

	<b>CD 8.5.1 DISCIPLINE SYLLABUS FOR UNIVERSITY STUDIES</b>	<b>Edition:</b> 10
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**FACULTY OF PHARMACY**  
**STUDY PROGRAM 0916.1 PHARMACY**  
**DEPARTMENT OF PREVENTIVE MEDICINE**  
**DISCIPLINE OF MICROBIOLOGY AND IMMUNOLOGY**

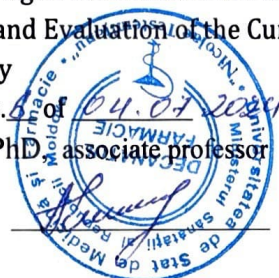
**APPROVED**

at the meeting of the Commission for Quality Assurance and Evaluation of the Curriculum in Pharmacy

Minutes No. 04 of 07.2024

Chairman PhD, associate professor

Livia Uncu



**APPROVED**

at the Council meeting of the Faculty of Pharmacy

Minutes No. 5 of 05.07.2024

Dean of Faculty PhD, associate professor

Nicolae Ciobanu



**APPROVED**

approved at the meeting of the Discipline of microbiology and immunology

Minutes No.13 of 01. 07. 2024

Head of chair, PhD, dr. hab. of med., associate professor

Greta Balan

Gretabalan

**SYLLABUS**  
**DISCIPLINE PHARMACEUTICAL MICROBIOLOGY**

**Integrated studies**

Type of course: **Compulsory**

Curriculum developed by the group of authors:

Greta Balan, PhD, dr. hab. of med., associate professor  
Vorojbit Valentina, , PhD, dr. of med., associate professor



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## **I. INTRODUCTION**

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

The aim of the course is to acquire basic knowledge in fundamental microbiology and studying of the general microbiology laws (morphology, ultrastructure, physiology, relationships in an ecosystem, infection, infectious process), bases and principles of nonspecific and specific immunity of the macroorganism, immunochemistry techniques, immunobiology and the principles of immunoprophylaxis and specific immunotherapy. The course of Pharmaceutical Microbiology has the objectives of competence development in the basic fields of medicine: medical research, microbiological diagnosis and epidemiology of infections, the study of etiology, pathogenesis, symptomatology and the interpretation of minimal necessary techniques for the diagnosis of bacterial and viral diseases.

The content of the course is well structured to highlight the role of pharmaceutical microbiology in developing of professional skills in further specialist; the relationships between the microorganism and the macroorganism, the complexity of the methods of studying these relationships; formulation of goals, tasks and objectives of etiological diagnosis of infectious disease, sampling rules, storage, transport and labeling, principles of laboratory diagnostics, methods of determining the susceptibility of microorganisms to antimicrobial preparations, studying the relationships between microorganisms in biocenosis, technologies for studying bacteriophage; studying the interaction between the macroorganism and the microorganism in different conditions, studying the bases of macro-organism non-receptivity; demonstrating of the importance of immunodiagnostics, the group of immunoprophylactic and immunotherapeutic biological preparations. Another objective of the course is the application of fundamental knowledge in the microbiology of pharmaceuticals and cosmetic products: the main germs that contaminate the pharmaceuticals, the origin of the contamination, norms and the technical normative documentation, the microbiological analysis proper: precontrol, bacteriostatic and fungistatic activity determination, sampling, microbiological purity of pharmaceuticals and cosmetic products.


The course of Pharmacy Microbiology is meant to help future pharmacists know the relationship between microorganism → macroorganism → microbiological techniques → results in accordance with current professional requirements.

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

The role of the course is to provide students with theoretical knowledge and practical skills that they can use in pharmaceutical practice: microbiological research, the role of pathogenic microorganisms and pathogenic condition in drug incompatibilities, the issue of industrial pharmaceutical contamination and pharmaceutical development, the enzymatic activity of microorganisms that debilitates the stability of active substances in the drug and the occurrence of pyrogenicity. The second objective is to understand the mechanisms of microbial nutrition and respiration, multiplication and biochemical activity in correlation with the final labeled drug, to know the theoretical bases and the particularities of the purity labeling techniques of the sterile labeled drug and methods of preventing pharmaceutical contamination. The third objective is understanding of the mechanism microorganism → pharmaceutical → macroorganism and the importance of this relationship.

