UNIVERSITY OF NICOSIA
ΠΑΝΕΠΙΣΤΗΜΙΟ ΛΕΥΚΩΣΙΑΣ

Course Code	**Course Title**	**Credits (ECTS)**
PHAR-320	Pharmaceutical Analysis, and QC/ Φαρμακευτική Ανάλυση, και Έλεγχος Ποιότητας I	5
Department	**Semester**	**Prerequisites**
Life & Health Sciences	Fall	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 TLC, IR, UV-Vis, Raman 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, in the service of Clinical Pharmacy and Toxicology. Chemistry, toxicology and 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, e.g. lithium or diphenylhydantoin

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 (control of quality of analytical methods, UV/VIS, IR)
- 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:

Introduction to Analytical Techniques, errors in Analysis, the role of analytical methods in pharmaceutical industry.

Analysis of drugs in pharmaceutical products covering a wide range of drug formulations e.g. tablets, parenterals and semi-solids. This includes the application of a wide selection of titrimetric, spectroscopic and chromatographic drug assays. Advanced analytical techniques used in pharmaceutical analysis, including fluorescence spectroscopy IR, UV/Vis, chromatographic methods.

Bioanalysis of drugs using radiochemical/tracer techniques as well as immunoassays for the analysis of drugs and their metabolites in various biological media and fluids. Assessment of drug purity including drug impurity profiling. Quality Assurance (QA) of pharmaceutical products including the code of GMP (Good Manufacturing Practice) and the Pharmacopeia standards.

Indicative Lab exercises

Exercise 1: Chromatographic (TLC) separation of a mixture;

Exercises 2-3: Spectrophotometric determination of a drugs using UV

Exercise 4: Spectrophotometric determination of a drugs using IR

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	