

Course Title	Pharmaceutical Analysis II and Drug Control				
Course Code	PHA403				
Course Type	Compulsory				
Level	BSc (Level 1)/ MPharm (Level 2)				
Year / Semester	4 th (7 th Semester)				
Teacher's Name	Dr Charalampos Triantis				
ECTS	6	Lectures / week	2	Laboratories/week	2
Course Purpose	<p>The aim of this course is to introduce the analytical techniques applied to drug quality control. Students will study application of chromatographic techniques such as thin layer chromatography (TLC), gas chromatography (GLC), high performance liquid chromatography (HPLC) and high performance liquid chromatography –mass spectrometry (HPLC-MS) to drug analysis. Furthermore, purity and stability control, determination of active materials, excipients and additives will also be studied. Application of the mentioned methods in the analysis of pharmaceutical formulations and biological fluids, in the service of Clinical Pharmacy and Analytical Toxicology. In this course the requirements of the packaging material for pharmaceutical products are extensively discussed (protection from air, light, humidity) are as well as probable contamination of the pharmaceutical products by the packaging materials. Another aim is to teach the students the special care and attention that should be given in the analysis of pharmaceutical products containing active ingredients with a limited and narrow safety margin.</p>				
Learning Outcomes	<p>By the end of this course, the students should be able to:</p> <ul style="list-style-type: none"> • Define terms: Void volume, capacity factor, column efficiency, asymmetric factor etc • Explain efficiency and resolution in chromatography • Describe and explain Gas Chromatography • Describe and explain HPLC • Describe and explain TLC • Compare chromatographic and spectroscopic techniques in Pharmaceutical Analysis • Apply analytical methods using biological fluids, so that they can be used in Clinical Pharmacy and Toxicology; • State quality control and stability tests of pharmaceutical products,; • Apply techniques for artificial ageing of pharmaceutical products or active materials, and accelerating ageing techniques • Apply the preparation of drugs containing active ingredients with narrow safety margin. 				

Prerequisites	PHA303	Corequisites	None
Course Content	<p>Theory</p> <ul style="list-style-type: none"> • Chromatographic theory • Gas chromatography • High pressure liquid chromatography • Thin layer chromatography • Application of analytical methods <p>Laboratory experiments/exercises:</p> <p>As part of the course, laboratory exercises are carried out on the course material for a better deepening and consolidation of the theoretical part. Indicative exercises cover the most important chromatographic techniques used in Pharmaceutical Analysis.</p>		
Teaching Methodology	<p>Teaching methodology includes lectures on theoretical background, and laboratory exercises to better apprehend the basic concepts of Pharmaceutical Analysis. The lecturer uses PowerPoint presentations with detailed notes in order to help students better understand theory. Methods such as discussion, questions/answers, pros/cons, brainstorming, debates, and cooperative learning are used to enhance the student's participation. Recent research results are included and discussed in the course. The laboratory part is conducted in the Laboratory of Pharmaceutical Analysis and Pharmaceutical Chemistry supported by proper infrastructure/equipment and supervised by the lab instructor/professor. Appropriate preparation and demonstration by the laboratory supervisor precedes each laboratory exercise. Assessment of laboratory exercises is done based on laboratory reports submitted by each student at the end of each lab exercise.</p>		
Bibliography	<p>(a) <u>Textbooks</u>:</p> <ul style="list-style-type: none"> • Watson D. Pharmaceutical Analysis. A Textbook for Pharmacy Students and Pharmaceutical Chemists. 3rd Edition. Greek Publisher Parisianos, 2015. • Pedersen-Bjergaard S, Gammelgaard B, Grønhaug Halvorsen T. Introduction to Pharmaceutical Analytical Chemistry. Greek Publisher Parisianos: Zazaris K, Markopoulos A. 2nd edition, 2022. <p>(b) <u>References</u>:</p> <ul style="list-style-type: none"> • Pharmaceutical Analysis. A Textbook for Pharmacy Students and Pharmaceutical Chemists. David Watson. 5th Edition, 2020 • HPLC Methods for Clinical Pharmaceutical Analysis: A User's Guide. Mascher H., Wiley-VCH, 2012 		

Assessment	<p>All written exams conclude open questions, multiple choice questions, critical thinking and problem-solving questions.</p> <p>Coursework 50%</p> <ul style="list-style-type: none"> • Midterm written exam 30% • Lab reports and final lab exam 20% <p>Final written exam 50%</p> <p>The evaluation of the course is performed by:</p> <p>(a) a written mid-term exam during the semester, which examines specific modules of the course and it accounts for 30% of the overall grade,</p> <p>(b) the laboratory reports during the semester, in which students present the collected and analysed experimental data as well as their conclusions, derived from theory and the experimental data (60% of lab grade) and final lab exam (40% of lab grade) and it accounts for 20% of the overall grade, and</p> <p>(c) a written final exam, which examines all modules of the course, and it accounts for 50% of the overall grade.</p> <p>The following criteria are taken into account when evaluating laboratory reports: (a) experimental data collection (30%), (b) data analysis (40%), and application of theory to draw conclusions (30%).</p> <p>Students are prepared by discussions, questions/answers, pros/cons and problem solving, related to the field of Pharmaceutical Analysis, in the class, while additional material is given to students for further practice at home.</p> <p>The final assessment of the students is formative and summative and is assured to comply with the subject's expected learning outcomes and the quality of the course.</p>
Language	Greek, English