MEDICAL UNIVERSITY - PLOVDIV

FACULTY OF PHARMACY

ACADEMIC STANDART

FOR ACADEMIC DISCIPLINE

"PHARMACOKINETICS"

SPECIALITY MASTER OF PHARMACY

Approved by decision of the Department Council - Protocol No. 3/17.03.2025г

1. Aim of the course

The pharmacokinetics curriculum for Master of Pharmacy students is designed to align with the competencies required for their professional qualification and the academic degree they are pursuing. The Pharmacokinetics course is mandatory in the training of Master Pharmacists. It provides students with a foundational understanding of pharmacokinetic principles, including fundamental concepts, mathematical models, and key pharmacokinetic parameters. The course emphasizes the clinical relevance of these parameters in optimizing drug therapy, ensuring a scientifically rigorous approach to medication management.

The main aim of the course is to provide knowledge and develop skills related to the pharmacokinetic characteristics of drugs from various pharmacological groups:

- drug assorption
- drug distribution
- drug metabolism
- drug excretion
- changes of drug effects after repeated and combined administration of different medications
- pharmacokinetic factors affecting drug action
- adverse drug reactions resulting from the pharmacokinetics of the drugs
- pharmacokinetic drug interactions

The goal is aligned with:

- the university's public mission, which includes providing education that contributes to the implementation of state policy for the advancement of higher medical education and medical science, the improvement of healthcare, and the enhancement of public health, as well as the training of highly qualified specialists with higher medical education;
- the scope and credit allocation of the course, as defined by the European Credit Transfer and Accumulation System (ECTS) in the curriculum;
- the qualification profile of the specialty;
- the corresponding educational degree, whether Professional Bachelor, Bachelor, or Master.

The aim is aligned with the role of the subject within the specialty, considering its significance and chronological placement in the curriculum.

Upon completion of the course, students should acquire the following knowledge and skills:

- Understand the fundamental pharmacokinetic parameters;
- Apply pharmacokinetic principles to make rational drug selections for various therapeutic scenarios;
- Efficiently search for and utilize up-to-date and relevant drug information related to pharmacokinetics;
- Calculate and adjust dosage regimens for at-risk patient populations, including pediatric and geriatric patients, as well as individuals with comorbid conditions such as renal or hepatic impairment.

2. Course content

The schedule of lectures, practical exercises, and course assignments, along with their respective hours, is available on the faculty's website.

The course content is structured chronologically, ensuring that each subsequent lecture builds upon previously acquired knowledge and concepts. It is aligned with the university's priority objectives and fosters the development of students' personal and professional competencies. The curriculum is designed to minimize unnecessary content overlap while preventing gaps between interrelated courses. This structured approach ensures the acquisition of essential competencies and skills critical for the student's future professional practice.

3. Prerequisites

To successfully begin and complete the pharmacokinetics course, students should have foundational knowledge in Biology, Biophysics, Pharmaceutical Chemistry, Biochemistry, Pharmacognosy, Pharmacology, Pharmacokinetics, Microbiology, Anatomy, Pathoanatomy, Physiology, and Pathophysiology, acquired during the early years of their university education.

4. Academic Resources

The department's academic staff comprises nine lecturers employed under an employment contract. Among them, four are habilitated lecturers, four are non-habilitated lecturers holding PhD degrees in the relevant specialty, and one is a non-habilitated lecturer without a PhD degree. Regarding specialization, five lecturers have a specialty in pharmacology, one in clinical pharmacology and therapy, three in clinical pharmacy, one in toxicology and toxicological analysis, and two in pharmacology and pharmacotherapy. Additionally, two lecturers are currently enrolled in training for their respective specialties.

The habilitated lecturer in the discipline of 'Pharmacokinetics' is an active member of expert committees, editorial boards of scientific journals, and state commissions for the acquisition of medical specialties. Additionally, he is affiliated with various scientific and professional organizations and serves as a reviewer for scientific articles, monographs, conference proceedings, and textbooks both in Bulgaria and internationally. He contributes to scientific juries for awarding the academic degree of 'Doctor' and the academic titles of 'Associate Professor' and 'Professor.'

