	CD 8.5.1 DISCIPLINE CURRICULUM	Edition:	06
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FACULTY OF PHARMACY

STUDY PROGRAM 0916.1 PHARMACY

CHAIR OF TECHOLOGY OF DRUGS

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 in pharmacy, associate professor
Livia Uncu

APPROVED
at the Council meeting of the Faculty of Pharmacy
Minutes No. 2 of 22.12.2017

Dean of Faculty, PhD in pharmacy, associate professor
Nicolae Ciobanu

APPROVED
approved at the meeting of the Chair technology of drugs
Minutes No. 3 of 26.10.2017
Head of chair, Dr. habil. in pharmacy, university professor
Eugen Diug

SYLLABUS

Practice at **PHARMACEUTICAL TECHNOLOGY I (EXTEMPORAL)**

Type of course: **practical internship**

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**

Practical experience in Extemporary Pharmaceutical Technology is an important component in the field of pharmacy and aims to prepare, prescribe and prepare pharmaceutical forms for release at the pharmacy level.

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

Creating the theoretical basis of the process of accumulation of skills and practical skills of drug preparation by the student under pharmacy conditions. The essential aim of the pharmacist is to prepare a chemically stable, physically and microbiologically stable, dose-stable, dose-stable, medicated and dosable drug to be administered.
The release of pharmaceutical forms must be accompanied by appropriate information and advice for each patient as well as the effects of their use.

- **Languages of the course:** Romanian, English;

- **Beneficiaries**: students of the III year, faculty of Pharmacy.

II. MANAGEMENT OF THE DISCIPLINE

Code of discipline		**S.06.O.068**	
Name of the discipline		Practice in Extemporary Pharmaceutical Technology	
Persons in charge of the discipline		**PhD in pharmacy, associate professor, Diana Guranda** **PhD in pharmacy, associate professor, Tamara Polișciuc** **PhD in pharmacy, associate professor, Cristina Ciobanu** **PhD in pharmacy, associate professor, Rodica Solonari**	
Year	**III**	Semester/Semesters	**VI**
Total number of hours, including: 60			
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:***

• To determine the objectives and content of the technology of the out-of-date medicines
• To determine the subject of study of the discipline;
• To define the concepts of the technology of the extemporaneous medicines and their evaluation according to the requirements of the DAN;
• To correctly interpret technological operations at different stages of preparation of medicaments in accordance with medical prescriptions and control vouchers;
• Identify the main physico-chemical and technological parameters of drug substances, auxiliary substances, adjuvants and packaging materials that determine the quality of the prepared drug.
• To know the rules of good practice in the manufacture of drugs under pharmacy conditions;
• Describe the pharmaceutical processes and devices used in the pharmacies' production facilities;
• Know the physico-chemical properties of drug substances, auxiliary substances, adjuvants and packaging materials.

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

- Identify the peculiarities of the application of technological operations in the preparation of the timeless forms;
-Categorize the principles of preparation of different forms of extemporaneous pharmaceutical according to the biopharmaceutical requirements;
-Explain the essence of the principles of selecting the physicochemical properties of auxiliary substances and packaging material in the preparation, packaging and release of non-temporal forms;
-To compare the practical experience and the doctrine of pharmaceutical technology at various stages of evolution in preformulation and formulation of drugs;
-Interpret pharmacopoeial quality standards and reference standards;
-Organize under pharmacy conditions the preparation of different types of pharmaceutical forms according to the technological process stages.

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

• To create new technological processes to optimize the preparation of the extemporal forms;
• Modify existing drug technologies to reduce costs;
• Validate the stages of the drug preparation technology process and quality control methods;
• To assess the influence of different factors on the quality of the time-consuming forms;
• To recommend new auxiliaries and adjuvants needed in the preparation of the extemporaneous forms;
• To elaborate technological prescriptions for the preparation of pharmaceutical elaborations;
• To propose new methods of evaluation of the quality of the extemporaneous medicines;
To select packaging materials suitable for packaging pharmaceutical forms.

IV. PROVISIONAL TERMS AND CONDITIONS

Practical experience in Extemporary Pharmaceutical Technology addresses a wide range of quite diverse concerns, such as: drug preparation in pharmacy; evaluating the formulation prescribed in terms of formulation, association of prescribed active substances and safety at administration; registration in the records for master preparations.

