

**MEDICAL UNIVERSITY PLOVDIV**  
**Faculty of Medicine**

**ACADEMIC STANDARD**  
**FOR ACADEMIC DISCIPLINE**

**“CLINICAL PHARMACOLOGY”**

## 1. Objective of the course in Clinical Pharmacology

The primary objective of training in the discipline of **Clinical Pharmacology** is to equip students with the knowledge and skills necessary for optimized, effective, safe, cost-efficient, and individualized pharmacotherapy based on evidence-based medicine. The training also aims to develop students' analytical abilities and their capacity to evaluate the results of clinical drug trials.

This objective aligns with:

- The public mission of the university, which emphasizes education that “contributes to the implementation of state policy for the development of higher medical education and medical science, and the improvement of population health,” as well as “the training of highly qualified specialists with higher medical education”;
- The volume and credit rating of the discipline as specified in the curriculum (ECTS system);
- The qualification requirements of the specialty;
- The degree level (professional bachelor, bachelor, or master).

The goal is consistent with the discipline's role and sequence within the curriculum. Clinical pharmacology is an integral clinical specialty, whose methodology underpins the conduct of clinical trials, the results of which form the basis of evidence-based therapy. The discipline provides students with the knowledge and skills necessary to implement safe and effective individualized drug therapy. As a core clinical discipline, it is taught in the fifth year of medical education (IX semester).

Upon completion of the course, students are expected to acquire the following knowledge and skills regarding drugs:

- Understanding the methodology of clinical drug trials and the analysis of obtained data;
- Knowledge of key pharmacokinetic parameters and their relevance to clinical practice;
- Awareness of the effects of diet, physiological, and pathological conditions on drug pharmacokinetics and pharmacodynamics;
- Ability to compare drugs within the same or across different pharmacological groups in the treatment of a disease (symptom, syndrome) based on effectiveness, safety, and suitability;
- Competence in selecting individualized therapy for a specific patient and preparing a corresponding treatment plan;

- Skills to obtain evidence on the efficacy and safety of a drug based on clinical trial results.

## **2. Course content**

The topics and schedules of lectures and exercises are listed on the MU-Plovdiv website: <http://mu-plovdiv.bg/studenti/>.

The course content is chronologically arranged so that each subsequent lecture/exercise uses already studied material and concepts. It is consistent with the priority goals of the university and provides an opportunity for the development of the student's personal qualities. Unnecessary overlap or the existence of "white spots" between "related" disciplines in the curriculum is avoided. The course content ensures the acquisition of key competencies and skills that are of paramount importance for the student's future professional realization.

## **3. Prerequisites**

The student must have basic knowledge of Pharmacology, Internal and Surgical Diseases, Microbiology, Clinical Pathology, Pathophysiology from the educational programs in the first years of study at the university in order to begin and successfully complete the study of clinical pharmacology.

## **4. Academic resources**

The academic staff of the Department of Pharmacology and Clinical Pharmacology consists of 7 lecturers. Of these, 4 are habilitated lecturers, and 3 are non-habilitated lecturers with PhD degrees in the respective specialty. Of all lecturers, 7 have a specialty in pharmacology, 1 in clinical pharmacology and therapy, 1 in toxicology. The lecturers in the department, occupying the respective academic positions, meet the national requirements specified in the Higher Education Act, Development of Academic Staff in the Republic of Bulgaria Act (DASRBA), the Regulations on the implementation of DASRBA and the Regulations on the structure and activities of MU-Plovdiv.

Habilitated and non-habilitated lecturers in Pharmacology possess excellent theoretical and practical training, demonstrate high levels of professionalism, and have extensive experience in both teaching and research. In addition to their primary qualification - a Master

of Medicine - one of the habilitated lecturers also holds a Master's degree in Health Management. One of the habilitated lecturers has successfully completed a course in homeopathic therapy. The habilitated lecturers from the Department of Pharmacology and Clinical Pharmacology are members of Expert Committees, Editorial Boards of journals, state committees for acquiring a specialty, scientific and professional organizations, reviewers of scientific articles, monographs, collections and textbooks in our country and abroad. They prepare reviews in scientific juries for acquiring the scientific degree "Doctor", scientific titles "Associate Professor" and "Professor". The lecturers from the Department actively participate in international exchange under the "Erasmus" and "Erasmus +" programs.

Lectures in Bulgarian and English are read by a habilitated lecturer (associate professor or professor) with an acquired PhD degree in pharmacology /incl. pharmacokinetics and chemotherapy/. Up to 30% of the lectures are assigned to non-habilitated lecturers holding a scientific PhD degree.

