



**CD 8.5.1 CURRICULUM DISCIPLINĂ
PENTRU STUDII UNIVERSITARE**

Edition:	09
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FACULTY OF PHARMACY

STUDY PROGRAM 0916.1 PHARMACY

DEPARTMENT OF PHARMACOLOGY AND CLINICAL PHARMACY

APPROVED

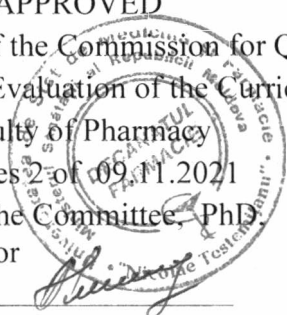
at the meeting of the Commission for Quality
Assurance and Evaluation of the Curriculum

Faculty of Pharmacy

Minutes No. 2 of 09.11.2021

Chairwoman of the Committee, PhD,
associate professor

UNCU Livia



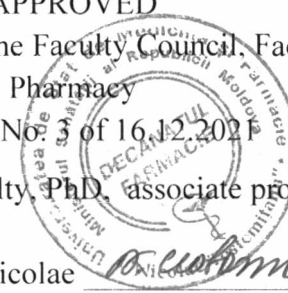
APPROVED

at the meeting of the Faculty Council, Faculty of
Pharmacy

Minutes No. 3 of 16.12.2021

Dean of the Faculty, PhD, associate professor

CIOBANU Nicolae



APPROVED

approved at the meeting of the Department of Pharmacology and
Clinical Pharmacy

Minutes No. 2 of 15.09.2021

Head of Department, PhD, associate professor,

SCUTARI Corina

SILLABUS

DISCIPLINE PHARMACOTOXICOLOGY

Integrated studies

Type of course: **Compulsory Discipline**

Curriculum developed by the team of authors:

Cazacu Vasiliu, PhD, associate professor

Bodrug Elena, PhD, associate professor

Chişinău, 2021



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I. PRELIMINARY

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

The course of *Pharmacotoxicology* has as primary objective the study of the toxic action of drugs in the following aspects: the study of the pharmacotoxic effects arising from drug over dosage at the molecular, cellular, tissue levels in the living organism: human and experimental animals.

The structure of the course is intended to help with the basic knowledge required in the field of drug pharmacotoxicokinetics and pharmacotoxicodynamics, adverse drug reactions and pathological conditions caused by drugs, acute and chronic drug intoxications as well as their prophylaxis and modalities of emergency medical assistance. Pharmacotoxicology is one of the major specializations that helps the student pharmacist to systematize the underlying risks involved in the of unjustified or abusive use of some drug groups to allow appropriate timely measures to effectively counteract the primary manifestations of toxic substances, to prevent the development of severe acute toxic poisoning with vital risk; creating the necessary skills to avoid intoxication and to resolve emergencies; helps systematize the most important drug groups, which can more easily cause poisoning and pharmaco-therapeutic complications; be able to prescribe prescription drugs in certain pathological conditions, especially in emergency situations, based on the pharmacotoxicodynamic and pharmaco-toxicokinetic particularities of high-risk medicinal products to develop intoxications in the event of overdose or to use unjustified, abusive, for iatrogenic treatment.

- Mission of the curriculum (aim) in professional training

The mission of the discipline is to develop basic knowledge about the risk of development of adverse reactions and possible intoxications, about etiology, pathogenesis and symptoms of the most common intoxications that the pharmacist can encounter in practical work; to determine the principles of treatment of these intoxications; to systemize the information about current and new high-risk drugs for development of intoxications existing in the pharmaceutical market and familiarization of physicians, pharmacy workers and the population with them; to have information on pharmaco-economic expenditures for prophylaxis of possible intoxications, and how to install a checkup over the correct administration of drugs.

- **Languages of the course:** Romanian, English.
- **Beneficiaries:** students of the fourth year, faculty of Pharmacy, specialty Pharmacy.



