FACULTY OF PHARMACY

STUDY PROGRAM 0916.1 PHARMACY

CHAIR OF DRUG TECHNOLOGY

APPROVED
at the meeting of the Commission for Quality Assurance and Evaluation of the Curriculum in Pharmacy
Minutes No.2 of 09.11.2021
Chairman, PhD, Associate Professor of Pharmacy
Uncu Livia_____

APPROVED
at the Council meeting of the Faculty of Pharmacy
Minutes No.3 of 16.12.2021
Dean of Faculty, PhD, Associate Professor of Pharmacy
Ciobanu Nicolae_____

APPROVED
at the meeting of the chair of Drug Technology
Minutes No.1 of 25.08.2021
Head of chair, PhD, Associate Professor of Pharmacy
Ciobanu Nicolae_____

SYLLABUS

PRACTICAL TRAINING**: EXTEMPORAL PHARMACEUTICAL TECHNOLOGY**

Integrated studies/Cycle I, Bachelor's degree

Course type: **practical training**

Syllabus developed by of author:

Guranda Diana, Doctor of pharmacy, Associate Professor

Chisinau, 2021

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

Name of the discipline		Practical training**: Extemporal pharmaceutical technology**	
Persons in charge of the discipline		**Guranda Diana**, Doctor of pharmacy, Associate Professor	
Year	**III**	Semester/Semesters	**VI**
Total number of hours, including: **60**			
Form of assessment	**E**	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 Standard Analytical Documentation (SAD);
• 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

The practical trainind from Extemporal Pharmaceutical Technology carried out by third year students, Faculty of Pharmacy, addresses a wide range of quite diverse concerns such as: preparation of pharmaceutical forms in pharmacy (production department); assessment of the prescribed formulation composition, combination of prescribed active substances and safety of administration; registration in the evidence documents for the main preparations, offering and issuing the pharmaceutical form.

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. PRACTICAL WORKS PURCHASED AT THE END OF THE COURSE

The essential practical tasks are:

- To organize in pharmacy conditions the preparation of different types of pharmaceutical forms according to the stages of the technological process;
- To create new technological procedures for optimizing the preparation of main pharmaceutical forms;
- Modify existing drug preparation technologies to reduce costs;
- To validate the stages of the technological process of drug preparation and quality control methods;
- To evaluate the influence of different factors on the quality of the main pharmaceutical forms;
- To recommend new auxiliary substances and adjuvants necessary in the preparation of main pharmaceutical forms;
- To correctly select packaging materials suitable for the prepared pharmaceutical form;
- To properly form and deliver the pharmaceutical form to the consumer.

VII. 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.

Objectives	Content units
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.

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

✓ **Professional competences (PC)**

CP1: Knowledge of the theoretical bases of the disciplines included in the faculty curriculum, of the general principles in the elaboration, analysis and registration of pharmaceutical and parapharmaceutical products; knowledge of the general principles of organization and operation of pharmaceutical institutions with different legal forms of activity; knowledge of the legislative framework in the field of pharmacy; knowledge of the rights and obligations of the pharmacist.

CP2: forecasting the basic economic indices of the pharmacy: achievements, stocks of pharmaceutical preparations; travel expenses; benefit; assessing trends in the development of drug care; performing various practical tasks related to the preparation, analysis and standardization of drugs of synthetic origin and phytopreparations; knowledge of the medicine in terms of its action, indications, contraindications, side effects, administration and interactions; implementation of patient counseling and pharmaceutical care in practice.

CP3: designing the practical activity in the pharmaceutical system according to the diversity of professional roles; use and adaptation of theoretical knowledge in the field of pharmacy to the situations of practical activity; streamlining professional activity by introducing innovative elements in the field of pharmaceuticals; application of the requirements of the normative acts in the field of pharmacy in the practical activity; possession of the computer as a working tool in the theoretical and practical pharmaceutical activity; establishing the

correlation between the components of the pharmaceutical activity process and the population care system; continuous efficiency of the pharmaceutical activity by introducing innovations and implementing inventions in the field.

CP4: diagnosis of the particularities and organizational culture of the institution in the pharmaceutical system, where the specialist carries out his activity; design and coordination of pharmaceutical activity in various institutions: open state or private pharmacies; hospital pharmacies; pharmaceutical warehouses; medicine factories, laboratories for quality control and certification of medicines, etc .; the active involvement of the specialist in the process of accomplishing the mission of the pharmaceutical institution; demonstrating the ability to make decisions aimed at improving the pharmaceutical system.

CP5: determining the criteria for evaluating the effectiveness of the pharmaceutical system and personal activity according to the real conditions and in a concrete social context; determining the ways of directing the pharmaceutical activity based on the evaluation results; identifying research problems in the field of pharmacy; knowledge of the methodology of scientific research in the practical activity of pharmacist or head of the pharmaceutical unit.

