

**MEDICAL UNIVERSITY PLOVDIV**  
**FACULTY OF PHARMACY**

---

**ACADEMIC STANDART**

**FOR ACADEMIC DISCIPLINE**

**“TOXICOLOGY”**

**SPECIALITY MASTER OF PHARMACY**



Approved by decision of the Department Council - Protocol No. 13 / 31.05.2017

## 1. Objective of the course in Toxicology

**Toxicology** is a science that studies the effects of xenobiotics on humans at doses over pharmacological ones. The main objective of the course in the course "Toxicology" is to prepare highly qualified personnel who are familiar with the toxicological risk of damage from xenobiotics of natural and synthetic species, incl. side effects.

The goal is coordinated with:

- the public mission of the university - training that "contributes to the implementation of the state policy for the development of higher medical education and medical science, for the improvement of the health and health status of the population" and "training of highly qualified specialists with higher medical education";
- volume and credit rating of the discipline (ECTS system), as shown in the curriculum;
- the qualification characteristic of the specialty;
- degree (professional bachelor, bachelor or master).

The purpose is in line with the place of the discipline in the specialty according to importance and chronology in the curriculum. Toxicology is a direct link and builds knowledge from disciplines such as anatomy, chemistry, biochemistry, biophysics, physiology, pathophysiology and pharmacology. As a fundamental discipline, it serves the next stages of training. In the training of pharmacists, the development of professional skills in dispensing medicines, preparing of medical prescriptions, and consulting patients for a pharmacovigilance is of critical importance.

This requires:

- Basic knowledge of the pharmacological safety profile of xenobiotics and drugs.
- Knowledge of the toxicological characteristics of biologically active chemical ingredients and excipients in medicinal products.
- Knowledge of adverse drug reactions and toxic effects of xenobiotics in overdose.
- Knowledge of indicative recognition of poisoning of high social importance - the most common drug and domestic intoxication.
- Knowledge of life-saving techniques for pre-medical assistance in poisoning.
- Toxicology training creates the necessary prerequisites for the proper use of medicinal products and the safe handling of chemicals and preparations.

The toxicology course for pharmacists is designed to:

1. Give future masters basic theoretical and practical knowledge in the field of general toxicology and partly about clinical toxicology in humans with an emphasis on medicinal side effects and toxic effects.
2. Create a correct conception and understanding of the interaction between xenobiotics and living systems in its various forms and manifestations.
3. Clarify the nature of the toxic process at the macro and micro level.

4. Prepare students for an adequate assessment of the effects of toxic environmental, industrial and domestic damage on the normal course of biological processes in living organisms and possible pathological deviations from toxic exposure.
5. Students to acquaint with the main toxic effects of intoxicants with the most significant medical and biological effects and with the basic methods of prevention and treatment.
6. To be trained in providing of first-aid in poisoning and to prepare for effective toxicological consultation.

Feature:

- The training course is anthropocentric and practical.
- Specific feature of the course is the understanding of the versatility of toxic interaction between xenobiotics and organisms and the unified criteria for recognizing toxic aggression, side effects and poisoning with the most commonly prescribed and used drugs and xenobiotics in real life.
- Students are also prepared for the first aid in case of poisoning based on general and specific knowledge and skills acquired.

### **Goals and main objectives of the course**

1. To present synthetically in a theoretical and practical aspect wide and multilayered interaction of xenobiotics with living systems, safety margins and hidden and obvious signs of toxicity.
2. To understand the toxic interactions as a manifestation of biological expediency, adaptation and disadaptation mechanisms in living organisms.
3. To acquire basic knowledge about:
  - intimate mechanisms of xenobiotics toxicity;
  - the pharmacological safety profile of xenobiotics and drugs;
  - toxicological characteristics of biologically active chemical components and excipients in drugs;
  - adverse drug reactions and toxic effects of xenobiotics;
  - recognition of poisonings of high social importance - the most common drug and domestic intoxications;
  - first-aid in poisoning.
4. To create the necessary prerequisites for:
  - correct use of drugs and safe handling of chemicals and preparations;
  - correct interaction and collaboration with medical structures for the prevention of drug toxicity;

- a basis for effective counseling of patients about the prevention of side effects and interactions - pharmacological prevention of poisoning.