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II. MANAGEMENT OF THE DISCIPLINE

Discipline's Code		S.08.O.066	
Discipline's name		Pharmacotoxicology/Toxicology of Medicines	
Person in charge of the discipline		PhD, associate professor, Cazacu Vasilii	
Year	IV	Semester	VIII
Total number of hours, including:			90
Course	15	Practical/laboratory hours	30
Seminars	-	Individual work	30
Form of assessment	E	Number of credits	3



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III. TRAINING AIMS IN WITHIN THE DISCIPLINE

At the end of the discipline, the student will be able to:

✓ *At the level of knowledge and understanding:*

- To know the history, the content of pharmacotoxicology and its tasks;
- to know the classification of drugs in general and within the group, the group membership of the drug (toxic);
- to determine the drug toxic kinetics (absorption, distribution, biotransformation, excretion pathways);
- to have knowledge about drug toxicology (main pharmacological effects, mechanism of action);
- to study the adverse/side effects of high-risk drugs for intoxications, to appreciate their main indications and counter-indications;
- to know the general formula, the pharmaceutical forms of medicines and their destination, the acquisition of therapeutic doses, lethal doses 50 and lethal doses 100;
- to know the emergency treatment measures.

✓ *At the application level:*

- to determine the group membership of the specific drug (toxic);
- to prescribe drugs used to treat intoxications in all possible pharmaceutical forms;
- to select the indications for the concrete preparation (toxic);
- to select the adverse drug reaction for the concrete preparation (toxic);
- to select the measures and principles of pharmacotherapy for acute drug intoxications;
- to reduce the probability of accidental administration, overdosing of preparations, or the release of prescriptions of incompatible substances;
- to check qualitatively the medicines' prescriptions according to knowledge of drug incompatibility (toxic dynamics, toxic kinetics), interference of medicinal remedies with food;
- to be able to substitute one preparation (toxic) with another, less toxic if necessary;
- to perform the comparative presentation of the drugs (toxics) from concrete group;
- to be able to inform the patient about possible adverse reactions in the event of preparation overdose or its abusive administration, their prophylaxis and prevention.

✓ *At the integration level:*

- to determine the position and importance of the discipline of Pharmacotoxicology in all disciplines provided by the study plan (pharmaceutical profile, pathophysiology, human physiology, biochemistry, etc.);
- to use the knowledge gained in other disciplines in the interdisciplinary integration of pharmacotoxicology;
- to accumulate the theoretical and applicative knowledge of drugs as a reference for their subsequent use in pharmacotherapy (pharmacy) and in clinical pharmacy;
- to form the basic knowledge of the main notions about the risk of adverse reactions and possible intoxications, etiology, pathogenesis and clinical picture of the most common intoxications with which the pharmacist can meet in his practice;



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- to determine the principles and place of medicines in the poisoning pharmacology;
- to accumulate a certain amount of knowledge in pharmacotoxicology and its interdisciplinary level to form the skills to consult physicians about possible drug poisoning, first aid measures, toxicology issues, toxicology of medicinal plants, etc.

IV. PROVISIONAL TERMS AND CONDITIONS

Student of the fourth year requires the following:

- Certified skills in fundamental sciences (physiology, pathological physiology, biochemistry, toxicological chemistry, toxicological plants, pharmacology);
- Digital competences (use of the Internet, document processing, electronic tables and presentations, use of graphics software);
- Ability to communicate and team work;
- Qualities - tolerance, compassion, autonomy.



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V. THE MESAND ESTIMATE ALLOCATION OF HOURS

Lectures, practical hours/seminars and self-training

No.	Theme	Number of hours		
		Lectures	Practical hours	Self training
1.	Introduction to General Toxicology and Pharmacotoxicology, Tasks. Quantitative Toxicology. Classification of toxic substances. Intoxication, etiology, classification.	1	2	2
2.	Basic clinical syndromes of intoxication. Particularities of poisoning in children.	1	2	3
3.	General healthcare measures in acute poisoning with drugs and other substances.	-	1	2
4.	Acute intoxications with cholinergic and adrenergic substances.	1	2	3
5.	<i>Totalization on themes 1-4.</i>	-	2	2
6.	Acute intoxications with psychotropic preparations part I (hypnotics, neuroleptics, tranquillizers)	1	2	3
7.	Acute intoxications with psychotropic preparations part II (tranquillizers, antidepressants, psychostimulants, analeptics).	-	2	3
8.	Acute intoxications with psychotropic preparations part III (psychostimulants, analeptics).	1	2	3
9.	Acute poisoning with analgesics.	1	2	3
10.	Acute intoxications with ethyl alcohol and its derivatives.	1	1	2
11.	Acute poisoning with heart medicines.	1	2	3
12.	<i>Totalization on themes 6-11.</i>	-	2	2
13.	Acute intoxication with diuretics. Acute intoxications with magnesium and calcium salts. Acute poisoning with antidiabetics, vitamins.	2	2	3
14.	Acute intoxications with antihistamine medicines, contraceptive preparations.	2	2	3
15.	Acute poisoning with antiseptics, antibiotics, anti-tuberculosis medicines, acids and bases.	2	2	3
16.	Acute poisoning with heavy metal salts, preparations containing iron.	1	1	3
17.	Practical lesson of generalization. Differentiated colloquium.	-	1	2
Total		15	30	45