**II. Languages of the course:** Romanian, Russian, English;

**III. Beneficiaries:** students of the 2<sup>nd</sup> year, faculty of Pharmacy.

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## II. MANAGEMENT OF THE DISCIPLINE

Code of discipline		S.03.O.026	
Name of the discipline		Pharmaceutical microbiology	
Person in charge of the discipline		PhD, associate professor <b>Greta Balan</b>	
Year	<b>II</b>	Semester/Semesters	<b>III</b>
Total number of hours, including:			<b>150</b>
Lectures	<b>30</b>	Practical/laboratory classes	<b>45</b>
Seminars		Self-training	<b>75</b>
Form of assessment	<b>E</b>	Number of credits	<b>5</b>

## 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:**
  - Theoretical basis of pharmaceutical microbiology.
  - The principles of classification and nomenclature of microorganisms.
  - The morphology, structure and physiology of bacteria and viruses.
  - The main families of antibiotics (classification, action mechanism, spectrum of activity).
  - The mechanisms of antibiotic resistance.
  - In vitro activity parameters of antibiotics (antibiogram, CMI, CMB).
  - The habitat of bacteria.
  - The pathogenicity of bacteria and understand the role of pathogenic factors in the pathogenesis of infectious diseases.
  - The importance of bacteria and viruses as etiological agents of different infectious clinical entities.
  - Specific prophylaxis and treatment of infectious diseases.
  - The methods of microbiological diagnosis.
  - The main microbiological diagnostic of bacteriological analyzes.
  - The basic notions of fundamental and medical immunology.
  - Isolated microorganisms in pharmaceutical products.
  - The origin of pharmaceutical contamination.
  - The importance of microorganisms in contaminated products in the etiology of the infectious process.
  - The schemes of microbiological analysis of pharmaceutical products.
  - The interpretation of results conditioned by the recommendations of national pharmacopoeias.
  - Microbiological purity control techniques.
  - Theoretical basics of cosmetics microbiology.
  - The schemes of microbiological analysis of cosmetic products.
- ✓ **at the application level:**
  - Differentiation of cellular and acellular forms of life;
  - Differentiation of eukaryotic and prokaryotic cell;
  - Abilities to comply with the rules / requirements of the antiepidemic regime and the safety technique in the microbiological laboratories;
  - Dexterity of collection of samples to be analyzed for microbiological investigations;
  - Skills for completing the analysis forms for microbiological analysis;



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- Skills to interpret the results of microbiological analysis;
- Dexterity of preparation and staining of smears from pure bacterial cultures;
- Skills for correct use of the optical microscope with immersion;
- Skills for the use of techniques for the determination of microorganisms in pharmaceuticals and cosmetic products;
- Dexterity to determine the pirogenicity of medicinal and cosmetic products.

✓ **at the integration level:**

- Microbiological knowledge obtained in the context of the future profession;
- Understanding of connection between microbiology and other related disciplines;
- Implementation and integration of microbiological knowledge in pharmaceutical disciplines;
- Implementing the knowledge gained in the research activity;
- Critical and reliable use of scientific information obtained using the new information and communication technologies;
- Using multimedia technology to receive, evaluate, store, produce, present and exchange information, and communicate over networks over the Internet.

**IV. PROVISIONAL TERMS AND CONDITIONS**

At the medical university studies level of the integration into one discipline of bacteriology, virology, mycology, the study of infection and immunity, as well as of the pharmaceutical microbiology aims to ensure a closest representation of the reality of what are the microorganisms and the relationships of the microorganisms with their human host and the abiotic environment in which they live.

For the good mastering of Pharmaceutical Microbiology, conceptual, methodological and factual support is required by the important contribution of chemistry, biochemistry, physics, biophysics, physiology, genetics, cellular and molecular biology.

