



## CD 8.5.1 DISCIPLINE CURRICULUM

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### FACULTY OF PHARMACY

### STUDY PROGRAM 0916.1 PHARMACY

### CHAIR OF TECHNOLOGY 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

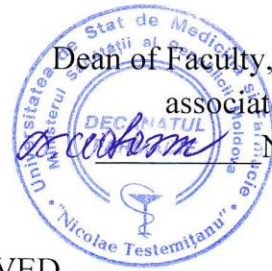
Chairman, PhD in pharmacy, associate professor

  
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

### DISCIPLINE PHARMACEUTICAL TECHNOLOGY I (EXTEMPORAL)

#### Integrated studies

Type of course: **Compulsory**



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### 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**

The course of Extemporary Pharmaceutical Technology is an important component in the field of pharmacy and has as objective the preparation of pharmaceuticals at the level of pharmacy, having the criterion for presenting the degree of dispersion of the pharmaceutical substances in the pharmaceutical form.

The content of the course is structured and is based on long-established practice techniques, but also brings new conceptual elements of modern pharmaceutical technology, transposed into preparation rules whose ultimate goal is to ensure the quality of the medicine, in accordance with current rules .

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

Creation of the theoretical basis of the process of accumulation of skills and practical skills of drug preparation by the student in both pharmacy and industry 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.

- **Languages of the course:** Romanian, English.
- **Beneficiaries:** students of the III year, faculty of pharmacy.



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### II. MANAGEMENT OF THE DISCIPLINE

|                                       |            |   |              |
|---------------------------------------|------------|---|--------------|
| Code of discipline                    |            | <b>S.05.O.052, S.06.O.061</b>                                 |              |
| Name of the discipline                |            | <b>PHARMACEUTICAL TECHNOLOGY I</b>                            |              |
| Persons in charge of the discipline   |            | <b>PhD in pharmacy, associate professor, Cristina Ciobanu</b> |              |
| Year                                  | <b>III</b> | Semester/Semesters  | <b>V, VI</b> |
| Total number of hours, including: 300 |            |   |              |
| Lectures                              | <b>34</b>  | Practical/laboratory hours                                    | <b>119</b>   |
| Seminars                              | -          | Self-training   | <b>147</b>   |
| Clinical internship                   |            |   |              |
| Form of assessment                    | <b>E</b>   | Number of credits   | <b>9</b>     |



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### 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 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;
- ***at the application level:***
- Identify the particularities of the application of technological operations in the preparation of the extemporal 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.
- ***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;



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- 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;
- Select packaging materials suitable for packaging pharmaceutical forms.



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### IV. PROVISIONAL TERMS AND CONDITIONS

Drug technology addresses a wide range of rather diverse concerns, such as the study of preformulation, formulation and bioavailability of drugs; the study of specific technological processes and processes used in the production of medicines, quality control, etc.



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### V. THEMES AND ESTIMATE ALLOCATION OF HOURS

- *lectures*

| No. d/o | THEME   | Lectures |
|---------|---|----------|
| 1.      | Drug technology as a science. Basic concepts and pharmaceutical terminology. State regulation in the production of medicines.   | 2        |
| 2.      | Classification of drug forms. Toxic and highly active substances. Getting Biopharmacy. Ancillary substances in drug technology. | 2        |
| 3.      | Powders.  | 2        |
| 4.      | Liquid medicinal forms. Classification. Solvents. Preparation of solutions by volume mass method.                               | 2        |
| 5.      | Dilution of standardized pharmacopoeial solutions. Preparation of mixtures.   | 2        |
| 5.      | Solutions of macromolecular substances.   | 2        |
| 6.      | Coloidal solutions.   | 2        |
| 7.      | Suspensions.  | 2        |
| 8.      | Emulsions.  | 2        |
| 9.      | Extractive aqueous solutions.   | 2        |
| 10.     | Liniments. Ointments.   | 2        |
| 11.     | Suppositories. Pills.   | 2        |
| 12.     | Injectable drug forms.<br>Stabilization of injectable solutions   | 2        |
| 13.     | Ophthalmic Drugs. Drugs with antibiotics.   | 2        |
| 14.     | Drugs with antibiotics.   | 2        |
| 15.     | Drugs for newborns.   | 2        |
| 16.     | Difficult prescriptions. Pharmaceutical incompatibilities.  | 2        |