V. THEMES AND ESTIMATE ALLOCATION OF HOURS

✓ ***Practical hours***

No. d/o	THEME	Practical hours
1.	Drug technology as a science. Basic concepts and pharmaceutical terminology. State regulation in the production of medicines.	**2**
2.	Technology for the preparation of solid pharmaceutical forms.	**8**
3.	Technology for the preparation of liquid medical forms (alcoholic solutions, non-aqueous solutions).	**8**
4.	Mixing technology.	**6**
5.	Particularities of preparation of solutions of macromolecular substances.	**4**
6.	Technology for colloidal solutions preparation.	**4**
7.	Particulars of preparation of suspensions.	**4**
8.	Particularities of preparation emulsions.	**8**
9.	Technology for the preparation of aqueous extractive solutions.	**2**
10.	Preparation of ointments and pastes.	**6**
11.	Technology of suppository preparation.	**6**
12.	Preparation of ophthalmic drugs. Drugs with antibiotics.	**2**
	TOTAL	**60**

VI. REFERENCE OBJECTIVES OF CONTENT UNITS

Objectives	Content units
Theme (chapter) 1. Technology of the drugs - as a scientific discipline	
• Define the pharmacist's role in medicine; • pharmacist-patient; • define the pharmacy as a science; • know the basic directions of science-pharmacy; • to have knowledge in the field of disciplines; • define the role of the pharmacist in the preparation of medicines;	Pharmacy-complex science. Basic directions of pharmacy science - disciplines. Pharmacist - medicine. Pharmacist - his role in medicine.
Theme (chapter) 2. Organizing the process of generic drug production	
-Know and observe the Health Regulations in the pharmaceutical enterprises and institutions; -know the sanitary requirements for the rooms and equipment; -to appreciate the sanitary requirements for the cleaning of the rooms and the pharmaceutical equipment; -know the requirements for workers' personal hygiene;	To get acquainted with the process of preparation of pharmaceutical forms in pharmacies with production sections in Chisinau. Health regime in pharmaceutical companies and institutions. General provisions for rooms and equipment. General provisions for workers' personal hygiene.
Theme (chapter) 3. Solid pharmaceutical forms. Powders.	
• Know the characteristics of the powders; • know the methods of prescribing the powders; • Define the classification of powders; • know the basic requirements advanced to the powders: - powder; - mass homogeneity; - precision of dosing; - stability. • to define the stages of the technological process for the preparation of powders; • integrate knowledge gained from other disciplines in the preparation process; • know the ways of improving the packaging of powders; • define the appreciation of the biopharmaceutical aspect; • appreciate component compatibility in compound prescriptions; • Capacity to argue students' actions in the process of preparing compound powders.	Pharmaceutical powder, which keeps up to date. The fairness of the accurate assessment of the methods of prescribing the powders by doctors (divided and non-divisive). Particulars of powder preparation depending on their use (for newborns and childrens, with antibiotics, which apply to wounds.) FR X. General monograph. Powders.

Objectives	Content units
Theme (chapter) 4. Conditions for obtaining purified water	
• Sanitary regulations for the preparation of purified water; • know the rules of water transportation at workplaces; • know the washing and disinfection of vessels necessary for bottling water; • know the storage conditions and the shelf life of the purified water.	Purified water required for drug preparation. Distillation chamber for the production and storage of purified water. Particulars of the conservation of purified water - 72 hours.

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

✓ Specific competences (SC)

SC1. A thorough understanding and understanding of pharmaceutical terms in drug technology.

SC2. Understanding the responsibility and the role of the pharmacist-technologist in the process of producing the medicine.

SC3. Knowing the principles of organizing the drug preparation process.

SC4. Understanding the importance of complying with the requirements of the health care regime under pharmacy conditions to obtain a qualitative product.

SC5. Understanding the role of pharmaceutical factors in the quality of biopharmaceutical preparations.

✓ Transversal competences (TC)

TC1. Applying the scientific and theoretical knowledge in the pharmaceutical field in the process of organizing the production. Compliance with professional rules.

