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# FACULTY OF PHARMACY

## STUDY PROGRAM PHARMACY

# CHAIR OF PHARMACOGNOSY AND PHARMACEUTICAL BOTANY

#### 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, associate professor, PhD of pharmacy

Uncu Livia

APPROVED

at the Council meeting of the Faculty of Pharmacy Minutes No 3 of 16.12.2021 Dean of Faculty, associate professor, PhD of pharmacy

Ciobanu Nicolae

APPROVED at the meeting of the Chair of pharmacognosy and pharmaceutical botany Minutes No. 27 of 30.06.2021 Head of chair, professor, Dr. hab. of biol.

Calalb Tatiana

# SYLLABUS

# DISCIPLINE TRANSGENIC ORGANISMS AND HUMAN HEALTH

Integrated studies

Type of course: Optional discipline

Curriculum was elaborated by author:

Calalb Tatiana, Dr. hab. of biol., 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

The optional discipline Transgenic organisms and human health for I<sup>st</sup> year students will allow them to complete their knowledge on the involvement of modern genetic engineering techniques in developing modern sources of natural raw material in producing the new generation of food and medicines. Knowledge of the genetic transformation of living organisms in order to obtain organisms with new features used in food/drug production will contribute to the formation of a contemporary and correct vision and attitude of the actual pharmacist in the era of modern biotechnology; developing critical thinking in addressing issues related to the implementation and use of GMOs; application of knowledge in promoting healthy lifestyle and valorization of quality vegetable products in the field of pharmacy.

#### • Mission of the curriculum (aim) in professional training

To familiarize the future pharmacists-specialists with genetically modified organisms, state policies, fields of application (pharmacy and alimentation), human risks and biosecurity. The course will enable students to acquire knowledge about genetic transformation of living organisms; awareness of the benefits and impact of the TGOs on the environment, the traditional natural gene pool and public health; training abilities to use and enforce norms, normative acts and policies for the implementation and use of TGOs and biosecurity.

- Languages of the course: English, Romanian, Russian
- Beneficiaries: students of the I<sup>st</sup> year, faculty of Pharmacy

## **II. MANAGEMENT OF THE DISCIPLINE**

Code of discipline		S.02.A.020.1	
Name of the discipline		Transgenic organisms and human health	
Person(s) in charge of the discipline		doctor habilitate in biology science, univ. prof., Tatiana Calalb	
Year	Ι	Semestre/Semestres	II
Total number of hours, including:			60
Lectures	15	Practical/laboratory hours	
Seminars	30	Self-training	15
Form of assessment	Exam	Number of credits	2



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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:
  - general notions regarding the genetic transformation of living organisms;
  - the risks and benefits of GTOs;
  - the global framework on biological security;
  - the national regulatory and monitoring system for GTOs activities;
  - GTOs in the pharmaceutical industry;
  - GTO and human biosecurity.

#### • at the application level:

- the correct use of biotechnological terminology and genetic engineering in connection with genetically modified organisms;

- knowledge of transgenic organisms in the pharmaceutical field;
- regulatory strategies for GMOs testing;
- knowledge of the impact of GMOs on public health;
- norms, normative acts and policies for the implementation and use of GMOs;
- the national legal framework for regulation and monitoring of GMOs activities.

#### • at the integration level:

- determining the position and importance of the discipline Genetically modified organisms in the disciplines provided by the study plan;

- forming the right attitude towards the contemporary generation of drugs/food based on genetic engineers;

- acquired knowledge will contribute to the formation of a conscious individual attitude and personal involvement in national policies on biological and public health;

- GMO knowledge will serve as a benchmark for the subsequent acquisition of Pharmacognosy, Toxic plants, Phytotherapy, Biofarmacy, Pharmaceutical technology.