**V. THEMES AND ESTIMATE ALLOCATION OF HOURS**

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

No. d/o	THEME	Number of hours		
		Lectures	Practical hours	Self-training
1.	Introduction in microbiology. Classification and nomenclature of bacteria. Morphology of bacteria. Microorganisms from the microbiological point of view of and pharmaceutical biotechnology. Morphology and ultrastructure of bacteria. The permanent elements of the bacterial cell structure. Chemical composition, biological functions and highlighting methods.	2	3	5
2.	Action of environmental factors on microorganisms. Sterilization. Media culture. Physiology of bacteria. Bacterial metabolism. Enzymes. Nutrition. Bioenergetics. Bacteriological examination.	2	3	5
3.	The relationships of microorganisms within an ecosystem. Antibiotics. Antibiotic mechanisms of action. Mechanisms of resistance of microorganisms to antibiotics. Bacteriocins. Bacteriophage. Genetics of microorganisms.	2	3	5
4.	The infectious process. Non-specific macro-organism resistance factors. Biological diagnostic method. Immunity. Immune response. Antigens. Antibodies. Serological diagnostic method.	2	3	5



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No. d/o	THEME	Number of hours		
		Lectures	Practical hours	Self-training
	Antigen-antibody reactions. Hypersensitivity.			
5.	Microbiology and laboratory diagnosis of pathogen cocci induced infections.	2	3	5
6.	Microbiology and laboratory diagnosis of infections caused by Gram-positive bacilli (aerobic, anaerobic).	2	3	5
7.	Gram-negative Bacilli (enterobacteria and nonenterobacteria). Morpho-biological characters.	2	3	5
8.	Microbiology and laboratory diagnosis of spirochetozes.	2	3	5
9.	Microbiology and laboratory diagnosis of infections caused by micro-organisms with intracellular parasite (rickettsioses, chlamidiosis, mycoplasmoses).	2	3	5
10.	Viruses. Biological probabilities. Virus classification and nomenclature. Principles of laboratory diagnosis of viral etiology infections. Laboratory diagnosis of respiratory diseases.	2	3	5
11.	Laboratory diagnosis of viral hepatitis, herpes and HIV / AIDS.	2	3	5
12.	Sanitary microbiology. Targets. Sanitary-microbiological analysis of purified water and air in pharmacies.	2	3	5
13.	Microorganisms affecting the pharmaceutical industry. Applications of microorganisms in the field of pharmaceutical biotechnology.	2	3	5
14.	The origin of pharmaceutical contamination. Rules for pharmaceutical products. Sampling techniques for microbiological monitoring of pharmaceutical products.	2	3	5
15	Microbiological analysis of pharmaceutical products. Control of microbiological purity of pharmaceutical products. Microbiology of cosmetic products.	2	3	5
<b>Total</b>		<b>30</b>	<b>45</b>	<b>75</b>

**VI. PRACTICAL TOOLS PURCHASED AT THE END OF THE COURSE**

Mandatory essential practical tools are:

- preparation and staining of smears from samples and from pure cultures of bacteria;
- sample collection techniques to be analyzed for microbiological investigations;
- techniques for isolating microorganisms from the sample;
- techniques for testing the sensitivity of microorganisms to antimicrobials.

(A compulsory compartment for specialized disciplines, for fundamental disciplines - as the case may be)



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*Note: The essential practical tools characteristic of the discipline, obligatory to be acquired by each student during the module, will be listed. These will serve as a basis for the stage of evaluating practical skills and will constitute their portfolio per study program.*

## VII. OBJECTIVES AND CONTENT UNITS

Objective	Content units
<b>Theme (chapter) 1. Basics of morphology and physiology of microorganisms</b>	
<ul style="list-style-type: none"><li>To know the main morphological forms of microorganisms.</li><li>To know the units of the nomenclature and the taxonomy of microorganisms.</li><li>To know the mandatory and optional elements of the microbial cell structure.</li><li>To demonstrate techniques for studying ultrastructure of microorganisms.</li><li>To comment on and to apply microscopy techniques.</li><li>To define the notions of sterilization, disinfection, aseptic and antiseptic.</li><li>To know the groups of media culture.</li><li>To develop own options regarding the physiological role of microorganisms.</li><li>To know elements of rational antibiotic therapy.</li></ul>	<p>Microbial cell - permanent and optional elements of microbial cell structure. Morphology and Ultrastructure - Methods of Study. Microscopy techniques. Action of environmental factors on the microbial cell. Methods of sterilization and disinfection. Culture media - practical application. Microbial metabolism. Resistance of microorganisms to antibiotics and methods of study.</p>
<b>Theme (chapter) 2. Infection and immunity</b>	
<ul style="list-style-type: none"><li>To define the notion of infection, infectious process and infectious disease.</li><li>To know the dynamics of the infectious process.</li><li>To know the factors of pathogenicity of microorganisms.</li><li>To know the role and particularities of specific and non-specific infectious immunity.</li><li>To demonstrate different immunoprophylaxis and specific immunotherapy algorithms.</li></ul>	<p>Non-specific resistance - physical barriers, humoral and cellular factors. Non-specific defense mechanisms:<ul style="list-style-type: none"><li>First line of defense - skin, mucous membranes, organ barriers;</li><li>Second line of defense - cellular factors; humoral factors</li></ul>Specific resistance - humoral immunity, cellular immunity. Specific natural resistance. Specific artificial resistance. Immune response. Humorous immunity. Antigens. Antibodies. Structure of antibodies. The classes of antibodies. Elaboration of humoral immune response (HIR) - Antibody biopsy. Steps of HIR development. Dynamics, intensity and quality of HIR. Primary, Secondary and Tertiary HIR. Practical applications of the Ag-Ab reaction.</p>