5. To gain theoretical knowledge and work out practical algorithms for providing first aid in poisoning.

### **Expected results**

1. At the end of the course, students should be aware and familiar with:

- The brief history of toxicology;
- The basic concepts and processes in toxicology;
- Types of toxic aggression on living organisms;
- Mechanisms of toxic effects of xenobiotics;
- Evolutionary adaptive and maladaptive mechanisms of physiological antitoxic protection;
- Medical detoxification protection - forms, strategy, tactics;
- Drugs for treatment of poisoning.

2. Know and be able to:

- Understand and explain the interaction between xenobiotics and the living organism in norm and pathology.
- Generally recognize the external signs of the toxic process - to make a "general biological diagnosis".
- Use an algorithm of behavior in case of environmental, industrial and domestic toxic incidents and be known with the mechanisms of cooperation with antitoxic organizations.
- Properly use toxicological literature, books, articles and monographs.
- To complete a literary review on a toxicological / toxicological-biological topic with a training or production character.
- Exercise first aid in acute exogenous poisoning (AEP)

## **2. Course content of the discipline**

The lectures and the hours of lectures ,exercises, course assignments are listed on the website of the faculty: <http://mu-plovdiv.bg/wp-content/uploads/2016/09/uchebna-programa-farmatsiya.pdf>

The course content of the subject is chronologically arranged so that each subsequent lecture/exercise uses already studied subject matter and concepts. It is in line with the university's priority goals and enables the development of the student's personal qualities. Unnecessary overlap or the existence of "white spots" between "related" curriculum disciplines

are avoided. Learning content provides the acquisition of key competences and skills that are of primary importance for the future professional realization of the student.

### **3. Prerequisites**

The student should have basic knowledge of Biology, Biophysics, Physiology, Pharmaceutical chemistry, Biochemistry, Pharmacognosy, Microbiology, Anatomy, Patoanatomy and Pathophysiology from the educational programs in the first years of university studies in order to begin and successfully complete Toxicology training.

### **4. Academic resources**

The academic staff of the department consists of 8 lecturers on an employment contract. Of these, 1 are habilitated lecturer, 7 non-habilitated lecturers with PhD degrees in the relevant specialty. Of all lecturers 3 have a specialty in pharmacology, 1 in clinical pharmacology and therapy, 2 in clinical pharmacy and 1 in pharmacology and pharmacotherapy.

The habilitated lecturer in Pharmacology has excellent theoretical and practical training, high professionalism, long-term experience in teaching and research work. Besides higher education - Master of Medicine, he also hold a Master's Degree in Health Management. Habilitated lecturer from the Department of Pharmacology and Drug Toxicology is member of the Expert Commissions, Editorial boards of Journals, State Commissions for Acquisition of Specialty. Habilitated lecturer is also an ERT (European Registered Toxicologist). The teachers in the department holding the respective academic positions meet the national requirements set out in the Higher Education Act, DASRBA, the Regulations for the implementation of the DASRBA and the RSA of MU-Plovdiv.

Lectures in Bulgarian and English are read by a habilitated lecturer (professor) with acquired PhD.

Practical exercises in Bulgarian and English are conducted by habilitated and non-habilitated lecturers – assistant professors, chief assistant professors. Non-habilitated lecturers have “master” of medicine or pharmacy and were appointed after a competition.