CP6: adopting messages to various socio-cultural backgrounds, including by communicating in several foreign languages; use of problem-solving skills in the pharmaceutical activity through collaboration with doctors; promoting the principles of tolerance and compassion towards patients; use of information technology (and computer) in the pharmaceutical business;

- ✓ **Specific competences (SC)**

SC1: thorough knowledge and understanding of pharmaceutical terms in drug technology.

SC2: understanding the responsibility and role of the pharmacist-technologist in the drug production process.

SC3: knowledge of the principles of organization of the drug preparation process.

SC4: understanding the importance of complying with the requirements of the health regime in pharmacy conditions in order to obtain a quality product.

SC5: understanding the role of the influence of pharmaceutical factors on the quality of biopharmaceutical preparations.

- ✓ **Transversal competences (TC)**

TC1: Promoting logical reasoning, practical applicability, evaluation and self-evaluation in

decision making; compliance with the rules of ethics and pharmaceutical ethics in the preparation, analysis, transport and release of medicinal remedies to the population and medical institutions.

TC2: Identifying the training needs according to the evolution of the pharmaceutical system; determining the priorities in the continuous professional training of the pharmacist; appreciation of changes in the pharmaceutical system as a condition of its functionality.

TC3: Carrying out activities and exercising the specific roles of teamwork. Promoting the spirit of initiative, dialogue, cooperation, positive attitude and respect for others, empathy, altruism and continuous improvement of one's activity.

Study outcomes

• To determine the study objectives of the discipline;
• To define the concepts of extemporaneous medicine technology and their evaluation according to the SAD requirements;
• To correctly interpret the technological operations at different stages of preparation of medicines according to medical prescriptions and purchase orders;
• To identify the main physico-chemical and technological parameters of medicinal substances, auxiliary substances, adjuvants and packaging materials, which determine the quality of the prepared medicine.
• To know the rules of good practice for the manufacture of medicines in pharmacy conditions;
• Describe the pharmaceutical processes and devices used in the production departments of pharmacies;
• Know the physicochemical properties of medicinal substances, auxiliaries, adjuvants and packaging materials.

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

IX. STUDENT'S SELF-TRAINING

No.	Expected product	Implementation strategies	Assessment criteria	Implementation terms
2.	Working with medical from	Choice and description of the recipe.	Prescription analysis, correct preparation,	During practice

	University Pharmaceutical Center (UFC"Vasile Procopișin")	Analysis of the stages of preparation of the medicinal form. Compilation of the written verification document and presentation of the person in charge of the practical internship within the department.	packaging and release of pharmaceutical forms to consumers.	

X. 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 SAD;

• 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: Exam.
Discussion with students about the activity and work organization processes in the sections of the University Pharmaceutical Center (UFC) "Vasile Procopisin". Presentation of the report on the activity carried out in the production section of the UFC “Vasile Procopișin”, on the practical skills related to the preparation of solid, liquid and soft pharmaceutical forms. Presentation of the booklet where the prepared pharmaceutical forms were registered (20 recipes). Discussion with students (according to the approved questions - 40 questions) on the reception, preparation rules and quality control of the main pharmaceutical forms.

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.

XI. RECOMMENDED LITERATURE:

A. Compulsory:

1. Eugen Diug, Diana Guranda, Tamara Polișciuc, Rodica Solonari. Tehnologie farmaceutică extemporală. Compendiu. Ed. ,,Universul". Chișinău, 2013.

2. Eugen Diug, Ion Trigubenco. Tehnologia medicamentelor în farmacie. "Universitas", Chişinău, 1992.

3. S.E.Leucuță, Marcela Achim, Elene Dinte. Prepararea medicamentelor. Îndrumător pentru studenții de la farmacie. Ediția II-a. Editura medicală universitară ,, Iuliu Hațieganu". Cluj-Napoca, 2009.

4. Diana Guranda. Indicații metodice la lucrările de laborator pentru studenții anului III, facutatea de farmacie. Chișinău, 2011.

5. Nomenclatorul de Stat al Medicamentelor. Chişinău, 2000.

B. Additional:

1. European Pharmacopoea, ed.7, 2010. Farmacopeea Română Ediția a X-a, 2005.

2. Farmacopeea Română Ediția a X-a, Editura Medicală, București, 2009.

3. Ordinul MS RM nr. 960 din 01.10.2012 ,, Cu privire la modul de prescriere și livrare a medicamentelor".

4. Eugen Diug, Diana Guranda, Cristina Ciobanu. Biofarmacie și farmacocinetică. Compendiu. Chișinău, 2019. 52.p. UDC: 615,015 (076) C51.