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Objective	Content units
	Estimation of cellular immune response (CIR) - RIC dynamics: primary cellular response, immunological memory. Immunosuppression. Immune tolerance. Autoimmunity. Hypersensitivity.
<b>Theme (chapter) 3. Particular bacteriology</b>	
<ul style="list-style-type: none"> <li>• To know the morpho-biological characteristics of pathogens.</li> <li>• To know the sources of infection and the mechanisms of transmission, pathogenesis and symptomatology of infectious diseases of bacterial etiology.</li> <li>• To know the sampling features.</li> <li>• To apply etiological investigation patterns in bacterial infections.</li> <li>• To know the principles of prophylaxis and specific treatment of bacterial infections.</li> </ul>	biological investigation of major infectious diseases of bacterial origin: <ul style="list-style-type: none"> <li>• Infections caused by piogens</li> <li>• Zoonthroposis</li> <li>• Anaerobic infections</li> <li>• Aerogenic infections</li> <li>• Spirochetosis</li> <li>• Intestinal infections</li> <li>• Infections caused by intracellular parasites</li> <li>• Severe acute respiratory infections</li> <li>• Enterovirus infections</li> <li>• Infections caused by herpesviruses, retroviruses</li> <li>• Irradiated transvaginal infections.</li> </ul> Particulars of sampling. Etiological investigation of bacterial infections. Clinical and ethio-pathogenetic aspects. Laboratory diagnosis. Prophylaxis and specific treatment.
<b>Theme (chapter) 4. Pharmaceutical microbiology</b>	
<ul style="list-style-type: none"> <li>• To define the basic notions of pharmaceutical and sanitary microbiology.</li> <li>• To know the microbiological control of water and air and the monitoring rules.</li> <li>• To know the microorganisms that affect the pharmaceutical industry and the group of microorganisms applied in pharmaceutical biotechnology.</li> <li>• To know the rules for pharmaceutical products, sampling techniques for microbiological monitoring of pharmaceuticals.</li> <li>• To know the microbiological analysis schemes of pharmaceutical and cosmetic products.</li> <li>• To know the harmful effects of microbial contamination of pharmaceuticals and cosmetics.</li> </ul>	Pharmaceutical microbiology and its targets. Sanitary microbiology and its targets. Sanitary-indicators micro-organisms of environmental objects and their requirements. The origin of pharmaceutical contamination. General concepts of pharmaceutical biotechnology and applied microorganisms. Sanitary-microbiological monitoring of pharmacies. Phytopathogenic microorganisms. Sampling techniques, pre-control, proprietary analysis. Interpretation of results conditional on national pharmacopoeial recommendations.

**VIII. PROFESSIONAL (SPECIFIC (SC)) AND TRANSVERSAL (TC)**

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## COMPETENCES AND STUDY FINALITIES

### ✓ Professional (specific) (SC) competences

**PC1:** 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.

**PC2:** 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.

**PC4:** diagnosing the features and organizational culture of the institution in the pharmaceutical system, where the specialist carries out his activity; design and coordination of the 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.

**PC6:** adjustment of 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; the use of information technology (and computer) in the pharmaceutical business.