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IV. CLINICAL SKILLS ACQUIRED AT THE END OF THE COURSE

- To determine the position and importance of the discipline of Pharmacotoxicology in all disciplines provided by the study plan;
- to use the knowledge gained in other disciplines in the interdisciplinary integration of pharmacotoxicology;
- to accumulate the theoretical and applicative knowledge of drugs as a reference for their subsequent use in pharmacotherapy (pharmacy) and in clinical pharmacy;
- to form the basic knowledge of the main notions about the risk of adverse reactions and possible intoxications, about etiology, pathogenesis and main symptoms of the most common intoxications with which the pharmacist can meet in his practice;
- to determine the principles and place of drugs in the poisoning pharmacology;
- to accumulate a certain amount of knowledge in pharmacotoxicology and its interdisciplinary level to form the skills to consult physicians about possible drug poisoning, first aid measures, toxicology issues, toxicology of medicinal plants.



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VII. REFERENCE OBJECTIVES AND CONTENT UNITS

OBJECTIVES	CONTENT UNITS
Chapter 1. The subject of clinical and general toxicology	
<ul style="list-style-type: none">• To define toxicology;• to know the tasks and departments of toxicology;• to be acquainted with general notions of toxic and intoxication, principles of classification of intoxications and toxics;• to learn the basic parameters of the toxometry;• to learn the basic clinical syndromes of acute intoxications and how to assess their severity;• to learn the general measures of urgent medical care in poisoning with drugs and other toxic substances.	<p>Pharmacotoxicology - a branch of medicine that studies the laws of interaction between living and toxic organisms.</p> <p>Toxicometry - determination of the toxic action area of the studied chemical.</p> <p>Intoxication - the penetration into the body of a toxic dose of foreign chemical.</p> <p>Basic clinical syndromes of acute intoxications. Urgent medical assistance in poisoning with drugs and other toxic substances. Administration of specific antidotes. Adverse drug reactions and their monitoring.</p>
Chapter 2. Intoxications with cholinergic and adrenergic preparations	
<ul style="list-style-type: none">• To know etiology, toxic kinetics, toxic dynamics, adverse reactions, symptomatology and treatment of poisonings with M-cholinomimetics; N-cholinomimetics;• to know etiology, toxic kinetics, toxic dynamics, adverse reactions, symptoms and treatment of poisonings with cholinesterase inhibiting drugs;• to know etiology, toxic kinetics, toxic dynamics, adverse reactions, symptoms and treatment of poisonings with M-cholinoblockers;• to know etiology, toxic kinetics, toxic dynamics, adverse reactions, symptoms and treatment of poisonings with N-cholinoblockers.• to know etiology, toxic kinetics, toxic dynamics, adverse reactions, symptoms and treatment of poisonings with alpha-adrenomimetics, beta-adrenomimetics and alpha, beta-adrenomimetics.• to know etiology, toxic kinetics, toxic dynamics, adverse reactions, symptoms and treatment of poisonings with alpha-	<p>Acute poisoning with M- and N-cholinomimetics. Acute intoxication with cholinesterase inhibiting drugs. Acute poisoning with M-cholino-blockers. Acute poisoning with ganglio-blockers and miorelaxant drugs. Adverse effects of cholinergic preparations. Urgent medical assistance. Acute intoxication with α- and β-adrenomimetics. Acute poisoning with α- and β-adrenoblockers. Acute poisoning with sympatho-mimetics and sympatholytics. Adverse effects of adrenergic preparations. First Aid Measures.</p>