## IV. PROVISIONAL TERMS AND CONDITIONS

#### Student of the I<sup>st</sup> year requires the following:

- knowledge of the language of instruction;
- knowledge in biology at the lyceum level;
- knowledge from the courses: Pharmaceutical botany (I<sup>st</sup> year), Molecular biology (I<sup>st</sup> year), Ecology and medicinal plants (I<sup>st</sup> year), Chemistry;
- competences in modern information technologies (using the Internet, document processing, electronic tables and presentations, using graphics software);
- teamwork skills;
- analysis and synthesis skills, generalization and communication skills, discussion and presentation;
- qualities tolerance, compassion, autonomy, collegiality.



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## V. THEMES AND ESTIMATE ALLOCATION OF HOURS Lectures, practical hours/laboratory hours/seminars and self-training

No.		Number of hours		
d/o	THEME	Lectures	Practical hours	Self-training
1.	Introduction. History of GTOs "evolution". General notions concerning genetic transformation. Necessity. Stages to obtain GTOs, genes of "interest", GTOs selection and testing.	3	2	1
2.	Benefits and risks for human health. Biosecurity, National and Global legal framework.	2	1	2
3.	Transgenic microorganisms. Transgenic techniques. Fields of application: food, pharmacy, medicine, cosmetics.	2	3	4
4.	Transgenic plants and their new properties. Techniques of obtaining. Transgenic cultivated plants. Impact on biodiversity, environment and human health. Areas of application: food, pharmacy, medicine, cosmetics, fodder, textiles, dyeing.	2	2	3
5.	Transgenic animals and their new features. Techniques of animal transgenesis. Impact on biodiversity, environment and human health. Fields of application: food, pharmacy, medicine, cosmetics.	2	1	2
6.	Transgenic organisms, processed transgenic products, chemical compounds in contemporary food and medicine. Benefits and risks to human health.	3	4	3
7.	GTOs global, national, policies and strategies. Balance on GTOs: the present and future of Genetically Transgenic Organisms. Consumer education, information and involvement of the population in decision-making. Own opinions, proposals.	1	2	-
	Total: 60 hours	15	15	30

## VI. PRACTICAL SKILLS PURCHASED AT THE END OF THE COURSE

- the correct use of biotechnological terminology and genetic engineering in connection with genetically modified organisms;
- knowledge of transgenic organisms in the pharmaceutical field; regulatory strategies for TGOs testing;
- knowledge of the impact of TGOs on public health;
- knowledge about norms, normative acts and policies for the implementation and use of TGOs;
- the national legal framework for regulation and monitoring of TGOs activities.



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VII. REFERENCE OBJECTIVES OF CONTENT UNITS				
Objectives         Content units				
Theme 1. Generalities about genetic transformation				
<ul> <li>To define the notion of genetically modified organisms.</li> <li>To know the terminology specific to genetic transformations.</li> <li>To understand the way and steps of obtaining the GMO.</li> <li>To know the strategies for identifying, isolating, cloning and transferring "interest genes".</li> <li>To demonstrate that they can highlight the specificity of genetically modified organisms.</li> <li>To be aware of the benefits and risks of transgenic</li> </ul>	Genetically modified organisms – organisms with new qualities and traits. Gene of interest. Methods and strategies for identifying, isolating, cloning and transferring "interest genes". Test methods for transgenic organisms. Advantages and risks of GMOs.			
organisms. Theme 2. Legal framework and biosecurity				
<ul> <li>To know the legal framework and biological security.</li> <li>To demonstrate that they know the specificity of genetically modified organisms.</li> <li>To be aware of the risks, benefits and role of the human factor in GMOs policy.</li> <li>To integrate knowledge about the involvement of transgenic organisms in food and medicine production.</li> </ul>	Global legal framework and biosecurity. Legislation, national framework in the field of biological security. Organisms and institutions responsible for biological security. The role of the human factor. Protection of producers and beneficiaries rights in the field of transgenic products or with transgenic content.			
• To know the fields of application of transgenic				
<ul> <li>To know the fields of upplication of datagenic organisms.</li> <li>To know transgenic microorganisms used in food, pharmaceutical and environmental field.</li> <li>To know the transgenic plants used in food and pharmaceutical field.</li> <li>To know the transgenic animals used in food and pharmaceutical field.</li> <li>To be able to integrate knowledge into the study of other pharmaceutical disciplines.</li> </ul>	Fields of application of GMOs. Transgenic microorganisms used in the production of drugs. Transgenic plants as a source of raw material in food and medicine production. Transgenic animals as a source of raw material in food and medicine production.			
Theme 4. Genetically modified organisms and human fa	actor			
<ul> <li>To know the aspects of global and national GMOs policies.</li> <li>To be aware of the acceptance, challenge, and rejection of transgenic organisms.</li> <li>To integrate knowledge into later studies and everyday life.</li> <li>To form and promote a fair civic attitude towards GMOs policies.</li> </ul>	GMOs and society. GMOs and human factor. Pros and cons of GMOs in Europe and other regions of the world. Education of producers and beneficiaries. Active attitude in transgenesis policies.			