The members of the department actively participate in the Erasmus + exchange program.

The faculty members in the department holding the respective academic positions comply with the national requirements outlined in the Higher Education Act, respective Laws and Regulations for the Implementation of the laws, and the specific requirements of MU-Plovdiv.

Lectures in both Bulgarian and English are delivered by a habilitated lecturer (Professor) holding a PhD and an acquired specialty certificate in 'Pharmacology' and 'Clinical Pharmacology and Pharmacotherapy'.

Practical classes are conducted by non-habilitated faculty members (Chief Assistant Professors and Assistant Professors) who hold a Master's degree in Medicine or Pharmacy.

5. Material resources

The Department is equipped with:

- **Six classrooms** covering a total area of approximately 140 sq.m.

- **One laboratory** designed for experimental work, equipped with various tests and apparatus. The laboratory area is approximately 30 sq.m. The laboratory's equipment includes both general and specialized instruments owned by the Department of Pharmacology and Clinical Pharmacology at the Faculty of Medicine, MU-Plovdiv.
- **Five offices**, each with an average area of 16 sq.m.
- **Nine computers**, enabling each faculty member to work independently. The Department has continuous Internet access and provides access to full-text publications through the MU-Plovdiv library.

6. Lecture training

Lectures are prepared and delivered through multimedia presentations. The content and format of the lectures are determined by the lecturer. The material covered in the lecture course precedes the practical exercises, providing a foundational understanding. The presentations used in lectures are designed to prepare students in advance for each practical session.

7. Practical exercises

The practical exercises consist of six sessions, conducted within student groups. The preparation for these practicals utilizes materials developed by the department, which include the analysis of various dosing regimens and their clinical applications. Both individual and team-based assignments are incorporated into the curriculum. Emphasis is placed on teamwork as the primary methodological approach. Additionally, the practical exercise program incorporates independent work, which includes the preparation of essay followed by their defense in subsequent sessions.

8. Seminar exercises

A single seminar practical is conducted throughout the term.

9. **Information resources. Basic literature. Sites.**

The lecturer has developed electronic versions of the lectures. The Library and Information Center of MU-Plovdiv offers an adequate collection of specialized resources to support students' academic endeavors.

Main literature sources:

1. ***Irini Doichinova, Tsvetanka Zhivkova.*** Pharmacokinetics, Sofia 2012
2. ***Karaivanova M., Danchev N.,*** Pharmacology - textbook for students and postgraduates, Sofia 2010.
3. ***Boyadjieva N., Lambev I.,*** Pharmacology - textbook for medical students, Sofia 2010.
4. ***Boyadjieva N.,*** Pharmacology for Stomatologists, Sofia 2012.
5. ***Krushkov I., Lambev I.,*** Pharmacotherapeutic Guide 2010.
6. Current reference literature and lecture course
7. Applied Clinical Pharmacokinetics, 7th edition. https://accesspharmacy.mhmedical.com/book.aspx?bookID=1374.
8. Clinical Pharmacokinetics and Pharmacodynamics 12 edition: https://accesspharmacy-mhmedical-com.ezproxy.mu-plovdiv.bg/searchresults.aspx?q=pharmacokinetics

9. Pharmaceutical calculations.
10. https://globex.coe.pku.edu.cn/file/upload/201807/05/124636651065.pdf

Access to and utilization of the information resources, as well as the service for the delivery of electronic articles, are provided free of charge to students, PhD candidates, and employees of MU-Plovdiv.

10. Students' assessment

Students have a dynamic and intense workload throughout the semester. Teachers monitor students' progress once per semester through a practice test, a theoretical question, and a clinical case. Information and guidance regarding these assessments are provided to students in advance. The results of these assessments are reviewed in the subsequent class, with feedback offered to support continued preparation. The outcomes of these evaluations contribute to the final grade for the semester.