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OBJECTIVES	CONTENT UNITS
adrenoblockers, beta- adrenoblockers and alpha, beta- adrenoblockers.	
Objectives	Content units
Chapter 3. Intoxication with preparations with action on the central nervous system	
<ul style="list-style-type: none">• To know etiology, toxic kinetics, toxic dynamics, adverse reactions, symptoms and treatment of poisonings with ethyl and methyl alcohol;• to know medical assistance in chronic intoxication with ethylic alcohol (alcoholism);• to know etiology, toxic kinetics, toxic dynamics, adverse reactions, symptoms and treatment of poisonings with hypnotic, anticonvulsive, antiepileptic preparations;• to know etiology, toxic kinetics, toxic dynamics, adverse reactions, symptoms and treatment of poisonings with analgesic preparations; group specificities of opiate and non-opiate analgesics;• to understand etiology, toxic kinetics, toxic dynamics, adverse reactions, symptoms and treatment of poisonings with psycholeptic preparations (antipsychotic, anxiolytic, sedative);• to understand etiology, toxic kinetics, toxic dynamics, adverse reactions, symptoms and treatment of poisonings with preparations psycho-analeptic (antidepressant, psychostimulators, nootropics);• to know urgent medical assistance in poisoning with psycholeptics, psychoanaleptics and psychodysleptics.	Acute and chronic poisoning with ethanol. Acute poisoning with psycholeptic preparations: hypnotics, neuroleptics, anxiolytics (tranquilizers), sedatives. Acute poisoning with psychoanaleptic preparations: nootropic, antidepressant. Acute poisoning with psychoso-mimetic drugs. Drug addiction. Clinical manifestations and medical-social aspect. Emergency medical attention in poisoning with preparations of the nominated groups.
Chapter 4. Intoxication with drugs that influence central nervous system.	



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OBJECTIVES

- To know etiology, toxic kinetics, toxic dynamics, symptomatology and treatment of acute poisoning with cardiotonic and cardiostimulator, diuretics preparations;
- to know etiology, toxic kinetics, toxic dynamics, symptomatology and treatment of acute poisoning with preparations affecting coagulation and hematopoiesis (anticoagulant, antiplatelet, fibrinolytic, hemostatic drugs);
- to understand etiology, toxic kinetics, toxic dynamics, symptomatology and treatment of acute poisoning with preparations affecting respiratory system.

CONTENT UNITS

Acute poisoning with cardiotropic preparations (cardiac glycosides, diuretics, calcium channel blockers, nitrates, musclotropic vasodilators, quinidine). Acute poisoning with anticoagulant, antiplatelet, fibrinolytic, hemostatic, antifibrinolytic preparations. Acute poisoning with preparations that are part of anti-anemic medication. Acute poisoning with respiratory analeptics, antitussive, expectorant, mucolytic, bronchodilator preparations. Over-exposure to preparations and urgent medical attention in case of intoxication.

Chapter 5. Poisoning with drugs that influence bronchopulmonary and cardiovascular systems

- To know etiology, toxic kinetics, toxic dynamics, symptomatology and treatment of acute poisoning with hormonal and antihormonal preparations;
- To know adverse effects which may occur when using anabolic preparations, sex hormones, glucocorticoids and their prophylaxis;
- to know etiology, toxic kinetics, toxic dynamics, symptomatology and treatment of acute poisoning with antidiabetic drugs and urgent medical assistance;
- to understand etiology, toxic kinetics, toxic dynamics, adverse reactions, symptomatology and treatment of acute poisoning with anti-inflammatory preparations;
- to understand etiology, toxic kinetics, toxic dynamics, adverse reactions, symptomatology and treatment of acute poisoning with antiallergic and immunomodulatory preparations;
- to know etiology, toxic kinetics, toxic dynamics, symptomatology and treatment of acute poisoning with vitamin preparations: their prophylaxis and/or urgent medical

Acute intoxications with hormonal preparations: contraceptives. Acute poisoning with oral antidiabetic agents. Acute intoxication with anabolic agents. Acute intoxication with mineralocorticoid preparations and their antagonists. Acute poisoning with non-steroidal and steroidal anti-inflammatory drugs. Acute poisoning with vitamin preparations: hydrosoluble and liposoluble. Acute intoxication with H1- and H2 antihistamines and mast cell degranulation inhibitors.



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OBJECTIVES

CONTENT UNITS

assistance;

- to know etiology, toxic kinetics, toxic dynamics, symptomatology and treatment of acute poisoning with heavy metals: lead, mercury, arsenic and cadmium.