TC2. Forming a responsible attitude towards the quality of the finished product.

TC3. The ability to run the drug production process in the team.

TC4. Adaptation to new technologies, professional-personal development through the solution of the problem.

TC5. The ability to identify a complicated problem and to analyze it with the aim of forming the plan of realization.

Study outcomes

• To determine the subject of study of the discipline;

• To define the concepts of the technology of the extemporaneous medicines and their evaluation according to the requirements of the DAN;

• To correctly interpret the technological operations at different stages of preparation of medicaments according to medical prescriptions and order vouchers;

• Identify the main physico-chemical and technological parameters of drug substances, auxiliary substances, adjuvants and packaging materials that determine the quality of the prepared drug.

• To know the rules of good practice in the manufacture of drugs under pharmacy conditions;

• Describe the pharmaceutical processes and devices used in the pharmacies' production facilities;

• Know the physico-chemical properties of drug substances, auxiliary substances, adjuvants and packaging materials.

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 the book and the computer	Work systematically in the library and at the department. Exploring the current electronic sources on the topic under discussion.	1. The quality of systematization of the informational material obtained through its own activity.	During practice
2.	Working with medical prescriptions	Choice and description of the recipe. Analysis of drug preparation steps. Compilation of the written verification document and presentation of the teacher	1. Work load. 2. Solving the problem of the situation (recipe), the correctness of drug release.	During practice

IX. METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT

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

• Practical internship at Extemporal Pharmaceutical Technology is individualized, each student must:
• to prepare medicinal forms as prescribed;
• assess the quality of the pharmaceutical form prepared according to the pharmacopoeial requirements;
• to provide the written verification document;
• to correctly interpret the technological operations at different stages of preparation of medicinal products in accordance with medical prescriptions and control vouchers;
• Identify the main physico-chemical and technological parameters of drug substances, auxiliary substances, adjuvants and packaging materials that determine the quality of the prepared drug.
• know the rules of good practice in the manufacture of medicines under pharmacy;
• describe the pharmaceutical processes and devices used in the pharmacies' production facilities;
• know the physicochemical properties of drug substances, auxiliary substances, adjuvants and packaging materials.

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

Current:
• To define the concepts of the technology of the extemporaneous medicines and their evaluation according to the requirements of the DAN;
• To correctly interpret technological operations at different stages of preparation of medicaments in accordance with medical prescriptions and control vouchers;
• Identify the main physico-chemical and technological parameters of drug substances, auxiliary substances, adjuvants and packaging materials that determine the quality of the prepared drug.
• To know the rules of good practice in the manufacture of drugs under pharmacy conditions;
• Describe the pharmaceutical processes and devices used in the pharmacies' production facilities;
• Know the physico-chemical properties of drug substances, auxiliary substances, adjuvants and packaging materials.

Final: colloquy
Discussion with students about organizational processes in pharmacy departments. Presentation of the activity carried out in the production department, about the practical skills related to the preparation of solid, liquid and soft forms. Discussion with students about the recipe about the rules of preparation and quality control.

Method of mark rounding at different assessment stages

Intermediate marks scale (annual average, marks from the examination stages)	National Assessment System	ECTS Equivalent
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**	

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. Eugen Diug., Diana Guranda., Tamara Polișciuc., Rodica Solonari. Extemporal pharmaceutical technology. Compendium. Ed. "Universul". Chisinau, 2013.
2. E.Diug, I.Trigubenco. Drug technology in pharmacy. “Universitas”, Chişinău, 1992.
3. S.E.Leucuță., Marcela Achim., Elene Dinte. Preparing medicines. A guide to pharmacy students. Ediția II-a. Editura medicală universitară „ Iuliu Hațieganu”. Cluj- Napoca, 2009.
4. Diana Guranda. Methodical guidelines for laboratory work for third year students, pharmacy faculty. Chișinău, 2003.
5. State Medicines Nomenclature. Chişinău, 2000.

B. Additional

1. European Pharmacopoea, ed.7, 2010.
2. The Romanian Pharmacopoeia The 10th Edition, Supplement 2006, Medical Publishing House. București, 2006.
3. Order MS RM no. 960 of October 1, 2012. “Regarding prescribing and delivery of medicines ".