UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
IMPH-320	Pharmaceutical Analysis and Quality Control I/ Φαρμακευτική Ανάλυση και Έλεγχος Ποιότητας Ι	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 pharmaceutical analysis and quality control performed in active pharmaceutical ingredients, excipients and final products are of utmost importance for assuring the effectiveness and safety of pharmaceutical products. A number of different methods are being used for testing the identity and purity of active ingredients and excipients, the content of active ingredients, and the stability of pharmaceutical products. These methods can also be used for the determination of the effectiveness and safety of packaging materials used for pharmaceutical products (protection from air, light, humidity, contamination by packaging materials), and the analysis of biological fluids in Clinical Pharmacy and Toxicology applications.

The objectives of this course are to familiarize the students with the basic terms and principles of pharmaceutical analysis and quality control, as well as the most commonly used analytical methods, especially for the elucidation of the drug's structure (identification), purity and drug content quantification. Moreover, the course aims to explain the criteria used for the selection of the appropriate analytical method based on the drug's structure and type of pharmaceutical product, to describe how to correctly interpret the results produced (including analytical method reliability assessment and validation, as well as statistical analysis of results), and to demonstrate the significance of paying special attention in the analysis of pharmaceutical products containing bioactive compounds with narrow safety margin (e.g., lithium or diphenylhydantoin). Amongst the various analytical methods discussed in this course are volumetric techniques, UV-Vis spectroscopy, IR spectroscopy, atomic absorption spectrometry, NMR, etc.

Learning Outcomes:

After completion of the course students are expected to:

- Understand the basic concepts of both qualitative and quantitative analysis of pharmaceutical products
- Understand the theory and applications of the most commonly used methods of pharmaceutical analysis (quality control analytical methods, UV/VIS, IR, etc.)
- Explain the basic principles and selection criteria for methods used in the identification and quantification of drugs and drug metabolites
- Select the appropriate analytical method for structure analysis of active pharmaceutical ingredients and quality control of pharmaceutical products
- Describe the correlation between the chemical structure of a drug and the characteristics of a spectrum obtained by various techniques, such as NMR, for drug identification purposes
- Identify and describe the various methods used for assessing the purity of a drug (i.e. determining the presence of impurities), as well as for drug content quantification and assessment of drug content uniformity
- Describe the methods used for pharmaceutical product stability assessment
- Recognize the reliability and appropriateness of methods used in pharmaceutical analysis and quality control
- Interpret results acquired from pharmaceutical analysis (error calculation, statistical analysis) and present the information obtained through these results for decision making activities
- Explain the development process of analytical protocols for the qualitative and quantitative analysis of pharmaceuticals
- Describe the use of Pharmacopoeia in pharmaceutical analysis and quality control

Course Content:

- Introduction to pharmaceutical analysis and quality control (errors in analysis, statistical analysis, accuracy and reliability, reporting of results etc.)
- Methods used in drug identification (physical constants, physicochemical constants, reactions for the identification of organic and inorganic active ingredients)
- Methods used in determining the purity of pharmaceutical products including drug impurity profiling
- Quantification of active pharmaceutical ingredients in pharmaceutical products
- Methods used for the determination of content uniformity in pharmaceutical products
- Volumetric methods (applications of volumetric methods in pharmaceutical analysis, acid/base titrations, weak acid and base titrations, redox titrations, complexometric titrations, etc.)
- Spectroscopic methods (UV-Vis spectroscopy, IR spectroscopy, Atomic Absorption Spectroscopy, molecular emission spectroscopy, NMR spectroscopy, etc.)

Indicative Lab exercises
Exercise 1: Quantification of propranolol hydrochloride in tablets
Exercise 2: Quantification of trimethoprim in tablets of trimethoprim- sulfamethoxazole
Exercise 3: Ascorbic acid titration with iodine solution
Exercise 4: Ibuprofen titration with NaOH 0.1 M using phenolphthalein as an indicator
Exercise 5: Spectrophotometric determination of acetylsalicylic acid and determination of the same active ingredient with a titration method – comparison and evaluation of the two methods used
Exercise 6: Identification of trimethoprim, propranolol and paracetamol with IR spectroscopy / Identification of unknown active ingredients with IR spectroscopy

Learning Activities and Teaching Methods:

Lectures, class discussion, assignments, laboratory exercises

Assessment Methods:

Final exam, Midterm exam, Lab reports

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	