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|            |                                       |           |
|------------|---------------------------------------|-----------|
| <b>17.</b> | Homeopathic and veterinary medicines. | <b>2</b>  |
|            | <b>Total</b>                          | <b>34</b> |

• *practical hours and self-training*

| N.<br>o<br>d/o    | THEME   | Number of hours        |                       |
|-------------------|---|------------------------|-----------------------|
|                   |   | Num<br>ber of<br>hours | Self-<br>traini<br>ng |
| <b>1.</b>         | Basics and pharmaceutical terminology used in drug technology. State Norms in the Production of Medicinal Products. Pharmaceutical literature.  | <b>3</b>               | <b>3</b>              |
| <b>2.</b>         | Dosage of the drug using mass balances. Dosage of liquid forms with the help of standard pointer.   | <b>3</b>               | <b>3</b>              |
| <b>3.</b>         | Powders. General rules for the preparation of compound powders differing in the prescribed quantity, specific weight and particle structure.  | <b>3</b>               | <b>4</b>              |
| <b>4.</b>         | Technology of powder preparation containing toxic and highly active substances.   | <b>3</b>               | <b>3</b>              |
| <b>5.</b>         | Technology of powder preparation containing toxic and highly active substances.<br>Titration powders. Single dose dosing check and nictemerals. Preparation of powders containing heavy-triturable substances, dyes, extracts and semi-finished products. | <b>3</b>               | <b>3</b>              |
| <b>6.</b>         | Totalization no.1.  | <b>3</b>               | <b>4</b>              |
| <b>7.</b>         | Dose Volume in Medicine Technology. Special cases of preparation of aqueous solutions.  | <b>3</b>               | <b>3</b>              |
| <b>8.</b>         | Non-aqueous solutions. Dilution of alcoholic solutions. Technology for the preparation of standard pharmacopoeial solutions.  | <b>3</b>               | <b>4</b>              |
| <b>9-<br/>10.</b> | Preparation of concentrated solutions. Preparation of mixtures using concentrated solutions.  | <b>6</b>               | <b>6</b>              |
| <b>11.</b>        | Preparation of solids dissolution mixtures.   | <b>3</b>               | <b>4</b>              |





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|--------------------|---|----------|-----------|
| <b>12.</b>         | Totalization no.2.  | <b>3</b> | <b>3</b>  |
| <b>13.</b>         | Solutions of macromolecular substances. Colloidal solutions.  | <b>3</b> | <b>3</b>  |
| <b>14.</b>         | Preparation of suspensions of hydrophilic substances.   | <b>3</b> | <b>4</b>  |
| <b>15.</b>         | Preparation of suspensions of strongly pronounced substances.   | <b>3</b> | <b>4</b>  |
| <b>16.</b>         | Pharmaceutical emulsions.   | <b>3</b> | <b>4</b>  |
| <b>17.</b>         | Totalization no.3   | <b>3</b> | <b>4</b>  |
| <b>18-<br/>19.</b> | Extractive aqueous solutions. Preparation of aqueous extractive solutions from vegetable products and standardized extracts. Quality control. Verification tests    | <b>8</b> | <b>8</b>  |
| <b>20.</b>         | Soft drug forms. Ointments. Rules for the incorporation of drug substances in the ointment base. Ointments - Solutions and Ointments - Suspensions. Qualitycontrol. | <b>4</b> | <b>5</b>  |
| <b>21.</b>         | Ointments - emulsions. Polyphase ointments. Quality control.  | <b>4</b> | <b>5</b>  |
| <b>22-<br/>23.</b> | Suppositories. Rules for the incorporation of drug substances into suppositories. Preparation of suppositories by manual modeling and casting. Quality control.     | <b>8</b> | <b>10</b> |
| <b>24.</b>         | Pills. Technology with dry extracts.  | <b>4</b> | <b>5</b>  |
| <b>25.</b>         | Totalization no.4.  | <b>4</b> | <b>6</b>  |
| <b>26.</b>         | Drugs that require preparation under aseptic conditions. Getting water for injections. Preparation of auxiliary material, sterilization.                            | <b>4</b> | <b>5</b>  |
| <b>27.</b>         | Injectable solutions. Preparation of injectable solutions consisting of strong acid salts and weak bases, weak acids and strong bases. Quality control.             | <b>4</b> | <b>5</b>  |
| <b>28.</b>         | Injection technology with strong oxidants. Injectable glucose solutions. Characteristics of stabilizers. Infusion technology. Isotonic. Quality control.            | <b>4</b> | <b>5</b>  |
| <b>29.</b>         | Totalization no.5.  | <b>4</b> | <b>5</b>  |



