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## ACADEMIC STANDARD FOR THE DISCIPLINE „DRUG-DELIVERY SYSTEMS”

### 1. Aim

The main objective of the course "Drug-delivery systems" is for students to acquire knowledge and skills for work in the field of developing new drug-delivery systems. The discipline is based on basic knowledge in pharmaceutical science and expands and deepens knowledge about the development and production of innovative dosage forms, in order to prepare students for experimental scientific work and industrial pharmaceutical activities on the topic. The following topics are covered:

- Characterization of physical properties of solids: solid state analysis, particle size analysis and particle statistics, shape analysis, surface area, mechanical properties.
- Principles of controlled/sustained drug release and absorption formulation: nasal, pulmonary and dermal drug delivery systems and basic physiological aspects of the pharmaceutical forms.
- Formulation, stabilization and lyophilization of protein-targeting drugs and their optimized delivery.

This objective correlates with the university mission and vision; the place of the discipline within the overall curriculum in terms of discipline's importance and timing in the curriculum.

### 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.

The program of the lectures and the seminars includes the following topics:

- Concept and models of drug delivery systems.
- Alternative routes of drug administration.
- Targeted drug-delivery systems.
- Protein/peptide-delivery systems.
- Biotechnologies in drug-delivery systems. Vaccines.
- New trends in personalized medicine.

In the exercises, delivery systems based on particle design are developed and characterized.

### **3. Prerequisites**

The students must have obtained basic knowledge in Inorganic chemistry, Organic chemistry, Analytical chemistry, Physicochemistry and Pharmaceutical technology in order to begin and successfully complete the Drug-delivery systems course.

### **4. Academic resources**

The academic staff of the discipline includes 1 professor and 2 (chief) assistant professors – 3 of them holding an educational and scientific degree „Doctor (PhD)“ and a specialization in Pharmaceutical technology with Biopharmacy.

### **5. Material resources**

For the discipline „Drug-delivery systems“ the department has scientific laboratories equipped with basic equipment – electronic and analytical scales, dryers, electromagnetic stirrers, laboratory centrifuge, distiller, ultrapure water system, laminar flow and testing equipment - pH-meter, spectrophotometer UV/VIS, apparatus 4 (PhEur) type flow cell. To conduct the laboratory exercises, the necessary substances, glassware and other auxiliary materials for the preparation of drug-delivery systems and their analysis are provided.

### **6. Lectures**

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

### **7. Practical classes**

Practical classes are held with student groups. Methodological guidelines are provided for every particular practical task within an exercise. Students prepare the assigned for the particular exercise drug-delivery systems. 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. Internet resources are also recommended, where appropriate materials for the student's preparation can be found.

1. *European Pharmacopoeia*
2. *Applied Physical Pharmacy, Third Edition*, Mansoor Amiji, Thomas Cook, Cary Mobley, McGraw Hill
3. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*, Editors: Kevin Taylor Michael Aulton, Elsevier

4. *Pharmaceutical Dosage Forms and Drug Delivery: Revised and Expanded; 3rd Edition*, Ram I. Mahato, Ajit S. Narang, CRC Press
5. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*, Loyd Allen, Wolters Kluwer
6. *Pharmaceutical Compounding and Dispensing Second edition*, John Marriott, Keith Wilson, Christopher Langley, Dawn Belcher, Pharmaceutical press
7. *Handbook of Extemporaneous Preparation First edition*, Mark Jackson, Andrew Lowey, Pharmaceutical press
8. *The Art, Science, and Technology of Pharmaceutical Compounding 5th Edition*, Loyd Allen, American Pharmacists Association
9. *Applied Biopharmaceutics & Pharmacokinetics*, Leon Shargel, McGraw Hill
10. *Pharmaceutics – Drug Delivery and Targeting 2E*, Perrie & Rades, Pharmaceutical press
11. *Basic Statistics and Pharmaceutical Statistical Applications 3rd Edition*, James E. De Muth, CRC Press
12. *Pharmaceutical Calculations, 15th Edition*, Howard Ansel; Shelly Stockton, Wolters Kluwer
13. *Cosmetic Formulation: Principles and Practice 1st Edition*, Heather Benson, Michael Roberts, Vania Rodrigues Leite-Silva, Kenneth Walters, CRC Press
14. *Martin's Physical Pharmacy and Pharmaceutical Sciences Seventh Edition*, Patrick J. Sinko, LWW
15. *Modern Pharmaceutics, Two Volume Set 5th Edition*, Alexander Florence, Juergen Siepmann, CRC Press
16. *Physicochemical Principles of Pharmacy: In Manufacture, Formulation and Clinical Use 6th edition*, Alexander Florence; David Attwood, Pharmaceutical Press
17. *Essentials of Biopharmaceutics and Pharmacokinetics, 2/e*, Ashutosh Kar, CBS Publishers & Distributors
18. *Handbook of Pharmaceutical Excipients 8th Revised edition*, Edited by Paul Sheskey, Walter Cook, Colin G. Cable, Pharmaceutical Press
19. *Access Pharmacy*, <https://accesspharmacy.mhmedical.com/>

## 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 oral examination.

## 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 student's results in practical classes, individual tasks, work of the student with the lecturer in scientific research etc.

## 13. Standards of evaluation:

The final grade in the discipline „Drug-delivery systems” 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 – oral examinations and the full and high-quality completion of the forms of independent work provided in the curriculum of the discipline.

**The second one** includes the theoretical 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;

Final control – preparing and providing a presentation on a topic from the syllabus and oral discussion (semester exam).

### ***Formation of a final grade:***

A final grade is formed as a result of the the examination during the semester and the final exam at the end of the semester.

The Final Grade (FG) 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 examination includes preparing and providing a presentation on a topic from the syllabus and oral discussion.

### ***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 practical exercises are performed by the students independently or in a team. 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 based on the preparation and providing a presentation on a topic from the syllabus and oral discussion.

## **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 „Technology of medical cosmetics” was approved by the Department council with a Protocol № 10/28.10.2025.