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## ACADEMIC STANDARD

### FOR THE DISCIPLINE „PHARMACEUTICAL TECHNOLOGY – PART II”

#### 1. Aim

The primary objective of education in the discipline „Pharmaceutical technology – part II” is to study the theoretical foundations and practical methods for the preparation of drug formulations. Drugs which are used in the pharmaceutical practice are chemically defined compounds or products of plant or animal origin. Processing these drugs into formulations involves suitable pharmaceutical operations that are determined by their physical-chemical and pharmacological properties. It is the right choice of working conditions and the proper route of administration of the formulation that allow the underlying purpose of pharmaceutical technology to be accomplished – the production of quality drug formulations with appropriate biopharmaceutical properties, which ensure maximum effectiveness of the therapy.

This objective correlates with the university mission and vision; discipline’s contents and credit rating (according to ECTS); qualification characteristics of the speciality; academic degree (master); 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.

#### 3. Prerequisites

The students must have obtained basic knowledge in Inorganic chemistry, Organic chemistry, Analytical chemistry, Physicochemistry and Mathematics, as well as in Pharmaceutical technology – part I in order to begin and successfully complete the Pharmaceutical technology course.

#### 4. Academic resources

The academic staff of the discipline includes 1 professor, 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 „Pharmaceutical technology – part II” the department has three laboratories equipped with basic equipment – electronic scales, dryers, water baths, electromagnetic stirrers, distiller, laminar flow, rotary-vacuum evaporators, spray-dryer, tablet machine, fume cupboard, granulator, tablet coater, capsule filler, as well as test apparatus - sieve analysis, spectrophotometer UV/VIS, dissolution tester for solid dosage forms, tapped density apparatus, friabilator, tablet hardness tester, disintegration tester for solid dosage forms, moisture content analyzer, 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. Protocol notebooks are provided for the practical exercises. 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*, Third edition, Churchill Livingstone, Elsevier, 2004
2. **Michael E. Aulton**, *Aulton’s Pharmaceutics, The design and manufacture of medicines*, Third edition, Churchill Livingstone, Elsevier, 2007
3. **Alexander T. Florence**. David Attwood, *Physicochemical principles of Pharmacy*, Fifth edition, 2011, ISBN 978 0 85369 984 2
4. **Gilbert S. Banker**, Christopher T. Rhodes, *Modern Pharmaceutics*, Fourth Edition, Marcel Dekker Inc, ISBN :0 – 8247-0674-9

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

6. **D. G. Grahame-Smith**, J. K. Aronson, Clinical pharmacology and drug therapy, Third edition, Oxford University press, ISBN 0 19 850944 8

7. **Patrick J. Sinko**. Martin's Physical Pharmacy and pharmaceutical Sciences, Fifth Edition, 2006

*Additional literature:*

8. Handbook of Extemporaneous Preparation, Mark Jackson, Andrew Lowey, 2011, Pharmaceutical Press

9. Martin Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences Category: Chemistry Publisher: Lippincott Williams & Wilkins; 4 Sub edition

10. **Volker Buhler**. Kollicoat grades, BASF, Ludwigshafen, Germany, 2007.

11. Pharm. European VII edition, 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 „Pharmaceutical technology – part II” is determined on the basis of two main elements:

**The first one** includes the assessment of the student's academic activity throughout the semester (no more than 30%). It includes all the assessments from the ongoing control (examinations) and the assessment from the practical examination, showing the acquired student's skills to prepare drug formulations.

**The second one** includes the exam grade (no more than 70%). 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 a final grade:***

A final grade 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 (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 (must not be „Poor 2“); and – EG - exam grade (must not be „Poor 2“).

If OG and/or 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 includes practical and written theoretical exam, and oral examination.

The written examination includes a test with MCQs and open answer questions.

##### ***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. A protocol is prepared for each exercise. Students defend the protocols in front of the tutor conducting the exercise. 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.“.

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