (Cochran), Q for data

Objectives	Contents units
eliminating of data; • to know the concepts of regression and calibration; • to apply the gained knowledge for the elaboration of the license thesis.	deletion. Linearity and correlation coefficient.
Chapter 4. Validation in pharmaceutical research.	
• to define the principles of validation of an assay method of an active substance from a dosage form; • to know the validation parameters of a method; • to elaborate a validation report.	Validation parameters - accuracy, precision, linearity, detection limit, quantification limit, specificity, reproducibility, robustness, stability.
Chapter 5. Stability studies of drugs.	
• to know the factors of degradation of drugs; • to explain how each degradation factor acts on drugs; • to know the accelerated drug stability studies; • to know how to calculate the shelf life of a drug.	Drug degradation factors: internal (pH, solvent), external (temperature, humidity, oxygen from the air). Accelerated drug stability studies. Shelf life of a drug: definition, methods of determination.

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

✓ Professional (specific) (SC) competences

- PC1. Identification and use of concepts, principles and theories in the practice of a scientific research from pharmaceutical field.
- PC2. Knowledge of logical succession of the operations that form the stages of a scientific research.
- PC3. Applying of ethical skills in scientific researches, license theses, etc.
- PC4. The use of contemporary methods in pharmaceutical scientific research.
- PC5. To solve the problems of situation and to draw the conclusions.
- PC6. Applying of theoretical and practical knowledge in pharmaceutical scientific researches.

✓ Transversal competences (TC)

- TC1. Applying of rigorous and efficient working rules, manifesting a responsible attitude towards the scientific and didactic field, for the optimal and creative valorisation of their own potential in specific situations, observing the principles and norms of professional ethics.
- TC2. Obtaining of moral markers, forming professional and civic attitudes, that allow students to be honest, non-conflict, cooperative, liable to help people interested in community development; to know and apply ethical principles related to medical-pharmaceutical practice; to recognize a problem when it comes out and provide solutions that are responsible for solving it.
- TC3. Selection of digital materials, critical analysis and draw up conclusions. Presentation of

individual scientific projects.

✓ **Study outcomes**

At the end of the course the student will be able to:

- choose a topic of research according to the importance of the topic, possibility of solving the problem, previous results, validation of the information;
- draw up correctly a research problem;
- carry out a specialized bibliographic study;
- establish the working hypotheses for research;
- choose correctly the variables of the study;
- use ethical norms in scientific research;
- determine the shelf life of a drug by classical method and by accelerated degradation method;
- know and to apply in practice the principles of validation of an assay method of drugs;
- create a review of a specialized scientific article;
- write and to edit a specialized scientific article;
- complete a pharmaceutical dossier.

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.	Cataloging data	Assessment of an individual theme by creating a bibliography; consultation of databases with a specialist, consultation of printed and electronic bibliographic resources; editing and presenting the bibliography on-line and printed in portfolio	The quality of the prepared bibliography is appreciated using well-defined criteria (number of accessed sources, actuality and year of publications, correctness of formatting etc.)	The first part of semester
2.	Editing of a scientific article	Evaluation of a scientific article that has been intentionally misrepresented; making corrections; presenting of edited article on-line and printed in portfolio	The quality of the editing article is appreciated by assessing the compliance with the publication requirements	The first part of semester
3.	Review of a scientific article	Evaluation of a scientific article and make a review; presenting of review on-line and printed in portfolio	The quality of the review is appreciated by the requirements of per-review	The first part of semester
4.	Statistics worksheets	Solving the individual statistical problems and completing of 5 statistical worksheets according to the elaborated algorithms; presenting of 5 statistical	Verifying the accuracy of calculations and results	The first part of semester

		files on-line and printed in portfolio		
5.	Validation worksheet and report	Solving the problems on validation and completing the validation report according to the elaborated algorithm; presenting the validation worksheet and report on-line and printed in portfolio	Verifying the accuracy of calculations and results	The second part of semester
6.	Stability worksheets and report	Solving the individual problems on stability of drugs; calculating and estimating the shelf life of drugs; completing the stability report according to the elaborated algorithm; presenting the stability worksheet and report on-line and printed in portfolio	Verifying the accuracy of calculations and results	The second part of semester
7.	Annotation of the license thesis	The elaboration of the for the license thesis according to the elaborated algorithm and according to the specificity of the department where the thesis will be done; presenting the annotation on-line and printed in portfolio	Verifying the structure and correctness of formatting	The end of semester

IX. METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT

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

During the course ***Drug development and pharmaceutical research*** different methods and didactic procedures are used, oriented towards the efficient acquisition and achievement of the objectives of the didactic process. At theoretical lessons, along with traditional methods (lesson-exposure, lesson-conversation, synthesis lesson), modern methods (lesson-debate, lecture-conference, problem-lesson) are also used. At practical lessons individual, frontal and group works are used. For the deeper learning of the material, different semiotic systems (scientific, graphical and computerized language) and teaching materials (tables, schemes, photographs) are used. Within the lessons and extracurricular activities Information Communication Technologies are used – PowerPoint presentations, informative material exposed on-line as well as the presentation of the individual on-line work in Word, Excel format.

- ***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 own thinking, using problem-solving, discovery, modeling, hypothesis formulation, heuristic dialogue, investigative experiment, assault of ideas, with the effect of stimulating 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) achievement of playing roles at the discussed topics;

(e) control assesments - 2;

(f) the current assessment of self-training at the end of the semester.

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

Final*:* Differentiated colloquium - test-control and oral answer.

The final mark obtained at ***differentiated colloquium*** is based on the average mark of the semester (50%), final test-control (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 marks of all stages of final examination (computer assisted, test, oral) - are expressed in numbers according to the mark scale (according to the table), and the final mark obtained is expressed in number with two decimals, which is transferred to student's record-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. European Pharmacopoeia - 8th edition. Council of Europe, 67075 Strasbourg Cedex, France – 2013.
3. Bojiţă M., Roman L., Săndulescu R., Oprean R. Analiza şi Controlul medicamentelor.Vol. I. - Cluj-Napoca: Editura Intelcredo, 2003.
4. Bojiţă M., Roman L., Săndulescu R., Oprean R. Analiza şi Controlul medicamentelor.Vol. II. - Cluj-Napoca: Editura Intelcredo, 2003.
5. Methodical indications.

B. Additional:

1. Farmacopea Română. Ediţia X-a –Bucureşti: Editura medicală, 1993.-1315 p.
2. British Pharmacopoeia. – London, 2009.
3. Popa L. Elemente de metodologia cercetării ştiinţifice în domeniul farmaceutic, Ediţia a II-a revizuită şi adăugită, Editura Printech Bucureşti, 2005.
4. Achimaş C.A. Metodologia cercetării ştiinţifice medicale, Editura Medicală Universitară „Iuliu Haţieganu" Cluj-Napoca, 1998.
5. Marczyk G., De Matteo D., Festinger D.: Essentials of Research Design and Methodology, John Wiley and Sons, 2005.
6. Chan C.C., Lam H., Lee Y.C., Zhang X. Analytical method validation and instrument performance verification, Wiley Interscience, 2004.
7. Ermer J., Miller J.H.McB. Method Validation in Pharmaceutical Analysis, Wiley-VCH, 2005.
8. Roman L., Bojiţă M., Săndulescu R., Muntean D.L.Validarea metodelor analitice, Editura Medicală, 2007.
9. Mullins E. Statistics for the Quality Control Chemistry Laboratory, The Royal Society for Chemistry, 2003.
10. Kumar R. Research Methodology. A Step-by-Step Guide for Beginners, Sage Publications, 2005.