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|            |  |            |            |
|------------|--|------------|------------|
| <b>30.</b> | Ophthalmic Drop Technology with the use of dry drugs and concentrated solutions. Quality control.                            | <b>4</b>   | <b>5</b>   |
| <b>31.</b> | Ophthalmic ointments. Ophthalmic Ointment Technology. Quality control. Ointments with antibiotics. Verification tests. Test. | <b>4</b>   | <b>5</b>   |
| <b>32.</b> | Pharmaceutical incompatibilities. Difficult cases of drug preparation. Avoiding routes.                                      | <b>4</b>   | <b>5</b>   |
| <b>33.</b> | Totalization no.6  | <b>4</b>   | <b>6</b>   |
| <b>34.</b> | Totalization no.7. Practical skills.   | <b>4</b>   | <b>8</b>   |
|            | <b>Total</b>   | <b>119</b> | <b>147</b> |



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### VI. REFERENCE OBJECTIVES OF CONTENT UNITS

| Objectives  | Content units  |
|---|--|
| <b>Theme (chapter) 1. Drug technology - as a scientific discipline</b>  |  |
| <ul style="list-style-type: none"><li>Define the pharmacist's role in medicine;</li><li>pharmacist-patient;</li><li>define the pharmacy as a science;</li><li>know the basic directions of science-pharmacy;</li><li>to have knowledge in the field of disciplines;</li><li>define the role of the pharmacist in the preparation of medicines.</li></ul>  | <ol style="list-style-type: none"><li>Pharmacy-complex science.</li><li>Basic directions of pharmacy science - disciplines.</li><li>Pharmacist - medicine.</li><li>Pharmacist - his role in medicine</li></ol>   |
| <b>Theme (chapter) 2. Organization of the production process of the magistral forms</b>   |  |
| <ul style="list-style-type: none"><li>Know and observe the Health Regulations in the pharmaceutical enterprises and institutions;</li><li>know the sanitary requirements for the rooms and equipment;</li><li>to appreciate the sanitary requirements for the cleaning of the rooms and the pharmaceutical equipment;</li><li>know the requirements for workers' personal hygiene.</li></ul>  | <ol style="list-style-type: none"><li>To get acquainted with the process of preparation of pharmaceutical forms based on the „Vasile Procopis University Center“</li><li>Health regime in pharmaceutical companies and institutions.</li><li>General provisions for rooms and equipment.</li><li>General provisions for workers' personal hygiene.</li></ol> |
| <b>Theme (chapter) 3. Solid Pharmaceutical Forms. Powders.</b>  |  |
| <p>Know the characteristics of the powders;</p> <ul style="list-style-type: none"><li>know the methods of prescribing the powders;</li><li>Define the classification of powders;</li><li>know the basic requirements advanced to the powders:</li></ul> <ul style="list-style-type: none"><li>- powder;</li><li>- mass homogeneity;</li><li>- precision of dosing;</li><li>- stability.</li></ul> <ul style="list-style-type: none"><li>to define the stages of the technological process for</li></ul> | <ol style="list-style-type: none"><li>Powders- Ancient pharmaceutical form, which keeps up to date.</li><li>The correctness of the fair assessment of the methods of prescribing the powders by doctors (divided and non-divisive).</li></ol>  |



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### Objectives

### Content units

the preparation of powders;

- integrate knowledge gained from other disciplines in the preparation process;
- know how to improve the powder packaging, such as capsule encapsulation using the "Feton" manual fitting set;
- 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.

3. Particulars of powder preparation depending on their use (for newborns and infants, with antibiotics, which apply to wounds.)
4. FR X. General monograph. Powders

### Theme (chapter) 4. Purified Water and Water for Injections.

- Sanitary regulations for the preparation of purified water and water for injections;
- know the rules of water transportation at workplaces;
- Emphasize the washing and disinfection of vessels necessary for bottling water;
- know the substances needed to remove pyrogenes;
- know the storage conditions and the shelf life of purified water and water for injections

1. Purified water required for drug preparation.
2. Water for injections necessary for the preparation of sterile forms
3. Distillation chamber for the production and storage of purified water and water for injection.
4. Water conservation features for injection - 24 hours.

