COURSE DESCRIPTION

Academic year: 2026/2027

University: Comenius University Bratislava

Faculty: Faculty of Pharmacy

Course ID:	**Course title:**
FaF.KFCh/01-Mgr-A/24	Drug Analysis

Educational activities:
Type of activities: lecture / laboratory practicals
Number of hours:
per week: 4 / 3 **per level/semester:** 56 / 42
Form of the course: on-site learning

Number of credits: 8

Recommended semester: 7.

Educational level: I.II.

Prerequisites:

Recommended prerequisites:
KFCH/05-Mgr-A/00 Pharmaceutical Chemistry (1); KFCH/06-Mgr-A/20 Pharmaceutical Chemistry (2); KFANF/01-Mgr-A/19 Analytical Chemistry (1); KFANF/02-Mgr-A/20 Analytical Chemistry (2).

Course requirements:
Participation in all compulsory forms of teaching, elaboration of protocols from laboratory practicals and completion of two written preliminary tests, each with a minimum success rate of 60 %. Completion of the written final examination test with a minimum success rate of 60 %. The content of all lectures and laboratory practicals will be included in the final examination test.
Classification grades: (A) 100 – 92 %, (B) 91 – 84 %, (C) 83 – 76 %, (D) 75 – 68 %, (E) 67 – 60 %, (FX) less than 60 %.
Scale of assessment (preliminary/final): 20/80.

Learning outcomes:
The aim of the course Drug Analysis is to teach students the basic principles of methods and tests used in the complex quality control of drugs, excipients and medicines in order to ensure their quality, safety and efficacy. The content of the course is based on the requirements of currently valid European Pharmacopoeia for the identification of drugs, evaluation of drug purity and determination of drug content. Students will get acquainted with the pharmacopoeial analysis of drugs using chemical, volumetric, gravimetric, chromatographic, spectral and electroanalytical methods. Theoretical knowledge is applied in laboratory practicals, where students experimentally perform drug quality control. When working with the European Pharmacopoeia, students learn to orientate quickly and with understanding in a wide range of pharmacopoeial procedures and statements.
The knowledges and skills acquired in course Drug Analysis can be then applied in practice in public and hospital pharmacies, in control laboratories, in state regulatory authorities for drug control, in pharmaceutical production and research, and in further postgraduate education of pharmacists.

Class syllabus:

– Content, mission and importance of Drug Analysis; The European Pharmacopoeia; The European Directorate for the Quality of Medicines & HealthCare.
– Qualitative analysis: Identification reactions of ions and functional groups; Specific identification reactions of drugs; Physical and physicochemical methods.
– Purity of drugs and its control: Limit tests for inorganic impurities; Physical and physicochemical methods.
– Quantitative analysis: Gravimetry; Titrimetric methods; Physical and physicochemical methods.
– Quality control of the final pharmaceutical products.
– Quality control of containers and materials used for the manufacture of containers.
– Stability of drugs and medicines.
– Validation in pharmaceutical analysis. Good manufacturing practice. Pharmaceutical analysis in registration of medicinal products. Safety data sheet.

