UNIVERSITY OF NICOSIA
ΠΑΝΕΠΙΣΤΗΜΙΟ ΛΕΥΚΩΣΙΑΣ

Course Code	**Course Title**	**Credits (ECTS)**
PHAR-321	Pharmaceutical Analysis, and QC II/ Φαρμακευτική Ανάλυση, και Έλεγχος Ποιότητας ΙΙ	5
Department	**Semester**	**Prerequisites**
Life & Health Sciences	Spring	PHAR-220
Type of Course	**Field**	**Language of Instruction**
Required	Pharmacy	Greek/English
Level of Course	**Year of Study**	**Lecturer**
1st Cycle	3rd year	Evroulla Hapeshi
Mode of Delivery	**Work Placement**	**Co-requisites**
face-to-face	N/A	None

Objectives of the Course:

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The quality control of pharmaceuticals has become of the utmost importance and therefore advances in analytical techniques have somewhat driven the development of analytical techniques.

Pharmaceutical analysis covers aspects of the theory and application of the most common analytical methods used in the elucidation of the structure of simple molecules which are directly applicable to pharmaceutical drug analysis.

The aim of this course is to pass to the students the knowledge and analytical techniques applied to drug quality control. They will study application of techniques such as Atomic Absorption, spectroscopic and chromatographic techniques like NMR spectroscopy, protein x-ray crystallography, mass spectrometry, CD spectroscopy, Atomic Absorption, and chromatographic techniques, GLC, HPLC and HPLC-MS, and computational methods to drug analysis. Furthermore, purity and stability control, determination of active materials, excipients and additives should be studied. Statistical processing of results, study of the reliability of the applied methods and evaluation of results obtained by various methods and validation of chromatogram quality are aims, too. Knowledge of methods described in Pharmacopoeia.

Application of the mentioned methods in the analysis of pharmaceutical formulations and biological fluids, efficiency of packaging material for pharmaceutical products (protection from air, light, humidity) and contamination of the products by the packaging materials are also aims of this course.

Another aim is to teach the students the special care and attention that should be given to the analysis of bioactive compounds with narrow safety margin and pharmaceutical products containing them.

Knowledge of methods described in Pharmacopoeia.

Learning Outcomes:

After completion of the course students are expected to:

- Apply various analytical techniques to drug analysis and control, e.g. spectroscopic, chromatographic, etc;
- Apply various analytical methods assessing the purity of formulations;
- Assess stability of pharmaceutical products, active ingredients, excipients and compounds like preservatives, taste and smell improving agents;
- Examine the reliability of various techniques in Pharmaceutical Analysis, including statistical processing;
- Examine the application of analytical methods using biological fluids, so that they can be used in Clinical Pharmacy and Toxicology;
- Use the Pharmacopoeia in drug analysis and control;
- Apply techniques for artificial ageing of pharmaceutical products or active materials, and accelerating ageing techniques
- Demonstrate an understanding of the theory and applications of the most common basic methods of pharmaceutical analysis (NMR spectroscopy, protein x-ray crystallography, mass spectrometry, CD spectroscopy, Atomic Absorption, and chromatographic techniques, GLC, HPLC and HPLC-MS, and computational methods to drug analysis)
- Be able to use GMP guidelines to develop processes, procedures, training and documentation to produce pharmaceuticals of appropriate quality and quality assure them.
- Be aware of how manufacturers should respond to a negative GMP inspection finding or a substandard/defective product including product rejection and recall.
- Use pharmaceutical analysis techniques to identify simple organic and pharmaceutical molecules, through problem solving
- Understand contemporary strategies for the elucidation, evaluation and simulation of three dimensional structures of biomolecules and biomolecule/small molecule complexes
- Take special care and attention for the preparation of drugs containing active ingredients with narrow safety margin.

Course Contents:

Chromatographic theory;
Gas chromatography;
HPLC techniques.
Extraction methods in pharmaceutical analysis.
GMP workshops: GMP workshops will be held that will investigate specific cases of issues of GMP non-compliance in the Pharmaceutical Industry. Cases will be used as examples to understand the application of the GMP code.
Application of modern spectroscopic and analytical techniques to drug design and development.
Introductory aspects of structural determination of biomolecules of relevance in drug development including the use of X-ray crystallography, NMR spectroscopy, surface plasmon resonance spectroscopy, and mass spectrometry, gas chromatrography. Application and relevance of these techniques to the elucidation of biomolecular structure and drug discovery.

Indicative Lab Exercises

Exercise 1: Two-dimensional thin layer chromatography for mixtures which cannot be easily separated;
Exercises 2-3: Combination of chromatographic and spectrophotometric techniques for the determination of the constituents of a pharmaceutical product (HPLC);
Exercise 4: Acceleration of ageing of a product by heat or radiation;
Exercise 5: Detection of the products of an aged pharmaceutical product (TLC, GLC, HPLC, UV-vis);
Exercise 6: Study and application of a determination of the European Pharmacopoeia

Learning Activities and Teaching Methods:

Lectures, class discussion, assignments, laboratory

Assessment Methods:

Course work, final exam

Required Textbooks/Reading:

Authors	Title	Publisher	Year	ISBN
H.J. Roth, R. Troschutz, K. Eger, Ellis Horwood	Pharmaceutical Chemistry: Drug Analysis			
D.G. WATSON	Φαρμακευτική Ανάλυση	Επιστημονικές Εκδόσεις ΠΑΡΙΣΙΑΝΟΥ Α.Ε		

Recommended Textbooks/Reading:

Authors	Title	Publisher	Year	ISBN
A. H. Beckett, J. B. Stenlake, D. Wilson	Practical Pharmaceutical Analysis	Continuum International Publishing Group, Limited	2001	