### Theme (chapter) 4. Liquid pharmaceutical forms. Solutions.

- Know the characteristics of the solutions;
- Know the prescribing methods;
- Know the basic requirements advanced to the liquid forms;
- Know how to take control of doses for toxic and highly active substances;
- Define the stages of the technological process of preparing solutions;
- Know the peculiarities of aqueous solutions;
- To know the particularities of the preparation of solutions with substances that are difficult to dissolve in cold water;

1. Solutions - a pharmaceutical form, often found in the local recipe.
2. Ensure the desired drug concentration.
3. Ensure physico - chemical stability of the drug substance.
4. Ensure clarity.
5. FR X. General monograph. Solutions

### Theme (chapter) 5. Liquid pharmaceutical forms. Solutions.



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### Objectives

### Content units

- Know the characteristics of the solutions;
- Know the prescribing methods;
  - Know the basic requirements advanced to the liquid forms;
  - Know how to take control of doses for toxic and highly active substances;
  - Define the stages of the technological process of preparing the solutions;
  - Know the peculiarities of aqueous solutions;
  - To know the particularities of the preparation of solutions with substances that are difficult to dissolve in cold water;

- 1.Solutions - a pharmaceutical form, often found in the local recipe.
- 2.Ensure the desired drug concentration.
- 3.Ensure physico - chemical stability of the drug substance.
- 4.Ensure clarity.
- 5.FR X. General monograph. Solutions.

### **Theme (chapter) 6. Technology of non-aqueous solutions. Alcoholic solutions.**

- Define the characteristics of alcoholic solutions;
- Know how the alcohol concentration is expressed;
  - Know the official alcoholic solutions;

- 1.General aspects.
- 2.Official alcoholic solutions. Conservation.

### **Theme (chapter) 7. Semisolid preparations. Ointments.**

- To know the characteristics of semisolid preparations;
- Define the classification according to different criteria of soft pharmaceutical forms;
- To know the requirements for ointments;
- Know the criteria for classifying excipients;
- To know the requirements of the excipients used in the preparation of the ointments;
- Define the formulation of ointments;
- Have knowledge of the particularities of ointment preparation;
- Appreciate the quality of the ointments.

- 1.Ointment formulation.
- 2.Classification of ointments.
- 3.Ointment bases.
- 4.Preparation of drug ointments.
- 5.Quality control of ointments.

### **Theme (chapter) 8. Suppositories.**



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| <b>Objectives</b>   | <b>Content units</b>   |
|---|--|
| <ul style="list-style-type: none"><li>• Know the characteristics of suppositories;</li><li>• Define criteria for classification of suppositories;</li><li>• To assess the requirements of FR X against suppositories;</li><li>• Be able to control dosage for some substances in suppositories;</li><li>• Define the classification and requirements advanced to excipients in suppositories;</li><li>• To know the methods of preparation of suppositories at the pharmacy level;</li><li>• Know how to prepare suppositories on different excipients;</li><li>• To be able to appreciate the quality control of technological and biopharmaceutical suppositories.</li><li>• Know the peculiarities of preparing alcoholic solutions;</li><li>• Define quality control:<ul style="list-style-type: none"><li>-stabilization of organoleptic characteristics;</li><li>-identifying and measuring active principles;</li><li>-total alcohol;</li><li>-possibility of acidity.</li></ul></li></ul> | <ol style="list-style-type: none"><li>1. Formulation of suppositories.</li><li>2. Bases for suppositories.</li><li>3. Preparation of suppositories.</li><li>4. Packaging and labeling of suppositories.</li><li>5. Control of suppositories.</li></ol> |
| <b>Theme (chapter) 9. Ophthalmic drops.</b>   |  |
| <ul style="list-style-type: none"><li>• Can define types of ophthalmic preparations;</li><li>• Know how to make eye drops;</li><li>• Know how to incorporate drug substances in eye drops;</li><li>• To assess the quality of the eye drops;</li><li>• Can define quality control of eye drops after FR X;</li></ul>  | <ol style="list-style-type: none"><li>1. The definition. Types of ophthalmic preparations.</li><li>2. Preparation of ophthalmic solutions.</li><li>3. Quality conditions.</li><li>4. Therapeutic efficiency.</li></ol>                                 |



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

#### ✓ PROFESSIONAL COMPETENCES (CP)

**PC1.** Knowledge of the theoretical bases of the disciplines included in the curriculum of the faculty, the principles of gene Knowledge of the theoretical bases of the disciplines included in the curriculum of the faculty, of the general principles in the elaboration, analysis and registration of pharmaceutical and para-pharmaceutical products; knowledge of the general principles of organization and functioning of pharmaceutical institutions with different legal forms of activity; knowledge of the legislative framework in the field of pharmacy; knowledge of the pharmacist's rights and obligations.