List of concerned general chapters in the European Pharmacopoeia:
1. General notices
2. Methods of analysis
2.2. Physical and physico-chemical methods: 2.2.1. Clarity and degree of opalescence of liquids; 2.2.2. Degree of coloration of liquids; 2.2.3. Potentiometric determination of pH; 2.2.4. Approximate pH of solutions; 2.2.5. Relative density; 2.2.6. Refractive index; 2.2.7. Optical rotation; 2.2.8. Viscosity; 2.2.9. Capillary viscometer method; 2.2.10. Viscosity – rotating viscometer method; 2.2.11. Distillation range; 2.2.12. Boiling point; 2.2.13. Determination of water by distillation; 2.2.14. Melting point – capillary method; 2.2.15. Melting point – open capillary method; 2.2.16. Melting point – instantaneous method; 2.2.17. Drop point; 2.2.18. Freezing point; 2.2.19. Amperometric titration; 2.2.20. Potentiometric titration; 2.2.21. Fluorimetry; 2.2.22. Atomic emission spectrometry; 2.2.23. Atomic absorption spectrometry; 2.2.24. Absorption spectrophotometry, infrared; 2.2.25. Absorption spectrophotometry, ultraviolet and visible; 2.2.26. Paper chromatography; 2.2.27. Thin-layer chromatography; 2.2.28. Gas chromatography; 2.2.29. Liquid chromatography; 2.2.30. Size-exclusion chromatography; 2.2.31. Electrophoresis; 2.2.32. Loss on drying; 2.2.38. Conductivity; 2.2.46. Chromatographic separation techniques; 2.2.47. Capillary electrophoresis; 2.2.49. Falling ball and automatic rolling ball viscometer methods; 2.2.54. Isoelectric focusing
2.3. Identification: 2.3.1. Identification reactions of ions and functional groups
2.4. Limit tests: 2.4.1. Ammonium; 2.4.2. Arsenic; 2.4.3. Calcium; 2.4.4. Chlorides; 2.4.5. Fluorides; 2.4.6. Magnesium; 2.4.7. Magnesium and alkaline-earth metals; 2.4.8. Heavy metals; 2.4.9. Iron; 2.4.10. Lead in sugars; 2.4.11. Phosphates; 2.4.12. Potassium; 2.4.13. Sulfates; 2.4.14. Sulfated ash; 2.4.17. Aluminium; 2.4.19. Alkaline impurities in fatty oils
2.5. Assays: 2.5.1. Acid value; 2.5.2. Ester value; 2.5.3. Hydroxyl value; 2.5.4. Iodine value; 2.5.5. Peroxide value; 2.5.6. Saponification value; 2.5.8. Determination of primary aromatic amino-nitrogen; 2.5.11. Complexometric titrations; 2.5.12. Water: semi-micro determination
3. Materials for containers and containers
4. Reagents
4.1. Reagents, standard solutions, buffer solutions: 4.1.1. Reagents; 4.1.2. Standard solutions for limit tests; 4.1.3. Buffer solutions
4.2. Volumetric analysis: 4.2.1. Primary standards for volumetric solutions; 4.2.2. Volumetric solutions
5. General texts
5.5. Alcoholimetric tables

Recommended literature:

– The European Pharmacopoeia. Current Edition and Supplements. Strasbourg: Council of Europe.
– Hansen, S., Pedersen-Bjergaard, S., Rasmussen, K.: Introduction to Pharmaceutical Chemical Analysis. Chichester: John Wiley & Sons, 2012.
– Kapustíková, I.: Drug Analysis, Laboratory Practicals. Bratislava: Comenius University in Bratislava, 2020.
– Kar, A.: Pharmaceutical Drug Analysis. New Delhi: New Age International, 2005.
– Pedersen, O.: Pharmaceutical Chemical Analysis. Methods for Identification and Limit Tests. New York: CRC Press, Taylor & Francis Group, 2006.
– Rouessac, F., Rouessac, A.: Chemical Analysis. Modern Instrumentation Methods and Techniques. 2nd Ed. Chichester: John Wiley & Sons, 2007.
– Watson, D. G.: Pharmaceutical Analysis. A Textbook for Pharmacy Students and Pharmaceutical Chemists. 4th Ed. Edinburgh: Elsevier, 2017.

Languages necessary to complete the course:
English language.

Notes:

Past grade distribution
Total number of evaluated students: 23

A	ABS	B	C	D	E	FX
34,78	0,0	21,74	17,39	13,04	13,04	0,0

Lecturers: PharmDr. Iva Kapustíková, PhD., doc. PharmDr. Katarína Maráková, PhD., PharmDr. Mária Bodnár Mikulová, PhD.

Last change: 09.05.2024

Approved by: PharmDr. Iva Kapustíková, PhD.