



## ACADEMIC STANDARD FOR THE DISCIPLINE „BIOPHARMACY”

### 1. Aim

The discipline Biopharmacy is one of the basic fields in the pharmaceutical science, which aims to build on the knowledge gained in Pharmaceutical technology, focusing on all processes and factors which influence the behavior of the drug in the body related to route of administration and type of the dosage form in order to optimize drug bioavailability.

Biopharmacy considers the interaction between the dosage form as a physicochemical system and the living organism as a complex biological macrostructure, mainly by studying the drug kinetics and drug metabolism in the biological environment. The basic concept of biopharmacy is that the therapeutic effect of drugs is determined not only by their specific molecular structure, but also by a number of additional factors (anatomical-physiological and biochemical characteristics of the organism, physicochemical and biopharmaceutical properties of the drug and the dosage form). Pharmacokinetics studies the processes of absorption, distribution and elimination of the drug and the factors that affect the interaction of the drug with the organism.

### 2. Learning

The topics and the hours for lectures and practical exercises are posted on the university website. Learning content is organized chronologically in such a way that each consecutive lection and related practical classes use previously studied topics and terms.

### 3. Prerequisites

The students must have obtained basic knowledge in Mathematics, as well as in „Pharmaceutical technology – part I” and „Pharmaceutical technology – part II” in order to begin and successfully complete the course.

### 4. Academic resources

The academic staff of the discipline includes 1 associate professor and 8 assistant professors – 6 of them holding an educational and scientific degree „Doctor (PhD)“ and 6 of them having a specialization in Pharmaceutical technology with Biopharmacy.

## **5. Material resources**

For the discipline „Biopharmacy” the department has one laboratory equipped with basic equipment – electronic scales, analytical scale, incubator, water bath, electromagnetic stirrers, centrifuge, as well as test apparatus – spectrophotometer UV/VIS, dissolution tester for solid dosage forms, microscope, pH-meter.

All of the necessary substances, glassware and other ancillary materials for the preparation and the control of the studied dosage forms are provided for the laboratory exercises.

## **6. Lecturing**

Lectures are prepared and given in the form of multimedia presentations. Lectures’ content and format are chosen by the leading lecturer.

## **7. Laboratory / practical classes**

Practical classes are held separately for each student group. Each student works individually and prepares the assigned for the particular exercise drug formulations. Tasks may also require working in groups. During the training, examination is carried out, which check student’s self-preparation, knowledge and results (obtained knowledge and skills) of the particular exercise.

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

A list of the main reference literature is presented, with a priority being given to the available resources that are published as "basic literature". Internet resources are also recommended, where appropriate materials for the student's preparation can be found.

### ***Basic literature:***

1. **A. J. Winfield**, R. M. E. Richards. Pharmaceutical Practice, Thitd edition, Churchill Livingtone, Elsevier, 2004.
2. Transport Prozesse in Pharmaceutical Systems, Amidon, 2000.
3. **Grahame Smith D. G.**, J. K. Aronson. Clinical Pharmacology and drug therapy, Third Eddition, Oxford University press, 2005. ISBN: 0 19 850944 8
4. **Dressman Jennifer**. Pharmaceutical Dissolution Testing. Taylor & Francis Group, 2005.
5. **Patrick J. Sinko**. Martins Physical Pharmacy and Pharmaceutical Sciences, Fifth edition, Lippincott William &Wilkins, 2009.

### ***Additional literature:***

6. Encyclopedia of Pharmaceutical technology, Third Edition, James Swarbrick.
7. Pharmaceutikal Process Validation, An International third Eddition, 2011.
8. Pharm. European.
9. **Sarfaraz K. Niazi**. Handbook of Bioequivalence Testing, executive Editor – James Swarbrick, 2011.

10. **Michael E.** Aulton, Aulton's Pharmaceuticals, The design and manufacture of medicines, Third edition, Churchill Livingstone, Elsevier, 2007

11. **Alexander T.** Florence and David Attwood, Physicochemical principles of Pharmacy, Fifth edition, 2011, ISBN 978 0 85369 984 2.

12. **Gilbert S.** Banker, Christopher T. Rhodes, Modern Pharmaceuticals, Forth Edition, Marcel Dekker, Inc. ISBN: 0-8247-0674-9.

13. **Howard C.** Ansel, Loyd V. Allen, Jr., Nicholas G. Popovich, Pharmaceutical dosage forms and delivery systems, Seventh edition, 1999, Lippincott Williams, USA.

14. **Mark Jackson and Andrew Lowey.** Handbook of Extemporaneous Preparation, Pharmaceutical Press, 2011.

### **9. Control assignments**

Students are occupied dynamically and intensively during the semester. It is assumed that the way in which knowledge and skills are acquired is an important factor in their depth, durability and applicability. Ongoing control of the students' progress is performed through tests or control assignments at least twice in the semester. Students are provided with timely information and explanations on the control results (on the next exercise), which assists their further preparation. Up to 3 (three) days after the announcement of the results the student has the right to get acquainted with his work.

### **10. Individual work and commitment of the students**

The individual work of the students must be led by the assistant professors, who have to guide them in the literary sources, and methods for learning, as well.

