FACULTY PHARMACY

STUDY PROGRAM PHARMACY

DEPARTMENT OF DRUG TECHNOLOGY

APPROVED
at the meeting of the Commission for Quality Assurance and Evaluation of the Curriculum faculty of 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 of Pharmacy, PhD, Associate Professor of Pharmacy
Ciobanu Nicolae _____

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

SYLLABUS

DISCIPLINE **PHARMACEUTICAL BIOTECHNOLOGIES**

Integrated studies/Cycle I, License

Tipe of course: **Optional discipline**

Elaborate curriculum:

Znagovan Alexandru, PhD, Associate Professor of Pharmacy

Chisinau, 2021

I. Introduction

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

  The discipline of Pharmaceutical Biotechnology is intended for 5th year students with the role of initiating knowledge and information on pharmaceutical biotechnology. Knowledge of biotechnologies for the production of active pharmaceutical ingredients and medicines will contribute to the multifaceted training of pharmacists. Students will be provided with information, from simple to compound, on biotechnologies as pharmaceutical techniques that are already an important source of traditional and non-traditional raw materials in the pharmaceutical industry.

  This knowledge will serve to support the understanding of the processes and principles of biotechnologies for the production of modern medicines.

- The mission of the curriculum (purpose) in vocational training
  Familiarization of future specialists-pharmacists with the techniques underlying the pharmaceutical biotechnologies for the industrial production of medicines.

  This knowledge is needed to train students in a state-of-the-art vision for the production of new industrial medicines from traditional and non-traditional raw materials - biotechnology products, which in the near future will become the main source of raw materials for the pharmaceutical industry.
  Language / languages of instruction: Romanian;

- Beneficiaries: 5th year students, faculty of pharmacy.

II. MANAGMENT OF THE DISCIPLINE

Code of discipline		**S.09.A.075.1**	
Name of the discipline		*Pharmaceutical Biotechnology*	
Person(s) in charge of the discipline		*Znagovan Alexandru*	
Year	*V*	Semester	IX
Total number of hours, including: *60*			
Lectures	*13*	Practical/laboratory hours	-
Seminars	*26*	Self trainings	*21*
Form of assessment	*exam*	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:***

  General notions regarding primary pharmaceutical biotechnologies;

  Biotech raw materials;

  Security technology in the biotechnology laboratory;

  The equipment and apparatus necessary for the primary biotechnological production process;

  The stages of the industrial biotechnological production process;

  The risks and benefits of pharmaceutical biotechnology for humans;

- ***At the application level:***

  Correct use of language and biotechnological notions;

  To determine the status of a biotechnological product;

  To determine the optimal parameters of a pharmaceutical biotechnological process;

  To determine the indications for increasing the efficiency of the biotechnological process;

  Identify the media and raw materials for a pharmaceutical biotechnological process;

- ***At the integration level:***

  Determine the need for biotechnology in the pharmaceutical industry;

  To compare chemical, traditional and biotechnological methods of pharmaceutical production;

  To determine the advantages of pharmaceutical biotechnologies;

  To determine the quality of biotechnological medicines;

  To be able to use the knowledge in the field of activity.

III. CONDITIONS AND PREREQUISITES

The fifth year student requires the following:

- knowledge of the language of instruction;
- knowledge in biology, chemistry, microbiology, pharmaceutical technology;
- skills in information technology;
- teamwork skills;
- communication skills and skills of analysis and synthesis, generalization;
- qualities - collegiality, compassion, autonomy.

IV. THEMES AND ESTIMATE ALLOCATION OF HOURS

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

Nr. d/o	Theme	Number of hours		
		Lectures	Practical hours	Self training
1.	**Introduction.** Biotechnology as a science. Notions. Appearance history and the development of modern biotechnology. Benefits and risks.	2	2	3
2.	**Biotechnological flow.** Machinery and apparatus. Industrial biotechnology scheme. The stages of the biotechnological process.	3	2 4	4
3.	**Media and raw materials.** Products obtained by fermentation.	2	2	2
4.	**In vitro biotechnologies applied in different industries:** - pharmaceuticals, cosmetics and food for the production of natural chemical compounds: vitamins, alkaloids, flavonoids (anthocyanins), carotenoids, volatile oils, cardiotonic heterosides, anthracenes, amino acids, proteins, fatty oils, enzymes, antibodies, etc. - Production of flavorings, stabilizers, pigments, dyes for cosmetics, food and pharmaceuticals. - Production of antibiotics, hormones and vaccines by biotechnological techniques. - Biotechnology centers, schools and seminars, biotechnology fairs and pavilions.	2 1 1	6 2 2	6
5.	**Pharmaceutical biotechnologies and the legal framework.** Global and national framework in the field of biological biosecurity. The risks of modern pharmaceutical biotechnology and the role of the human factor.	2	4	4
6.	**Prospects for pharmaceutical biotechnology.** Development directions. The future of modern pharmaceutical biotechnology. Staff training for biotechnology industries. Continuing information and education of producers and consumers of biotechnology products.	-	2	2
Total		**13**	**26**	**21**

