Study program: Integrated Academic Studies in Pharmacy

Course title: Pharmaceutical Technology I

Teacher: Mladena N. Lalić-Popović, Zoran P. Zeković

Course status: compulsory

ECTS Credits: 7

Condition: Physical chemistry, Pharmaceutical chemistry III, General pharmacology

Course aim

To acquaint with the formulation development procedures in the pharmacy or pharmaceutical industry. To acquaint with the characteristics of the active pharmaceutical substance and excipients that are of importance for the quality, safety and efficacy of the pharmaceutical dosage form. To acquaint with the aspects of formulation development, compounding/manufacturing and pharmaceutical-technological testing of solid pharmaceutical forms (powders, tablets, capsules and suppositories), inhalation preparations (inhalation powders) and therapeutic systems.

Expected outcome of the course:

Pharmacy students will acquire knowledge and skills on the way of development and compounding/manufacturing of pharmaceutical-technological formulations of solid forms, inhalation preparations and therapeutic systems, the way of testing their quality, the proper way of packaging, signaling and storage.

Course description

Theoretical education

1. Preformulation testing of active pharmaceutical ingredients and excipients. General principles of drug formulation development
2. Properties of powdered substances. Characterization of powders. Compounding/manufacturing and pharmaceutical-technological testing of powders
3. Types and properties of excipients in formulations of powders and granules. Co-processing of excipients. Specific requirements for the pediatric population. Interactions of excipients and active pharmaceutical ingredients
4. Powders as pharmaceutical dosage forms
5. Granules and pellets
6. Capsules: Types, formulation development and pharmaceutical-technological testing
7. Tablets: Characteristics of the manufacturing process. Regulatory requirements in manufacturing. Quality by design (QbD) concept
8. Tablets: Coating and coating materials
9. Tablets: Types and characteristics of tablets, pharmaceutical-technological testing
10. Modified-release dosage forms
11. Pharmaceutical technology of rectal and vaginal preparations
12. Suppositories: definition and general terms
13. Suppositories: composition, formulation development and compounding /manufacturing methods
14. Suppositories: pharmaceutical-technological testing
15. Pharmaceutical technology of inhalation preparations
16. Therapeutic systems
17. Micro and nano drug carriers
18. Medicines packing: Types, packaging materials, pharmaceutical form requirements

Practical education

1. The role and parts of pharmacy and the professional literature and regulations that are important for magistral and galenic compounding of pharmaceutical-technologica formulations.
2. Powders as Master Medicines: Prescribing and Interpreting Medical and Veterinary Medicinal Products
3. Unallocated and divided powders (Conspergentia, Pulveres ad usum dermicum, Dosipulveres and Pulveres peroralia): formulation and pharmaceutical testing
4. Triturationes and trituration as a technique for making split powders for children: examples from pharmaceutical practice. Drug Risk Assessment.
5. Tablets and capsules (Compressi et Capsulae): Introduction

6. Filling hard gelatin capsules. Content uniformity testing
7. Tablet formulation: Characterization of powders and granulations
8. Tablet formulation: tableting, excipients in tablets
9. Tablet formulation: physicochemical characteristics of the active pharmaceutical ingredient and testing of the rate of dissolution of the drug from solid drug preparations (Dissolution test for solid dosage forms)
10. Rectal and Vaginal Preparations (Rectalia et Vaginalia): Introduction
11. Suppositories as main forms of medicine: prescribing and interpreting prescriptions
12. Laboratory determination of factors relevant to the suppository formulation: calibration value of the mold and extrusion factor of the drug substance. Suppository breakdown testing
13. Production of suppositories for rectal administration and solid-fat vagitory as substrate
14. Production of suppositories for rectal administration and vaginatorium with glycerol-gelatin substrate
15. Production of suppositories for rectal administration and vagitarias with macrogol substrates

Literature

Compulsory

1. European Pharmacopoeia. 10th ed. Strasbourg: European Directorate for the Quality of Medicines & Healthcare (EDQM), Council of Europe; 2020.
2. Fahr A. Voigt´s Pharmaceutical Technology. Scherphof G, translator. Hoboken, NJ: Wiley; 2018.
3. Aulton M, editor. Aulton´s Pharmaceutics – The Design and Manufacure od Medicines. 4th ed. Philadelphia: Elsevier; 2013.
4. Allen L, editor. Remington: The Science and Practice of Pharmacy. 22nd ed. London: Pharmaceutical Press; 2012.

Additional

1. Swarbrick J, Boylan JC. Encyclopedia of Pharmaceutical Technology. New York, Basel: Marcel Dekker Inc; 2007.
2. Allen L, Popovich N, Ansel H, editors. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems. 9th ed. Philadelphia: Lippincott Williams & Wilkins; 2010.
3. Cormmelin A, Lipper R, editors. Pediatric Formulations – A Roadmap. Aapspress, Springer; 2014.
4. Resolution CM/Res(2016)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients. Committee of ministers Councile of Europe; 2016.

Number of active classes	**Theoretical classes:** 45	**Practical classes:** 60

Teaching methods: oral lectures, interactive classes, practical classes, laboratory work

Student activity assessment (maximally 100 points)

Pre-exam activities	**points**	**Final exam**	**points**
Lectures	10	Written	50
Practices	10		
Colloquium	30		
Essay			