11. Independent work and academic engagement of the student

The student's independent work is supervised by the lecturer, who provides guidance on both the literary sources and the methods for their acquisition and analysis. Sample tests and self-study questions are incorporated into the curriculum and are accessible online via the MU-Plovdiv website.

12. Collaboration between students and teaching staff

This collaboration entails:

- The tutor's dedication to supporting the student, addressing their prior preparation, current challenges in mastering the material, and providing opportunities for individualized learning programs to facilitate enhanced achievement.
- Utilization of office hours for academic consultations.
- Engagement of students in teams for scientific tasks, research initiatives, projects, and related activities.

13. Exams

The current grades in the pharmacokinetics program are based on the following components: solving multiple-choice questions, a theoretical question, and analyzing a clinical case during the oral examination

14. Assessment Standards

At the onset of the Pharmacokinetics course, the lecturer familiarizes students with the assessment criteria, the procedures for continuous evaluation, and the opportunities for feedback on their academic progress throughout the semester.

Assessment standards for student achievement are established to ensure the objectivity of student evaluations.

The assessment criteria are as follows:

- **Weak (2)**: Insufficient knowledge that does not provide a foundation for subsequent levels of education, including preclinical and clinical disciplines.
- **Average (3)**: Reproduction of knowledge on the pharmacokinetics of drugs in a "ready-made" framework, including absorption, distribution, metabolism, and excretion;

presentation of unsubstantiated solutions to simple problems; lack of ability to independently apply acquired professional competencies; inadequate mastery of terminology; the presentation is marked by poor language proficiency.

- **Good (4)**: Demonstrates descriptive mastery of key and supplementary knowledge on the pharmacokinetics of drugs, including absorption, distribution, metabolism, and excretion; limited independence and basic problem-solving skills, with good language proficiency; however, there are inaccuracies in the concepts used.
- **Very Good (5):** Demonstrates a thorough mastery of pharmacokinetic parameters, including absorption, distribution, metabolism, and excretion for various drug groups. Exhibits independence and creativity in developing new algorithms and analyzing literature data; proficient in solving complex problems. Makes efforts to formulate and justify their hypotheses; appropriately applies concepts from the scientific domain of the discipline studied and demonstrates a strong command of language.
- **Excellent (6):** Exhibits exceptional knowledge of information sources related to the pharmacokinetics of drugs, including absorption, distribution, metabolism, and excretion. Demonstrates comprehensive mastery of both core and supplementary knowledge in pharmacokinetics. Displays independent logical thinking and a correct understanding of the therapeutic use of drugs. Possesses strong skills in applying learned concepts to solve complex problems, with precise and articulate language in the presentation.

15. Formation of the final assessment grade

The final grade reflects the degree to which a student has achieved the learning objectives outlined at the beginning of the course. The semester examination in Pharmacokinetics consists of three components:

- **Initial test**: A 15-minute test, which is considered passed with a minimum of 70% correct answers.
- **Written examination**: A one-hour exam consisting of two questions selected from the syllabus.
- **Oral examination**: Involves solving a clinical case study followed by a discussion of the case.

A student receives a poor mark under the following conditions:

- Withdrawal from the examination.
- Failure to meet the minimum requirements for the test.
- Scoring a poor mark on one or both written questions.
- Failing to successfully resolve the clinical case during the oral examination.

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

The final score is obtained as the sum of the scores on a six-point system of the different components, multiplied by the respective significance factors, namely:

$$Q_{\text{final grade}} = k_1 Q_{\text{grade of the written exam}} + k_2 Q_{\text{grade of the oral exam}} k_3 Q_{\text{grade of current control (through the semester)}}$$

$k_{1 =} 0.33$; $k_{2 =} 0.33$; $k_{3 =} 0.33$.

In case of a failure at the entry test, a poor mark in the written examination, or in the oral examination, the final grade will necessarily be 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 term.

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

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