Chapter 6. Acute poisoning with chemotherapeutic drugs.

- To know etiology, toxic kinetics, toxic dynamics, symptomatology and treatment of acute intoxications with antiseptics and disinfectants;
- to know etiology, toxic kinetics, toxic dynamics, symptomatology and treatment of acute antibiotic intoxications;
- to know the etiology, toxic kinetics, toxic dynamics, symptomatology and treatment of acute intoxications with TB chemotherapies;
- to understand first aid measures in chemotherapy poisonings.

Acute poisoning with antiseptics and disinfectants (phenol, boric acid, hydrogen peroxide, iodine preparations, potassium permanganate, magnesium and calcium salts). Acute intoxication with antibiotics: beta-lactamases, aminoglycosides, tetracyclines, with aralkylic structure, macrolides, from various groups, antibacterial sulfa drugs. Acute intoxication with TB chemotherapies. Urgent medical assistance



VIII. PROFESSIONAL (SPECIFIC (PC)) AND TRANSVERSAL (TC) SKILLS AND STUDY OUTCOMES

✓ Professional Skills (PS)

PS1: knowledge and understanding of classification of drugs in general and within the group, group membership of drug substance (toxic), drug toxicokinetics (absorption, distribution, biotransformation, routes of excretion), explanation and interpretation of drug toxic dynamics (main pharmacological effects, mechanism of action).

PS2: knowledge of pharmacological action, indications, contraindications, adverse effects of drug remedies with increased intoxication risk; knowledge of emergency treatment measures.

PS3: use and adaptation of pharmacology knowledge in drug prescription control, learning of therapeutic posology, lethal doses 50 and lethal doses 100.

PS4: presentation of individual scientific projects and scientific research circle partaking with reports in the field of acute and chronic intoxications with medicinal remedies and first aid measures.

PS5: knowledge of the preclinical drug research methodology: determination of acute and chronic toxicity according to duration of administration in humans, identification of scientific research problems in the field of pharmacotoxicology and their scientific correlation with the knowledge from medical fields.

PS6: the use of capacity to solve situations; the use of information technologies for the reproduction of toxicological effects in various drug intoxications via digital technologies.

✓ Transversal Skills (TS)

TS1: promoting effective, safe and pharmacoeconomically advantageous drugs in the treatment of various intoxications; compliance with pharmaceutical ethics and deontology rules in acute and chronic intoxications; compliance with the Code of Ethics/Deontology in prescribing OTC medicines, and releasing them to the population and medical institutions.

TS2: forming the competent personal attitude; the correct interaction ability of pharmacist-patient, and pharmacist-physician types, group-efficient activity with different drug counseling roles; enhancing decision-making autonomy in the prescription, selection and release of drugs in acute and chronic poisoning.

TS3: performing teamwork by carrying out scientific projects; promoting the spirit of initiative, dialogue and cooperation through various techniques of material study; positive attitude respect, empathy and respect for others, critical analysis and formulation of certain conclusions, for the pharmacist's daily activity.

✓ Study Outcomes

At the end of the course the student will be able to:

- To assess the importance and role of pharmacotoxicology in the context of general medicine and integration with related pharmaceutical disciplines.
- to determine the specific drug (toxic) group membership;
- to prescribe drugs used to treat intoxications in all possible pharmaceutical forms;
- to select the adverse reactions for concrete drug (toxic);
- to select the measures and principles of pharmacotherapy in acute drug intoxications;



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- to reduce the probability of accidental administration, overdosing of preparations or the release of incompatible prescriptions;
- to check qualitatively the prescription according to knowledge of toxic incompatibility (toxic dynamics, toxic kinetics), the interference of drugs with food;
- to be able to inform the patient of possible side effects in case of overdose or abusive administration, their prophylaxis and prevention.
- to inform the patient about the rational use of the drug, possible side effects, their prophylaxis and prevention.