V.REFERENCE OBJECTIVES AND UNITS OF CONTENT

Obiectives	Content units

Obiectives	Content units
Introducere. Biotehnologia ca ştiinţă	
• To define the notion of biotechnology and biotechnological product in vitro. • To know the premises for the emergence of modern biotechnologies. • Demonstrate that they can identify the advantages and disadvantages of biotechnology. • Apply knowledge to other disciplines.	1. Modern biotechnologies and biotechnology products. Short history. 2. The need for modern biotechnology. Benefits and risks. 3. Sources of traditional and non-traditional natural raw materials.
Topic (chapter) 2. In vitro cell and tissue media and cultures	
Define cell and tissue media and cultures in vitro. To know the notions of: biotechnological laboratory, cultivation process, nutrient media, growth regulators, etc. Demonstrate understanding of the in vitro laboratory biotechnology scheme. To integrate knowledge in the field of contemporary medicine production, based on biotechnologies.	1. In vitro cell and tissue media and cultures. 2. Terminology specific to modern biotechnologies. 3. Necessary and conditions (physical, chemical, utensils and equipment) in the biotechnology laboratory. 4. Working rules. 5. Laboratory biotechnology scheme. 6. Optimal nutrients. 7. Physical, chemical and biological factors that can be manipulated in in vitro cultures.
Topic (chapter) 3. Biotechnologies applied in different industries	
Know the sources of raw materials for the production of natural compounds for pharmaceutical and food purposes. Demonstrate understanding of the principles of the industrial biotechnology scheme. To develop their own opinions regarding the role of the human factor in obtaining qualitative and ecologically pure biotechnological products. To integrate knowledge in their development as specialists-pharmacists.	1. Industrial bio-technological scheme (bio-industry). 2. Sources of raw materials and advanced rigors. 3. Physical and chemical factors in the direction of industrial technological lines. 4. In vitro production of various chemical compounds (primary and secondary metabolites) for the pharmaceutical, food and cosmetic industries: amino acids, proteins, lipids, organic acids, volatile oils, alkaloids, vitamins, cardiotonic heterosides, flavonoids (anthocyanins), anthracenes, carotenoids, , vegetable pigments, enzymes, antibodies, etc. Production of antibiotics, hormones and vaccines by biotechnological techniques.
Topic (chapter) 4. Pharmaceutical biotechnologies and the legal framework	
Know the national and global legal framework. To understand and be aware of the role of the human factor in biotechnological	1. Legal and national framework. 2. Modern biotechnology, biosecurity and the role of the human factor.

Obiectives	Content units
production. • Demonstrate that they can identify the risks of modern biotechnology in drug production. • To integrate their knowledge in the formation of the correct professional and civic attitude in the “era of modern biotechnologies”.	3. National policies and strategies in in vitro biotechnology. 4. Continuing biotechnology education of the young generation. 5. The role of the pharmacist in the "biotechnology era".

VI. PROFESSIONAL COMPETENCES (SPECIFIC (CS) AND TRANSVERSAL (TC)) ŞI FINALITĂŢI DE STUDIU

- **Professional skills (specific) (CS)**
- CS1. Knowledge of the theoretical basis of the discipline Pharmaceutical Biotechnology, general theory of biotechnological microtechnics; knowledge of the principles of activity of the biotechnology laboratory.
- CS2.Knowledge of the advantages and risks of pharmaceutical biotechnology products. Assessing the development trend and prospects of biotechnologies in drug production.
- CS3. Use and adaptation of theoretical knowledge in the field of modern biotechnology in pharmaceutical and everyday activity, streamlining professional activity by introducing innovative elements in the field of pharmaceutical biotechnology. Implement the requirements of the legal framework on biotechnology products and biosecurity.
- CS4.The active involvement of the pharmacist in the conscientious promotion of biotechnological products (medicines / foods) and the development of the correct civic attitude.
- CS5.Highlighting and awareness of the risks in the application of pharmaceutical biotechnologies for the production and promotion of the biotechnology product and determining the role of the human factor in ensuring quality and safety.
- CS6. Involvement in volunteer social activities to promote a conscientious attitude towards biotechnology products, continuous information with news in the field of pharmaceutical biotechnology.

- **Transversal competences (TC)**
- TC1. Awareness and observance of the norms of ethics and pharmaceutical deontology when applying modern biotechnologies in professional activity.
- TC2. Identifying the need to know the biotechnological techniques and the specific application in the production of medicines for the contemporary specialist-pharmacist.
- TC3. Promoting the spirit of initiative, cooperation and collegiality in the work teams and the continuous improvement of the quality of biotechnological products in the "era of biotechnologies".

- **Study purposes**

• To know the principles of elaboration of the biotechnological lines for the production of natural compounds for the production of contemporary medicine.
• Be able to highlight the benefits and be aware of the risks of biotechnology products.

• To know the biotechnological lines and the culture media.
• To be informed and competent to use biotechnological knowledge in becoming a modern specialist pharmacist.
• Be competent to use rationally and reliably the scientific information obtained using new information and communication technologies.