**PC2.** Prediction of basic economic indices of pharmacy: achievements, stocks of pharmaceuticals; travel expenses; benefit; assessing trends in the development of population assistance with medicines; performing various practical work related to the preparation, analysis and standardization of synthetic and phytopreparate medicines; knowledge of the drug in terms of action, indications, contraindications, adverse effects, mode of administration and their interactions; the practical implementation of patient counseling and pharmaceutical assistance.

**PC3.** designing practical work in the pharmaceutical system according to the diversity of professional roles; use and adaptation of theoretical knowledge in the field of pharmacy to practical work situations; making professional work more efficient by introducing innovative pharmaceutical elements; applying the requirements of pharmaceutical legislation in practice; possessing the computer as a working tool in the theoretical and practical pharmaceutical activity; establishing the correlation between the components of the pharmaceutical business process and the healthcare system of the population; continuously streamlining pharmaceutical activity by introducing innovations and implementing inventions in the art.

**PC4.** diagnosis of the particularities and organizational culture of the institution in the pharmaceutical system where the specialist operates; designing and coordinating pharmaceutical activity in various institutions: state-owned or private-type pharmacies; hospital pharmacies; pharmaceutical stores; drug factories, laboratories for quality control and certification of medicines, etc .; the active engagement of the specialist in the process of accomplishing the mission of the pharmaceutical institution; demonstrating the capacity to make decisions aimed at improving the pharmaceutical system.

**PC5.** Determining the criteria for assessing the efficacy of the pharmaceutical system and the personal activity according to the actual conditions and the concrete social context; determining how to conduct pharmaceutical activity based on the results of the evaluations; identifying research issues in the field of pharmacy; knowing the methodology of scientific research in the practical work of a pharmacist or a head of the pharmaceutical unit.

**PC6.** Adoption of messages in various socio-cultural environments, including through multilingual communication; use of the capacity to solve the problems of the situation in the pharmaceutical activity in collaboration with doctors; promoting the principles of tolerance and compas

in relation to patients; the use of information technology (and computer) in pharmaceutical activity;

in the development, analysis and registration of pharmaceutical and para-pharmaceutical products; knowledge of the general principles of organization and functioning of pharmaceutical



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institutions with different legal forms of activity; knowledge of the legislative framework in the field of pharmacy; knowledge of the pharmacist's rights

### ✓ **Specific competences (SC)**

*SC1.* Thorough knowledge 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.





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### VII. 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.<br>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 the semester  |
| 2.  | Referred and other research papers     | Analysis of relevant sources on the topic of the paper.<br>Preparation of papers and other analysis and research papers.<br>Compilation of the report in accordance with the requirements in force and presentation to the chair. | 1. Additional literature - magazines from the Republic of Moldova (Pharmaceutical Magazine of Moldova), Romania, Bulgaria, Belarus and others are recommended; clinical journals for understanding the issue.<br>2. Concordance of information with the proposed theme. | During the semester  |
| 3.  | Working with medical prescriptions     | Choice and description of the recipe.<br>Analysis of drug preparation steps.<br>Compilation of the written verification document and presentation of the teacher  | 1. Workload.<br>2. Solving the problem of the situation (recipe), the correctness of drug release.  | During the semester  |



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### VIII.METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT

**Teaching and learning methods used** The discipline of Pharmaceutical Technology I Extemporal is taught in classical terms: course and practical work, individual work. The course is held by the course holder. In the practical work, the student's work is individualized, each student prepares the medicine according to the prescription, appreciates the quality of the pharmaceutical form prepared in accordance with the pharmacopoeic requirements, correctly interprets the technological operations at the different stages of preparation of medicaments according to medical prescriptions and control vouchers, will identify the main physicochemical and technological parameters of drug substances, auxiliary substances, adjuvants and packaging materials that determine the quality of the prepared drug, it is necessary to know the rules of good practice in the manufacture of drugs under pharmacy conditions, to describe the processes and devices pharmacies used in pharmacies' production facilities, know the physicochemical properties of drug substances, auxiliary substances, adjuvants and packaging materials will compile the verification document in writing.