### ✓ Transversal competences (TC)

**TC1:** promotion of 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 finalities

Upon completion of the course the student will be able to:

- Have skills to observe the rules of the antiepidemic regimen of aseptic, antiseptic, disinfecting and safety technology in the drug technology;
- Possess skills for completing the forms for the samples to be analyzed;



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- Perform physical and chemical decontamination of infected materials, processing rooms, objects, equipment and hands, inactivating microbial cultures;
- To be able to prepare microscopic preparations from pure microorganisms and samples to be analyzed.
- Possess skills to carry out sampling for microbiological analysis of pharmaceutical products depending on the drug form, sample preparation according to consistency and physico-chemical status.
- Possess microbiological techniques for the analysis of pharmaceutical and cosmetic products;
- Possess skills and competencies for formulating and interpreting the results obtained and applying them in the context of national pharmacopoeia.

### IX. STUDENT'S SELF-TRAINING

No.	Expected product	Implementation strategies	Assessment criteria	Implementation terms
2.	Working with the Practical Workbook:	Until solving the tasks in the workbook – to analyze the information and images from the every subject in the lecture and textbook. Solving the student's individual training tasks. Formulation of conclusions in the end of each laboratory. Verify end results and evaluate their achievement.	Workload, problem solving, ability to formulate conclusions	Semester long assignment
3.	Project	Initiate a study in a specific direction.	The volume of work, the level of insight into the subject, the level of scientific argumentation, the quality of the conclusions, the elements of creativity, the demonstration of the understanding of the problem, the formation of the personal attitude	The final assignment

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

- **Teaching and learning methods used**  
Exposing, interactive lecture, heuristic conversation, questioning, brainstorming, group work, individual study, work with textbook and scientific text, debate, problem solving, interactive listening.
- **Applied teaching strategies / technologies** (specific to the subject)
- **Observation** - Identification of elements characteristic for the microbial cell, description of the structure elements of the microbial cell (permanent and non-permanent elements).

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- **Analysis** - Imaginary decomposition of the entire inner component parts. Highlighting the essential elements. Studying each element as part of the entire structure.
- **Scheme / figure analysis** - Select the required information. Recognition based on knowledge and information selected structures indicated in the drawing. Analysis of the functions / role of recognized structures.
- **Comparison** - Analysis of the first object / process in a group and the determination of its essential features. Analysis of the second object / process and the determination of its essential features. Comparing objects / processes and highlighting common features. Comparing objects / processes and determining differences. Establishment criteria for decommissioning. Formulation of conclusions.
- **Classification** - Identification of structures / processes to be classified. Determining the criteria on which classification is to be made. Distribution of structures / processes by groups according to established criteria.
- **Schematic drawing** - Selection of elements, which must be included in the scheme. Playing the Elements Selected by Different Symbols / Colors and Indicating Their Relationships. Wording of an appropriate title and legend of the symbols used.
- **Modeling** - Identify and select the elements needed to model the phenomenon. The imaging (graphical, schematic) of the phenomenon studied. Realizing the phenomenon using the developed model. Formulation of conclusions, deduced from arguments or findings.
- **Experiment** - Formulating a hypothesis, based on known facts, on the process / phenomenon studied. Verifying the hypothesis by performing the processes / phenomena studied under laboratory conditions. Formulation of conclusions, deduced from arguments or findings.
- **Methods of assessment** (including the method of final mark calculation)

**Current:** individual control via:

- the application of docimological tests,
- analysis of case studies
- control work
- the assessment of the workload of the individual tasks

**Final:** Exam

The final mark will consist of the average score of three control papers and the score from the individual work assessment (0.5 part), the final test sample (share 0.5).

The average annual mark and the marks of all the final exam stages (assisted by computer, test) - all will be expressed in numbers according to the scoring scale (according to the table), and the final mark will be expressed in two decimal places to be passed in the note 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>	



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6,01-6,50	6,5	<b>D</b>
6,51-7,00	7	
7,01-7,50	7,5	<b>C</b>
7,51-8,00	8	
8,01-8,50	8,5	<b>B</b>
8,51-9,00	9	
9,01-9,50	9,5	<b>A</b>
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 in the failed exam.*

## **XI. RECOMMENDED LITERATURE:**

### *A. Compulsory :*

1. Kenneth J. Ryan, Sherris Medical Microbiology, Seventh Edition, 2018.
2. Jawetz, Melnick, Adelberg's Medical Microbiology 28th Edition, 2020.

### *B. Additional:*

1. Junie M. Microbiologie clinică: Bacteriologie și virusologie medicală. Cluj-Napoca. Cluj-Napoca: Editura Medicală Universitară "Iuliu Hațieganu", 2017, 238 p.