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

VII. THE INDIVIDUAL WORK OF THE STUDENT

Nr.	Expected product	Implementation strategies	Evaluation criterias	Deadline
1.	Working with information sources	- Analysis of the informational material from the classes. - Work with recommended bibliographic sources. - Selecting the main postulates, highlighting the basic elements of the topic discussed, arguing, exemplifying. - Explore current electronic sources on the topic under discussion. - Formulation of conclusions.	Ability to extract the essential; interpretive skills; workload	During the semester
2.	Thematic report (thematic project)	- Analysis of relevant sources for the thematic project. - Compilation of the work plan and presentation of the report. - Analysis, systematization and synthesis of information on the proposed topic. - Compilation of the report in accordance with the requirements in force and its presentation at the department.	- The quality of the systematization and analysis of the informational material obtained through own activity. - Consistency of the information with the proposed topic. - Ability to highlight key positions, the need to address the topic and the volume of concrete information on the topic.	During the semester
3.	Graphic PPT presentation	- Establishing the components of the	- The quality and correctness of the presentation.	During the semester

	and presentation of presentations / portfolios	PowerPoint project / presentation - theme, purpose, results, conclusions, practical applications, bibliography. - Select the graphic presentation mode (tables, figures, diagrams, graphs, etc.). - Determining the way of presentation (narrative, by asking questions, formulating the case problem, individual analysis of a problem, in the form of a dispute, etc.).	- Volume of information material. - Balanced use of different forms of graphic presentation. - Ability to describe and present concrete and accessible material. - The volume of work, the degree of penetration in the essence of the project theme, the level of scientific argumentation, the quality of the conclusions, elements of creativity, attitude formation. - Ability to answer questions.	

VIII. METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-EVALUATION

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

The discipline of Pharmaceutical Biotechnology is taught in the classic way: classes and seminars. The course hours are read by the course holder through the involvement of modern information technologies. At the seminars, students will prepare reports from current and up-to-date information on websites and forums for opinions and discussions on the Internet. The methodological-didactic procedures will be practiced: disputes, interactive discussion, mini-conferences, team debates with arguments, evidence, opinions and pros and cons regarding the activities related to modern biotechnologies in the pharmaceutical, cosmetics, food industries.

All activities will be aimed at raising awareness, informing and accumulating knowledge about modern pharmaceutical biotechnologies by students, which will be capitalized and promoted by them during their professional activity.

Applied teaching strategies / technologies (specific to the discipline)

Frontal work, individually and in microgroups. Interactive discussions "Round table", debates "Case study"; "Creative controversy"; "Portfolio". Virtual practical work.

- ***Assessment methods (including how to calculate the final grade)***

Curent:

o Frontal discussions;
o Individual discussions;
o Thematic debates;
o Presentation of the thematic report.

- ***Final****:* exam with mark.

The final assessment will consist of the average mark from 2 (0.5 / 0.5) assessments of the knowledge obtained (individual oral discussions, involvement in discussions / debates, the quality of elaboration and presentation of the thematic report) and the mark from the exam.

How to round the grades at the assessment stages

Grade of intermediate grades (annual average, grades from exam stages)	National scoring system	Equivalent ECTS
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**	

Annual average grade and grades of all stages of the final examination (computer-assisted, test, oral answer) - all will be expressed in numbers according to the grading scale (according to the table), and the final grade obtained will be expressed in two decimal places, which will be entered in the notebook.

Failure to appear for the examination without good reason is recorded as "absent" and is equivalent to a grade of 0 (zero). The student is entitled to 2 repeated examinations of the non-passed exam.

IX. RECOMMENDED BIBLIOGRAPHY:

A. Compulsory:

1. *Milică C. Biotehnologiile viitorului. Iaşi, Ed. "Ion Ionescu de la Brad". 1999. 351 p.*
2. *Raicu P., Badea E. Cultura de celule şi biotehnologiile moderne. Bucureşti. Ed. Ştiinţifică şi Encilopedică. 1986.*
3. *Sasson A. Biotehnologiile: sfidare şi promisiuni. Bucureşti. Editura Tehnică. 1986. 280 p.*
4. *Milică C. Biotehnologii moderne. Iaşi. Centrul universitar de multiplicare. 1994.*

B. Supplementary

1. Sasson A. *Biotehnologii şi dezvoltare*. Bucureşti. Editura Tehnica. 1993.
2. Егоров Н. И. др. *Биотехнология. Проблемы и перспективы*. Москва. Изд.”Высшая школа”. 1987.
3. Газарян К. и др. *Биотехнология за рубежом*. Москва. Изд.”Знание”. 1990.
4. Вакул В. *Биотехнология: что это такое*? Москва. 1989.
5. Бекер М. *Введение в биотехнологию.* Москва. 1978.
6. Сассон А. *Биотехнология: свершения и надежды*. Москва. Изд. “Мир”. 1987.
7. Scorpan V., Lozan A. Dicţionar de termeni biotehnologici. Tipografia Centrală, 2005.
8. Новости биотехнологии. Биотехнология. Теоретический и научно-практический журнал. 2011, 1, стр. 3-7.
9. Surse internet;