UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
IMPH-321	Pharmaceutical Analysis and Quality Control II/ Φαρμακευτική Ανάλυση και Έλεγχος Ποιότητας ΙΙ	6
Prerequisites	**Department**	**Semester**
IMPH-108	Health Sciences	Fall/Spring
Type of Course	**Field**	**Language of Instruction**
Compulsory	Pharmacy	Greek/English
Level of Course	**Lecturer(s)**	**Year of Study**
1st Cycle	Dr Hapeshi Evroula/Dr Magda Psychoudaki	3rd
Mode of Delivery	**Work Placement**	**Corequisites**
Face-to-Face	N/A	N/A

Course Objectives:

The main objectives of the course are to:

- The study and understanding of the basic principles that govern pharmaceutical analysis and quality control of final pharmaceutical products as well as active ingredients and excipients
- To provide students with knowledge on the usage and applications of contemporary analytical techniques employed in pharmaceutical analysis and quality control, especially for separation techniques that can be used in quantitative and qualitative analysis of active ingredients and impurities such as High-Performance Liquid Chromatography (HPLC), Gas Chromatography (GC), as well as mass spectrometry (MS) and its conjugation with other separation analytical techniques
- To familiarize students with the methods used for the analysis and quality control of various active ingredients and pharmaceutical products
- To explain the process of experimental results elaboration for determining the appropriateness of the analytical method used in quality control
- To demonstrate to students how to use the pharmacopoeia for the analysis of pharmaceutical active ingredients and impurities (identification, quantitative analysis, Case study)
- To describe to students how to perform statistical processing and evaluation of the acquired results

- To familiarize students with performing various analytical methods in pharmaceutic analysis and quality control
- To provide students with knowledge on the usage and applications of the Green Pharmaceutical analysis employed in pharmaceutical industry (innovation to the Pharmaceutical Analysis)

Learning Outcomes:

After completion of the course students are expected to be able to:

- Understand the theory and application of pharmaceutical quantitative and qualitative analysis with the use of chromatographic techniques such as HPLC and GC
- Explain the combination of various techniques (chromatographic, spectroscopic, spectrometric) for the identification, content determination (quantification) and content uniformity evaluation of pharmaceutical preparations
- Describe the process of detecting and determining active pharmaceutical ingredients and their metabolites through the use of the above-mentioned techniques
- Select the appropriate procedures used to separate active pharmaceutical ingredients
- Explain how to develop and optimize a new analytical protocol for drug analysis
- Identify active pharmaceutical ingredients by correlating spectrum characteristics with structural characteristics, when using various spectroscopic techniques
- Recognize which technique to use for purity assessment of active ingredients or pharmaceutical products (i.e. identify the presence of impurities), interpret the results obtained and determine the source of detected impurities
- Discuss basic principles related to pharmaceutical analysis and quality control
- Select the appropriate analytical technique for the identification and / or quantification of active ingredients in pharmaceutical products such as synthetic and physical pharmaceuticals
- Understand the effect of various parameters in the quality control of pharmaceutical products
- Examine the reliability of various techniques, including statistical processing
- Explain how to develop and optimize an analytical method based on Green Chemistry for drug analysis at pharmaceutical industry

Course Content:

- Separation / chromatographic techniques (performance of various chromatographic techniques, theoretical plate theory, classification of chromatographic techniques, parameters that affect the separation ability of each technique, performance evaluation)
- Chromatographic terms (retention factor, selectivity, separation efficiency, number of theoretical plates, distribution coefficient, correlation between the number and height of theoretical plates)

- Gas chromatography (theory, operation, differences with liquid chromatography, types of columns used, advantages and disadvantages)
- Liquid chromatography (classification of various chromatographic techniques, advantages and disadvantages in pharmaceutical analysis)
- Thin layer chromatograph (TLC)
- High-performance liquid chromatography (HPLC) (theory and operation, column types, parameters affecting column selection, detectors used, advantages and disadvantages in pharmaceutical analysis, applications, protocol development and study of the chromatographic parameters)
- Mass spectrometry (basic principles, fragmentation methods, advantages and disadvantages, applications)
- Chromatographic techniques coupled with mass spectrometry (new trends and developments)
- Criteria for the selection of the appropriate analytical technique for quantification and identification of active ingredients
- Active ingredient extraction techniques (Solid Phase Extraction, SPE)
- Quality control of pharmaceutical products (raw materials and final product, specifications, acceptance criteria)
- Study of case study
- Introduction to Green Chemistry/Green Pharmaceutical analysis (application on the pharmaceutical industry)

Indicative Lab Exercises

Exercise 1: Usage of Gas Chromatography for analysing compounds with different polarity and different boiling point

Exercise 2: Usage of Gas Chromatography for quantitative analysis of different volatile compounds with both an internal standard method and a calibration curve

Exercise 3: Analysis of three different active pharmaceutical ingredients belonging to the class of b-blockers (e.g. atenolol, propranolol and metoprolol) using High-Performance Liquid Chromatography (HPLC)

Exercise 4: Ibuprofen stability testing

Exercise 5: Analysis of a mixture of different active ingredients (e.g. paracetamol, caffeine, trimethoprim, sulfamethoxazole) with HPLC

Exercise 6: Quantification of propranolol hydrochloride in tablets using HPLC and UV-Vis – Comparison of results obtained with the two analytical different techniques

Exercise 7: Quantification of trimethoprim in sulfamethoxazole-trimethoprim tablets - Comparison of results obtained with the two different techniques, i.e. HPLC and UV-Vis

Assignment (Laboratory Exercise): Case study of the analysis of pharmaceuticals based on pharmacopoeia (identification, quantification, content uniformity, impurities).

Learning Activities and Teaching Methods:

Lectures, class discussion, assignments, laboratory exercises, presentation of the case study

Assessment Methods:

Final exam, Midterm exam, Lab reports, assignment (case study), presentation of case study, presentation of the application of the Green Pharmaceutical analysis

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
Φαρμακευτική Ανάλυση	D.G. Watson	Επιστημονικές Εκδόσεις ΠΑΡΙΣΙΑΝΟΥ Α.Ε	2011	978-960-394-722-6
Αρχές Ενόργανης Ανάλυσης, μετάφραση 6ης έκδοσης	D. A. Skoog, F. James Holler, T. A. Nieman, M. I. Καραγιάννης, K. H. Ευσταθίου	Εκδόσεις Κωσταράκη	2014	978-0-495-01201-6
Handbook of Modern Pharmaceutical Analysis, 1st edition	S. Ahuja, St. Scypinski	Elsevier	2001	978-0-12-045555-3
Μέθοδοι Ελέγχου Φαρμάκων	Μανόλης Γεωργαράκης	Εκδόσεις Πήγασος	2009	960-317-004-6
Practical Pharmaceutical Analysis	A. H. Beckett, J. B. Stenlake, D. Wilson	Continuum International Publishing Group, Limited	2001	

Challenges in Green Analytical Chemistry: Edition 2	Salvador Garrigues, Miguel de la Guardia	Royal Society of Chemistry	2020	978-1-78801-537-0