Course Title	**Pharmaceutical Technology II**				
Course Code	PHA 402				
Course Type	Compulsory				
Level	BSc (Level 1)/ Integrated MSc (Level 2)				
Year / Semester	4rh Year/ 7th Semester				
Teacher's Name	Dr M. Malamatari, Dr Th. Karydas				
ECTS	6	Lectures / week	3	Laboratories/week	2
Course Purpose	The aim of this course is to teach the students the required properties, methods and purposes of preparation of various dosage forms, such as oral solid dosage forms (tablets and capsules), sterile ophthalmic forms and injectables, semisolids for local application to the skin, as well as the specific dosage forms of targeted drug delivery to the gastrointestinal tract (stomach, small intestine or colon), to the skin or via the skin (transdermal administration) and to the lungs. Specifically, the students will be toughed the purpose of use and the technological and physicochemical properties of excipients, as well as the methods of quality evaluation (technological tests) of the final dosage forms (e.g. mechanical strength, disintegration, and drug dissolution for tablets, particle size of powdered materials and viscosity of liquid and semisolid products). The specifications/requirements of industrial production areas for sterile and non-sterile medicinal products (black, grey, and white areas). Design and operation of clean and aseptic rooms and laminar flow units. The sources of microbial contamination. The determination of microbial load in raw materials and final products, as well as their sterility testing. Also, during the course the following topics will be studied: a) formulation strategies for prolonging the duration of drug absorption (action) (e.g. sustained release tablets or capsules and by transdermal delivery), and b) pulmonary drug delivery using nebulisers, pressurised metered-dose inhalers and dry powder inhalers The students will be familiarized with the different aspects of Industrial Pharmacy, the Regulations for the establishment of Pharmaceutical Plants and the sections of pharmaceutical industry. Good Manufacturing Practice rules, scaling-up process, and the massive production.				
Learning Outcomes	By the end of this course, the students should be able to: • Refer to the common (standard) and modern dosage forms; • Describe ways of preparing these forms. • Identify industrial and compendial specifications and testing methods of these forms. • Describe the appropriate excipients and their physicochemical properties as well as their use. • The principles and applications of sterilisation methods as well as				

<table>
<tr><td></td><td colspan="3">the sterility assurance and testing methods of different dosage forms.
• List the factors (physiological and technological) which affect the transdermal absorption of drugs and the skin penetration enhancers.
• Describe the mechanisms of drug deposition to the respiratory tract and types of pulmonary dosage forms.
• Identify and describe the sections of pharmaceutical industry, their function and their interactions;
• Recognise the importance of the application of good manufacturing practice;
Finally, the overall learning outcome will be the complete knowledge of drug formulation in industrial scale, in combination with their use in therapy practice.</td></tr>
<tr><td>Prerequisites</td><td>PHA308</td><td>Corequisites</td><td>None</td></tr>
<tr><td>Course Content</td><td colspan="3">Theory
Various pharmaceutical preparations.
Solid dosage forms: tablets (standard, film-coated, enteric coated, effervescent), capsules, lozenges;
Semisolid: foams, gels, ointments, creams, (tooth) pastes, suppositories; Sterile: ophthalmic and injectables.
Pulmonary: liquids-solutions (by nebulization and pMDIs); dry powders (by special devices).
Transdermal: ointments, patches (fentanyl, nicotine, hormones).
Technological and physicochemical properties of the excipients, the active pharmaceutical ingredients, the intermediate and final products.
Presentation and application of quality control and assessment methods of final medicinal products.
Sources of microbiological contamination and determination of microbial load in excipients, active pharmaceutical ingredients, and pharmaceutical preparations.
Preservatives used in Pharmaceutical Technology and sterilization methods.
Design and preparation of dosage forms for targeted therapeutics: prolonged and delayed release, transdermal delivery, and pulmonary administration.
General aspects of Industrial Pharmacy. The Regulations for the establishment of Pharmaceutical Plants.
Organization of a pharmaceutical industry: Chemical section, production of the active principle compounds. Formulation section, solid, liquid, injectable forms. Analytical control section. Sterile area.
Good Manufacturing Practice
Scaling-up process, from laboratory to pilot plant quantities. Massive</td></tr>
</table>

	production. Problems and solutions of industrial-mass production. Prevention and assessment of trans contamination. Washing and cleaning machines. Sterilization, sterile area, disinfection, control and assessment. **Laboratory experiments/exercises:** As part of the course, laboratory exercises are carried out on the course material for a better understanding of the theoretical part. Indicative exercises are the following: *Exercise* 1: Preparation of a mixture for effervescent tablets; *Exercise 2*: Determination of disintegration and strength of tablets; *Exercise 3*: Determination of dissolution of tablets; *Exercise 4*: Examination of sterility of injectable preparations, and *Exercise 5*: Determination of microbial load of an ophthalmic solution (eye drops).
Teaching Methodology	Teaching methodology includes lectures on theoretical background, and laboratory exercises to better understand the basic concepts of Pharmaceutical Technology. The lesson is delivered using PowerPoint presentations with detailed notes to facilitate students' better understanding of theory. Methods such as discussion, questions/answers, pros/cons, brainstorming, debates, videos, and cooperative learning are used to enhance the students' participation. Recent research results are included and discussed in the course (i.e. research-informed teaching). The laboratory part is conducted in the Laboratory of Pharmaceutical Technology supported by proper infrastructure/equipment and supervised by the lab instructor/professor. Appropriate preparation and demonstration by the laboratory supervisor precede each laboratory exercise. Assessment of laboratory exercises is done based on laboratory reports submitted by each student at the end of each lab exercise.
Bibliography	1) "Remington: The Science and Practice of Pharmacy", A. Adejare, Elsevier Science / Academic Press; 23rd ed., 2020 2) "Aulton's Pharmaceutics: The Design and Manufacture of Medicines", K.M.G. Taylor, M.E. Aulton, Elsevier;6th edition, 2021 3) Aulton Φαρμακευτική Τεχνολογία, Σχεδιασμός και Παρασκευή Φαρμάκων, M. E. Aulton, K. Taylor, Επιμέλεια Ελληνικής έκδοσης Κ. Καχριμάνης και Ι. Νικολακάκης, Επιστημονικές εκδόσεις Παρισιανου Α.Ε., 2019. 4) Theory and Practice of Industrial Pharmacy. L. Lachman Lieberman, CBS Publishers & Distributors, 4th ed, 2013. 5) «Τεχνολογία Υγρών και Στείρων Φαρμακευτικών Μορφών», Σ. Μαλαματάρης, Αριστοτέλειο Πανεπιστήμιο Θεσσαλονίκης, Υπηρεσία Δημοσιευμάτων, 2004. 6) «Τεχνολογία Στερεών Φαρμακευτικών Μορφών», Σ. Μαλαματάρης, Αριστοτέλειο Πανεπιστήμιο Θεσσαλονίκης, Υπηρεσία Δημοσιευμάτων, 1995.

Assessment	Laboratory performance 30% Midterm exam 20% Final Examinations 50% The evaluation of the course is performed by (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, (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 and it accounts for 20% of the overall grade, and (c) a written final exam, which examines all modules of the course, and it accounts for 50% of the overall grade. Students are prepared for the above written exams by discussion, questions/answers, pros/cons, and case studies, related to the field of Pharmaceutical Technology, in the class and by using the e-learning platform of the University. 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.
Language	Greek, English