IX. STUDENT'S INDIVIDUAL WORK

No.	Expected Product	Implementation Strategies	Assessment criteria	Implementation terms
1.	Working with information sources:	Read the lecture or the material in the manual to the theme carefully. Reading self-training questions in the subject that require reflection on the matter. To get acquainted with the list of additional information sources on the topic. Select the source of additional information for that theme. Reading the text entirely, carefully and writing the essential content. Wording of generalizations and conclusions regarding the importance of the theme/subject.	Ability to extract the essentials; interpretative skills; the volume of work	During the semester
2.	Working with the practical hours' notebook:	Until solving the tasks in the notebook, analyze the information on the subject in the lecture and the manual. Task solving from methodological guidelines: brief characterization of mandatory preparations, prescription of all pharmaceutical forms of mandatory drugs, indication of preparations in various intoxications. Selection of additional information, using electronic addresses and bibliographic sources.	Workload, situational problem solving skills, ability to formulate conclusions	During the semester
3.	Preparing and defending presentations	Selection of the research theme, establishment of the research plan, setting the terms of realization. Establishing PowerPoint presentation components - theme, purpose, results, conclusions, practical applications, bibliography.	The volume of work, the level of insight into the essence of the presentation, the level of scientific argumentation, the quality of the conclusions, the elements of creativity, the formation of the personal attitude, the coherence of the exposure and the scientific correctness, the graphic presentation, the way of presentation	During the semester



X. METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT

Teaching and learning methods used

The teaching of the *Pharmacotoxicology* discipline uses different didactic methods and procedures, oriented towards the efficient acquisition and achievement of the objectives of the didactic process. At the lectures, along with traditional methods (lesson-exposure, lesson-conversation, synthesis lesson), modern methods (lesson-debate, lecture-conference, problem-lesson) are also used. During practical works are used following forms of activities: individual, frontal, group-based. Control work (characterization of preparations, indications in intoxications with various preparations) in writing to highlight the initial level of knowledge; practical activities (group work): discussing cases of acute and chronic poisoning with drug remedies in case of overdose or self-administration, demonstration of video films. During lessons and extracurricular activities are used Communication Technologies - PowerPoint presentations.

Verifying knowledge on questions from methodological guidelines and putting tasks on the next topic of practical hours (self-training work).

Final: Exam (semester VIII).

- ***Applied teaching strategies/technologies (specific to the discipline);***
"Brainstorming", "The round table"; "Case Study"; "Presentation".
- ***Methods of assessment (including the method of final mark calculation).***

Current: frontal and/or individual control by testing, control papers, group discussions, case study analysis. The formative assessment is made up of two totalizations and one mark for individual work. Each totalization and self-training work is marked separately with grades from 0 to 10 and can be sustained 2-3 times. The annual average is formed from the sum of points accumulated during the study year divided by 3. The totalizations consist of two self-training questions and two indications for the use of the corresponding preparations in the respective disorders.

Final: exam. At the exam of *Pharmacotoxicology* are not accepted students with the average annual score below grade 5, as well as students who have not recovered absences from lectures and practical works. The Exam includes the oral test. The oral test includes four questions from the *Pharmacotoxicology* discipline and four indications for the use of appropriate drugs.

Final mark consists of two components: average annual mark (coefficient 0.5) and oral test (coefficient 0.5).

The roundup of the grades at the evaluation steps

INTERMEDIATE MARKS SCALE (annual average, marks from the examination stages)	National assessment system	ECTS Equivalent
1.00-3.00	2	F
3.01-4.99	4	FX
5.00	5	E



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5.01-5.50	5.5	D
5.51-6.0	6	
6.01-6.50	6.5	
6.51-7.00	7	C
7.01-7.50	7.5	
7.51-8.00	8	
8.01-8.50	8.5	B
8.51-9.00	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 and oral test) - are expressed in numbers according to the mark scale (according to the table), and the final obtained mark is expressed in a number with two decimals, which is transferred to student's record-book.

Absence on examination without good reason is recorded as "absent" and equivalent to 0 (zero). The student has the right to have two re-examinations on failed subject.

XI. RECOMMENDED BIBLIOGRAPHY

A. Mandatory:

1. Gonciar V., Cazacu V., Cheptea Ed. Farmacotoxicologie, Chişinău, 2008, 264 p.
2. Ghicavîi N., Bacinschi N., Guşuila Gh. Farmacologie: Manual. Ediția a II-a. Chişinău, 2010.
3. Gonciar V. ş.a. Indicații metodice pentru lucrări de laborator la farmacotoxicologie (facultatea Farmacie). 2006.

B. Additional:

1. Butnaru E., Proca M. Toxicologie, vol. II, Editura Timpul, Iași, 2001, 368 p.
2. Harrison. Principiile medicinei interne. V.2. Teora, București, 2001, 2838 p.