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

## ✓ Professional (specific) (SC) competences

- CP 1. Knowledge and understanding of the theoretical bases of genetic engineering in the production of GMOs and especially those involved in the pharmaceutical, food, feed, energetic industries.
- CP 2. To know the transgenic techniques in obtaining GMOs (bacteria, algae, fungi, plants, animals) as producers for obtaining the new generation of medicines and food. Evaluation of the benefits and risks of transgenic products in terms of the norms of the global and national legal framework in order to ensure the biosecurity.
- CP 3. Use and adaptation of knowledge gained from the field of transgenic organisms in everyday life and subsequent professional activity. Improving the pharmaceutical field and promoting correct attitude towards transgenic products by continuously updating knowledge in the field of applied genetic engineering.

## ✓ Transversal competences (TC)

- CT 1. Responsible implementation of tasks in compliance with the rules of professional ethics and application of ethical norms in national policies on the current generation of medicines and food based on genetically modified organisms (recombinogenesis and transgenesis).
- CT 2. Developing the trend of information and continuous perfection of practical knowledge and skills in the field of genetically modified organisms. The ability to design and present thematic projects.
- CT 3. Ability to work with respect and collegiality in the team. Developing the spirit of initiative in deepening and promoting knowledge about drugs and food, based on genetic engineering techniques.

## ✓ Study outcomes

- To know the techniques and stages of obtaining genetically modified organisms.
- To be able to distinguish the benefits and risks of growing and using GMOs.
- To know transgenic organisms (bacteria, algae, fungi, plants, animals) as producers in pharmaceutical, food, feed, energy industries.
- To be informed and competent to use the knowledge of GMOs to become a contemporary pharmacist specialist.
- To be competent to use critical and reliable scientific information obtained using the new information and communication technologies.
- **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
1.	Working with information	Analysis of the informational material from the class hours.	Ability to analytical analysis and highlighting	During semester



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	sources	<ul> <li>Working with recommended</li> <li>bibliographic sources.</li> <li>Selection of the main postulates,</li> <li>highlighting the basic elements</li> <li>of the topic discussed,</li> <li>argumentation, exemplification.</li> <li>Exploring current electronic</li> <li>sources on the subject.</li> <li>Formulation of conclusions.</li> </ul>	a the essential; Logical orientation skills in the volume of informational material. Interpretive skills and balanced selection of information.	
2.	Thematically project	Analysis of relevant sources in the thematic project. Compilation of the work plan and presentation of the paper. Analysis, systematization and synthesis of information on the proposed theme. Compilation of the paper according to the requirements in force and presentation to the chair.	The quality of systematization and analysis of the informational material obtained through own activity. Concordance of the information with the proposed theme. The ability to highlight key positions, the need to address the subject, and the amount of concrete information on the subject.	During semester
3.	Graphic representation and presentation support	Establishing PowerPoint project / theme components - theme, purpose, results, conclusions, practical applications, bibliography. Selection of graphical presentation (tables, figures, diagrams, graphs, etc.). Determining the way of presentation (narrative, forwarding challenging questions, formulating the case issue, individual analysis of a problem, in the form of a dispute, etc.)	Quality and fairness of presentation formulation. The volume of information material. Balanced use of different forms of graphical 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, the elements of creativity, the formation of the attitude. Ability to answer questions.	During semester