### **5. Material resources**

The department has at its disposal:

- 4 study rooms with a total area of approx. 103 sq.m.;

- 1 laboratories equipped with equipment for conducting experimental work. The total laboratory area of the department is about 30 m<sup>2</sup>. The department's laboratory facilities include general and specific equipment, owned by the Department of Pharmacology and Clinical Pharmacology at the Medical University of Plovdiv, for the study of anti-inflammatory action, acute and chronic stress, pain, inflammation, training and memory.
- 4 cabinets - 16 square meters average area.
- 8 computers, allowing each teacher to work independently. The department has a continuous Internet connection and access to full-text publications through the library of MU - Plovdiv.

## **6. Lectures**

The lectures are prepared and presented in the form of multimedia presentations. The volume and format of the lectures are chosen by the lead lecturer. The material discussed in the lecture course precedes the practical exercises on the subject. Presentations used for lecturing allow preliminary training of students for each practical. The lecture course also introduces demonstrations of important and current manifestations of xenobiotic toxicity - from periodicals, from experience of victims and from documented cases of toxicity.

## **7. Practical exercises**

Practical exercises are conducted with student groups. Literature sources available in the department and in the library are used to prepare them. Their content is updated periodically to provide training consistent with dynamic changes in science. Individual and team tasks are handed out. Advantage is given to teamwork. Testing examines the student's preparation and the knowledge and skills gained from the specific exercise. The Practical's curriculum also includes assignments for independent outreach work, preparation of the abstract and their defense of the next exercise.

The course provides an opportunity to visit a toxicological center and acquaintance with the manifestations of xenobiotic toxicity, which creates lasting psychophysical connections with the theoretical material. Short training on first aid in poisoning is implemented.

## **8. Seminars**

Students are provided with advance information and clarification about the upcoming examination. Seminar exercises take place with a whole group of students and beginning with an individual oral examination, followed by a written examination on an individual topic. The results are discussed at the next exercise.

## **9. Information resources. Basic literature. Websites.**

Teachers have developed lectures in an electronic version. Practical exercises are conducted on the basis of a published handbook. The Library and Information Center of MU-Plovdiv provides a sufficient amount of specific specialized information to assist the students' training.

1. A textbook of modern toxicology. Earnest Hodson/ed/ IVed. J. Wiley and sons, Hoboken, New Jersey, 2010
2. Poisoning and Toxicology handbook. 4<sup>th</sup> edition. Jerrold B. Leikin, MD. Frank P. Paloucek, PharmD/ Lexi-Comp, USA. 2008
3. Pharmaceutical toxicology 1<sup>st</sup> edition by G. Mulder and L. Dencker. ULLA Pharmacy, 2006.

The access to and use of information resources, as well as the service for the delivery of electronic articles for students, PhD students and employees from the Plovdiv University are free of charge.

## **10. Control work**

Students are loaded dynamically and intensive during the semester. Teachers control students' progress twice during the semester - during colloquiums and seminars. Ongoing control involves six prescription tasks and one theoretical question. Students are provided with advance information and explanations about the control work. The results are discussed at the next practical exercise with the students with explanations to assist in further preparation. The results of these tests are included as a component in the final grade for the semester.

## **11. Student's independent work and engagement**

The student's independent work is supervised by the lecturer (assistant) who guides the student both in the literary sources and in the methods of their acquisition and study. Sample tests and self-study questions are included in the curriculum and are available *online* at the MU-Plovdiv website: <http://mu-plovdiv.bg/wp-content/uploads/2016/09/uchebna-programa-farmatsiya.pdf>

## **12. Collaboration between students and the teaching staff**

This cooperation is expressed in:

- The teacher's commitment to the student and their preliminary preparation, current learning difficulties and opportunities with an individual learning program to achieve more.

- The use of reception counseling hours.
- Participation in a toxicology study group.
- Involving students in teams for scientific tasks, research, projects, etc.

### 13. Exams

The on-going evaluations, provided in the pharmacology program, are given for:

- The student's results in practical exercises, discussions, solving of test and prescription tasks, work of the student with the assistant on scientific research and projects, etc.;
- Written tests (colloquiums and seminars).