Practical exercises in Bulgarian and English are conducted by habilitated and non-habilitated lecturers.

## **5. Material resources**

The department comprises:

- Eight classrooms with a total area of approximately 180 sq. m.
- Five laboratories equipped for experimental work, with a combined area of about 65 sq. m. The laboratory facilities include both general and specialized equipment owned by the Department of Pharmacology and Clinical Pharmacology at the Faculty of Medicine, Medical University of Plovdiv, supporting research on anticonvulsant activity, acute and chronic stress, pain, inflammation, learning, and memory.
- Nine offices, each with an average area of 15 sq. m.
- Eleven computers, enabling each lecturer to work independently.

The department maintains continuous internet access and provides availability of full-text publications through the Medical University of Plovdiv library.

## **6. Lectures**

Lectures are prepared and delivered in the form of multimedia presentations. The volume and format of the lectures are chosen by the leading lecturer. The material considered in the lecture course precedes the practical exercises on the relevant topic. The presentations used for lecture training allow for preliminary preparation of students for each lesson.

## **7. Practical exercises**

Practical exercises are conducted in student groups. For preparation, the Department has developed clinical cases in which students analyze the effectiveness and safety of drug therapy, select appropriate medications, and prepare individualized therapeutic plans. The content of these case studies is periodically updated to ensure training remains aligned with the evolving field of clinical pharmacology.

Both individual and group tasks are assigned, with particular emphasis placed on teamwork. Student preparation, along with the knowledge and skills acquired during each exercise, is assessed through testing. The practical curriculum also includes assignments for independent, extracurricular work.

## **8. Seminars**

Seminar sessions are conducted with the full group of students and focus on topics not covered in the lecture course. During these sessions, students' questions related to the teaching material are addressed and discussed. Selected students may be assigned to present additional information on debatable issues concerning the efficacy and safety of various medicinal products. Opportunities for student participation in clinical pharmacology-related scientific forums are also discussed.

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

Lecturers have developed electronic versions of their lectures. Practical exercises are conducted using a published textbook. The Library and Information Center of the Medical University of Plovdiv provides ample access to specialized resources to support students' learning.

### **Basic literature**

1. Katzung's Basic and Clinical Pharmacology 16<sup>th</sup> edition (LANGE Basic Science), 2023.
2. Goodman and Gilman's The Pharmacological Basis of Therapeutics, 14<sup>th</sup> edition by Brunton and Knollman, 2022.
3. Clinical pharmacology, Brown, Sharma, Mir, Bennet eds., 12th Edition, Elsevier, 2018.
4. Principles of Clinical Pharmacology, Atkinson, Huang, Lertora, Markey eds., 3<sup>rd</sup> ed, Elsevier, 2012.

### **Additional literature**

1. Ritter, J., Lewis, L., Mant, T., & Ferro, A. (2008). A Textbook of Clinical Pharmacology and Therapeutics, 5Ed (5th ed.). CRC Press.
2. Emmett, Stevan R, Nicola Hill, and Federico Dajas-Bailador, *Clinical Pharmacology for Prescribing* (Oxford, 2019; online edn, Oxford Academic, 12 Nov. 2020).
3. Oxford textbook of clinical pharmacology and drug therapy. Edited by D. G. Grahame-Smith and J. K. Aronson. Published by Oxford University Press, 2002.
4. Introduction to Clinical Pharmacology, 6<sup>th</sup> edition, by Marilyn W. Edmunds, 2009.
5. Principles of Clinical Pharmacology, 2<sup>nd</sup> edition, by Atkinson, Abernety, Daniels, Dedrick and Markey, Academic Press, 2011.

Access to and use of information resources, as well as the service for the delivery of electronic articles for students, PhD candidates, and staff of the Medical University of Plovdiv, are provided free of charge.

## **10. Assessment**

Student progress is assessed during the semester through colloquia and seminar activities. Students are informed in advance about the format and requirements of these assessments. Evaluation includes a written test on a specific topic as well as clinical case solving tasks.

The results are reviewed with students during the subsequent practical session and are also discussed at departmental meetings to identify measures for improving the quality of clinical pharmacology training. The group assistant provides detailed feedback on identified deficiencies to support further student preparation.

The results of these assessments are included in the calculation of the final semester grade. One colloquium is held during the semester of the clinical pharmacology course.

### **11. Independent work and student engagement**

Independent student work is supervised by the lecturer (assistant), who provides guidance on both the selection of relevant literature and the methods for its effective acquisition and study.