Individual work includes virtual training with CDs and form making films pharmaceuticals, the setting of notebooks where the stages of the technological flow are described in detail preparation of the drug form according to the doctor's prescription after an established algorithm and deepening the knowledge by studying the additional literature.

The chair has computers (PC Workstation PC1330 Navigator and PC Mini Nettop Seli 3Q Core and BENQ monitor). Computers are connected to the Internet via Wireless (Router Model WR941 ND).

- **Suggestions for individual activity**

Individual work in the learning process includes the study of additional material for each subject from basic and additional bibliographic sources from the databases available through the communication networks and the library library.

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

- **Current:** Front and individual control via:

To determine the subject of study of the discipline;

Define the concepts of time-based drug technology and their assessment according to DAN requirements;

To correctly interpret technological operations at different stages of preparation of medicinal products in accordance with medical prescriptions and control vouchers;

To identify the main physico-chemical and technological parameters of drug substances, auxiliary substances, adjuvants and packaging materials, which determine the quality of the prepared drug.

To know the rules of good practice in the manufacture of medicines under pharmacy;

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



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To know the physico-chemical properties of drug substances, auxiliary substances, adjuvants and packaging materials.

During the study year, there are 7 totals.

**Final:** The promotion essay (summative assessment) is a complex one, consisting of the test-editor sample, and the oral test.

The test-editor sample consists of 6 variants of 100 tests. For this sample, 120 minutes are reserved. The test is scored with grades from 0 to 10.

For the oral test each student receives a ticket containing 3 questions (2 questions - theoretical, 1 question - the recipe). The student has 30 minutes to prepare. The test is scored with grades from 0 to 10.

The final note consists of three components: the annual average mark (Coefficient 0.5); test-editor (coef. 0.2), oral interview (coef.0,3). The final weighted score is calculated on the basis of positive grades ( $\geq 5$ ) automatically according to the SIMU program. The average annual grade and the final stage grades will be expressed in numbers according to the scoring scale indicated in the table. The final mark obtained will be expressed in two decimal places, which will be entered in the notes book.

### Method of mark rounding at different assessment stages

| Intermediate marks scale (annual average, marks from the examination stages) | National Assessment System | ECTS Equivalent |
|--|----------------------------|-----------------|
| <b>1,00-3,00</b>   | <b>2</b>                   | <b>F</b>        |
| <b>3,01-4,99</b>   | <b>4</b>                   | <b>FX</b>       |
| <b>5,00</b>  | <b>5</b>                   | <b>E</b>        |
| <b>5,01-5,50</b>   | <b>5,5</b>                 |                 |
| <b>5,51-6,0</b>  | <b>6</b>                   |                 |
| <b>6,01-6,50</b>   | <b>6,5</b>                 | <b>D</b>        |
| <b>6,51-7,00</b>   | <b>7</b>                   |                 |
| <b>7,01-7,50</b>   | <b>7,5</b>                 |                 |
| <b>7,51-8,00</b>   | <b>8</b>                   | <b>C</b>        |
| <b>8,01-8,50</b>   | <b>8,5</b>                 |                 |
| <b>8,51-8,00</b>   | <b>9</b>                   |                 |
| <b>9,01-9,50</b>   | <b>9,5</b>                 | <b>A</b>        |
| <b>9,51-10,0</b>   | <b>10</b>                  |                 |



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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.*



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### IX. 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", Chișinău, 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. Diana Guranda., Tamara Polișciuc. Pharmaceutical emulsions. Methodological indication for pharmacy students. Chișinău, 2017.
6. State Medicines Nomenclature. Chișinău, 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".
4. Iuliana Popovici, Dumitru Lupuleasa., Pharmaceutical Technology (Treated) vol.1.- Ed. a 4-a. Iași, 2017.
5. Iuliana Popovici, Dumitru Lupuleasa., Pharmaceutical Technology (Treated),vol.2.- Ed. a 2-a. Iași, 2017.
6. Iuliana Popovici, Dumitru Lupuleasa. vol.3.- Pharmaceutical Technology (Treated), Ed. a 2-a. Iași, 2017.