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

This collaboration consists of:

- The teacher's commitment to the students' preparation on current difficulties in learning the subject and the opportunities with an individual learning program.
- Use of meeting hours for consultations.
- Including students in teams for scientific tasks, research projects, etc.

### **12. Exams**

Ongoing assessments provided on the curriculum of the specialty are given for:

1. Student's results in practical classes, individual tasks, work of the student with the lecturer in scientific research etc.
2. At least two (in the middle and at the end of the semester) written or oral examinations.

### **13. Standards of evaluation:**

The final grade in the discipline „Biopharmacy and pharmacokinetics” is determined on the basis of two main elements:

**The first one** includes the assessment of the student's academic activity throughout the semester. It includes all the assessments from the ongoing control (examinations) and the assessment from the practical exercises and individual assignments, showing the acquired student's.

**The second one** includes the exam grade. The exam regulations are designed to minimize the possibility of manipulating the results.

Clear standards for evaluation are developed for the discipline.

The level of reproduction and use of knowledge by students is defined as information-reproductive, technological-productive, problem-productive, innovative-creative. Based on the above, the standards for evaluation are developed as follows:

**Poor (2)** – for showing scant knowledge and gross errors that cannot be the basis for the next levels of training;

**Satisfactory (3)** – simple reproduction and key knowledge of the subject; not ready for analysis of the knowledge gained; poor language culture with a lot of mistakes;

**Good (4)** – for developed additional knowledge, good knowledge of the subject; but without being able to develop learning to analysis; comparatively good language culture; but with inaccuracies in the use of different concepts and terms;

**Very good (5)** – for well-developed key and additional knowledge, thinking and understanding the subject, good skills to apply the knowledge, adequate use of scientific concepts from the studied field, good language culture.

**Excellent (6)** – for shown individual and logical thinking, additional knowledge and skills, for excellent knowledge of the subject, creativity, interpretation of the concepts, skills to solve complex tasks and right argumentation for the decisions taken, accuracy and rich language culture of the presentation

When starting classes, students should be familiar with the evaluation standards, the procedures for conducting ongoing control, and the opportunities to receive feedback on their progress during the semester.

#### **14. Final grade formation**

##### ***Forms of evaluation:***

Ongoing control – oral examination during the practical exercises, written examinations;

Final control – practical exam and written theoretical exam in controlled electronic environment (semester exam).

##### ***Formation of the final grade:***

The Final Grade (FG) is formed as a result of the the examinations during the semester and the final exam at the end of the semester.

The final grade of the acquired knowledge in the course is rounded to a whole unit and is derived from the equation:

$$FG = 0.2 OG + 0.8 EG$$

where: OG - ongoing grade from the control throughout the semester; and – EG - exam grade (must not be „Poor 2“).

If EG is „Poor 2“, the final grade is „Poor 2“.

The final grade is rounded to a whole unit and is written in the documentation.

#### ***Semester examination:***

The semester exam is written in a test format in a controlled electronic environment (questions related to calculations and graph plotting are submitted on paper) and an oral examination. The written exam includes a test containing MCQs and open theoretical questions, as well as questions related to calculations and graph plotting.

#### ***Aspects of the evaluation:***

The system for controlling the preparation of the students during the semester includes their presence at lectures and practical exercises, questions on the topic of the exercise. At the end of each exercise, the acquired knowledge is monitored and a control is performed by discussing the exercise. The laboratory exercises are performed by the students independently. The grade for each student is formed on the basis of his/her theoretical preparation for the developed exercise and the accomplishment of the assigned tasks. The semester grade is formed through the practical and theoretical exam, carried out in a controlled electronic environment, and oral examination.

### **15. Documentation, result storage and control of the assessment procedure**

- Assessed students have the right and obligation to be informed about the assessment regulation procedures and results, and to make claims and complaints in case of violation of the current rules.
- The students' rights, in accordance with the meaning of the preceding paragraph, are guaranteed provided that technical omissions or errors have occurred (e.g. in the calculation or assessment) or that there are reasons for a vast contrast between the knowledge, skills and competencies the student have actually shown and his/her final grade.
- Corrections of the grades in cases regarding the provisions of the previous paragraph shall be made in the Student Book, the examination report or the account in the General Registry only by the leader of the discipline.
- Potential disagreements and claims on the part of the students should be directed in a written form to the assessment team, whose responsibility is to provide an argued answer by the end of the next working day.

- Revealed and proven cases of serious violation of the rights of the student in terms of assessing his / her knowledge, skills and competences are directed with a written complaint to the Vice-rector for quality and accreditation.

Exam materials are preserved and the students are informed about them. The period during which the students have access to the examination tests and results is up to 3 working days after the examination.

This requirement shall be in accordance with the Higher Education Act Art. 56. par. 1, „The members of the academic board shall be obliged to develop and announce in an appropriate way a description of the provided by them course of lectures, including number, titles and sequence of topics of the curriculum, recommended literature, method of evaluation of the mark and form of checking of knowledge and skills“.

The Academic Standard for the discipline „Biopharmacy” was approved by the Department council with a Protocol № 10/28.10.2025.