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

#### • Teaching and learning methods used

Discipline Transgenic organisms in human health is taught in classical ways: lectures and seminars. Course hours are read by the course owner through the involvement of modern information technologies. At the seminars, the students will discuss the topics planned using different methodicaldidactic methods: frontal / individual interactive discussion, disputes, mini-conferences, debates in teams with arguments, evidence, opinions, beliefs and oppositions on GMO activities, involvement of GMOs in the food, pharmaceuticals, cosmetics, conscientious attitude to existing policies and strategies, consumer education on human biosecurity and environment in relation to transgenic products. Presentation and discussion of thematically papers. All the activities will be targeted to raise awareness, knowledge of GMOs by students, which will be harnessed and promoted by them during their work in the field of national pharmacy and in strengthening the health of the national society.

## • Applied teaching strategies / technologies (specific to the discipline)

Front work, individually and in micro teams. Interactive discussion "Discussion at Round Table"; debates "Case Study"; "Creative Controversy"; Thematic videos; Virtual Practices.

- *Methods of assessment* (including the method of final mark calculation)
- ✓ *Current:* will be done through 2 assessments of students' knowledge (1 assessment written on topics or frontal discussions, individual, thematic debates; 1 assessment the thematic project).
- ✓ *Final:* Exam

**The final assessment** will consist of the annual average grade (consisting of the grade of the individual work on the project/thematic portfolio and the grade from a knowledge assessment) with the coefficient 0.5 and the grade from the oral test - the coefficient 0.5.

*Note:* At the final exam, students with the average annual score below grade 5, as well as students who have not recovered absences from the practical works are not admitted.

National Assessment	ECTS	
System	Equivalent	
2	F	
4	FX	
5		
5,5	Ε	
6		
6,5	D	
7		
7,5	С	
	System           2           4           5           5,5           6           6,5           7	

#### Method of mark rounding at different assessment stages



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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.

## **XI. RECOMMENDED LITERATURE:**

#### A. Compulsory:

- 1. Course support intormation on Department web-site.
- 2. Lozan A. Biosafety Concerns in the Republic of Moldova: opportunities and challenges. Ministry of Ecology and Natural Resources, UNEP-GEF Biosafety, Chişinău, 2008. 52 p.
- 3. First Biennial Update Report of the Republic of Moldova under the United Nations Framework Convention on Climate Change, Resp. V. Munteanu, Tipogr. "Bons Offices", Chisinău, 2016.
- 4. Watson R., Preedy V. Genetically Modified Organisms in Food: Production, Safety, Regulation and Public Health, 1<sup>st</sup> Edition, Caroline Johnson, 2016.
- B. Additional
- 1. Duca M., Teleuță A., Port A. Plante modificate genetic. Beneficii și riscuri. Tipografia Centrală, Chisinău, 2003, 96 p.
- 2. Duca M., Lozan A., Port A., Glijin A., Lupașcu V. Aspecte metodologice în testarea plantelor modificate genetic. Tipografia centrală, Chisinău, 2008.
- Cadrul Național pentru Securitatea Biologică. Elaborat în cadrul Proiectului UNEP/GEF nr. GE/2716-02-4520. Tipografia Centrală, Chişinău, 2004, 47 p.
- Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. National Research Council (US) Committee on Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health. Washington (DC): National Academies Press (US); 2004.
- 5. Impacts of GMOs on biodiversity and human health Information Paper, IUCN, 2007.
- 6. Current national and mondial publications on OMGs domain.