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

This collaboration is reflected in:

- The lecturer's commitment to supporting students through their preparation, addressing current learning difficulties, and identifying opportunities for progress through individualized learning approaches.
- The use of scheduled consultation hours.
- Involvement of students in research teams, scientific projects, and related academic activities.

### **13. Examinations**

Continuous assessment, as outlined in the Clinical Pharmacology curriculum, is based on:

- Student performance during practical exercises, participation in discussions, completion of clinical cases.
- Written assessments, including colloquia and seminar-based tests.

### **14. Assessment standards**

At the beginning of the Clinical Pharmacology course, students are introduced by the assistant to the assessment standards, the procedures for continuous evaluation, and the opportunities for receiving feedback on their progress throughout the semester.

Clear assessment criteria are established to ensure objectivity and fairness in grading. The evaluation standards are as follows:

- **Excellent (6)** – Demonstrates outstanding knowledge of information sources and drug classification, with thoroughly mastered key and complementary knowledge that enables the selection of individualized, effective, safe, and cost-efficient therapy. Shows independent reasoning, critical thinking, and a correct understanding of potential adverse drug reactions (ADRs) and drug interactions. Effectively applies knowledge in solving clinical cases, providing well-reasoned decisions. Exhibits precision, rich language, and correctly prescribes medicinal products according to the patient's therapeutic plan.
- **Very Good (5)** – Demonstrates very well-mastered key and additional knowledge, enabling the selection of individualized, effective, safe, and cost-efficient therapy. Shows meaningful understanding of possible ADRs and drug interactions across different drug groups. Applies knowledge in clinical cases with attempts to explain and justify decisions. Uses discipline-specific concepts appropriately, communicates clearly, and correctly prescribes medicinal products according to the patient's treatment plan.
- **Good (4)** – Shows descriptive knowledge of key and complementary content, allowing for selection of individualized, effective, safe, and cost-efficient therapy, but with limited understanding of potential ADRs and drug interactions. Demonstrates partial autonomy in applying knowledge to clinical cases, with minor conceptual inaccuracies tolerated. Language use is adequate, though prescription-writing skills are insufficiently developed for patient-specific therapeutic plans.
- **Average (3)** – Reproduces knowledge needed for individualized, effective, safe, and cost-efficient therapy, as well as ADRs and drug interactions, in a schematic manner. Provides unjustified solutions to clinical cases, with limited prescription-writing skills according to patient treatment plans. Lacks the ability to personally apply acquired professional competencies; terminology is poorly mastered, and expression is linguistically weak.
- **Poor (2)** – Fails to meet any of the above requirements.

## 15. Formation of the final grade

The final assessment determines the extent to which each student has achieved the learning objectives established at the beginning of the course. The semester examination in Clinical Pharmacology consists of two components:

- **Written examination** – a multiple-choice test comprising closed questions, with a duration of 60 minutes. The test is considered successfully passed with a minimum of 60% correct answers.
- **Practical/oral examination** – completion of two clinical cases within 15 minutes, followed by a discussion.

A student receives a failing grade in the following cases:

- Quitting the examination;
- Failure to meet the minimum requirements for the written test;
- Failure to correctly complete at least one of the clinical cases.

**In the case of a retake, the student must complete all components of the examination again.**

During the oral examination, the student's performance in colloquia and seminars conducted throughout the academic year is also taken into account. If a student has received a low grade in these assessments, they are required to answer an additional question based on the respective material. The response to this additional question contributes to the oral examination grade.

The final grade is calculated as a weighted sum of the grades (on a six-point scale) obtained from the different components, each multiplied by its respective weighting coefficient, as follows:

$$Q_{\text{final grade}} = \kappa_1 Q_{\text{grade of the written exam}} + \kappa_2 Q_{\text{grade of the oral exam}} + \kappa_3 Q_{\text{grade of the on-going control}}$$

$$\kappa_1 = 0.33; \kappa_2 = 0.33; \kappa_3 = 0.33$$

In the event of failure on the written test or a poor grade on the practical/oral examination, the final grade is automatically recorded as failing.

Examination materials are archived, and students are given the opportunity to review them, along with the assessment criteria, according to procedures announced in advance. Access to exam materials and results is provided within no more than five working days following the examination date.

Each course is accompanied by a course description, to which students are given access at the beginning of their training.

The academic standard for the course has been approved by a decision of the Department Council (Protocol No. 2/09.02.2026) and is published on the website of the Medical University of Plovdiv.

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