### 14. Evaluation standards

At the beginning of the classes in Toxicology, the assistant acquaints students with the standards of assessment, the procedures for conducting current control and the opportunities for obtaining feedback on their progress during the semester.

Standards for assessing student achievement are defined to objectify students' grades are unbiased. The evaluation criteria are as follows:

- **Poor mark (2)** – scant knowledge that can not serve as the basis for the next levels of pre-clinical and clinical training.
- **Average (3)** – reproduction of knowledge about medicines in a "ready scheme" - classification, toxicodynamics, lack of basic knowledge about adverse drug reactions; representing unresolved solutions to simple tasks; toxic risk assessment; lack of knowledge for personal use of the obtained professional competencies; terminology is not well adopted, presentation is characterized by poor language.
- **Good (4)** – key and additional knowledge on the classification, toxicokinetics, toxicodynamics of xenobiotics and medicinal products and their adverse drug reactions (ADRs) are descriptively mastered; there is limited independence and skills to solve simple tasks, although there is a good language culture, inaccuracies in the concepts used are allowed; prescription of medicinal products in a prescription.
- **Very good (5)** – very well mastered key and additional knowledge on the classification, toxicokinetics and toxicodynamics of xenobiotics and medicinal products; meaningful and correct understanding of the material, possible ADRs and drug interactions of individual drug groups. Independent, non-standard, search for a new algorithm and analysis of used literary data; skills to solve difficult tasks; tries to explain and substantiate their thesis; adequate use of the concepts of



the subject of the discipline studied, good language culture; prescription of medicinal products in a prescription.

- **Excellent (6)** – excellent knowledge of information sources and classification of drugs; thoroughly mastered key and additional knowledge about toxicokinetics and toxicodynamics of drugs; independent logic, thinking and correct understanding of the potential for ADRs and drug interactions; skills to apply the learned material to solve complex tasks; presence of creative elements; accuracy and rich language culture; accurate prescriptions of medicinal products.

### **15. Formation of the final mark**

The final grade determines to what extent the student has achieved the learning goal set at the beginning. Semester examination in toxicology includes three elements:

- Entry test with a duration of 30 minutes. The test is considered successfully passed with 70% correct answers.
- Written examination with a duration of one hour and thirty minutes.
- Oral examination – discussion on written exam and test.

The student gets a poor mark if:

- they quit the exam.
- they do not comply with the minimum requirements for the entry test.
- they not write on all questions included in the written examination, no matter how they developed the other questions.

Upon re-sit of the exam, the student attends all three parts of the examination.

During students' oral examinations the grades of the colloquiums and seminars held during the academic year are taken into account. The current control score is obtained as the arithmetic mean of these assessments. In case of poor assessment of the colloquiums / seminars, the student receives an additional question from the colloquium / seminar. The answer to the supplementary question takes part in the final evaluation of the oral examination.

The final score is obtained as a sum of the six-point scores of the different components multiplied by the relevant coefficients of significance, namely:

$$Q_{\text{final grade}} = K_1 Q_{\text{grade of the written exam}} + K_2 Q_{\text{grade of the oral exam}} + K_3 Q_{\text{grade of the on-going control}}$$

$$K_1 = 0.33; K_2 = 0.33; K_3 = 0.33$$

In case of a failed entry test, a poor assessment of the written or oral examination the final grade is necessarily a poor one.

The exam materials are stored and the students are given an opportunity to get acquainted with them and the grounds for their evaluation according to a procedure announced in advance. The period during which the students have access to the exam materials and results is not longer than 5 working days after the exam date. Each discipline has a characteristic to which the student is given access at the beginning of the training.

The academic standard for an academic discipline is approved by Decision of the Academic Council - Protocol No. 9 / 26.11.2015 and published on the website of MU - Plovdiv.

**Prof. V. Iliev, MD, PhD, M.H.M, ERT**

*Department of Pharmacology and Drug toxicology*

