UNIVERSITY OF NICOSIA
ΠΑΝΕΠΙΣΤΗΜΙΟ ΛΕΥΚΩΣΙΑΣ

Course Code	Course Title	Credits (ECTS)
PHAR-305	Pharmaceutical Technology II/ Φαρμακευτική Τεχνολογία ΙΙ	**5**
Department	**Semester**	**Prerequisites**
Life & Health Sciences	To be determined	PHAR-210, PHAR-250
Type of Course	**Field**	**Language of Instruction**
Required	Pharmacy	Greek/English
Level of Course	**Year of Study**	**Lecturer**
Bachelor	3rd year	Nicolas Stylianides
Mode of Delivery	**Work Placement**	**Co-requisites**
face-to-face	N/A	None

Objectives of the Course:

Achieving effective treatment of a disease while minimizing adverse effects of a drug requires rational selection, formulation and administration of an appropriate delivery system and form. This course teaches the scientific background and technical aspects vital in dosage form design and preparation. The aim of this course is to teach students how to develop pharmaceutical formulations in liquid and semi-solid form with the appropriate properties including prolonged release dosage forms. The function and value of excipients, their quality specifications, their technological and physicochemical properties and their practical applications are elaborated in this course. Preparation of liquid forms (sterile and not sterile) forms, ophthalmic and injectable preparations will be studied. The control of sterility and the determination of the microbial load are critical study objectives of this course. The importance of cross contamination in the pharmaceutical industry is studied along with Good manufacturing Practices (GMP) for the industry for liquids and semisolids. The Pharmaceutical Technology II module will be focused on the semi-solids and liquid (sterile or non-sterile) pharmaceutical forms

Learning Outcomes:

After completion of the course students are expected to know:

- The development and properties of liquid pharmaceutical dosage forms.
- The production methods and quality testing of liquid formulations.
- The production methods and quality testing of semi-solid formulations.
- The most common excipients and their physicochemical properties.
- About sterilisation techniques and methods of testing of sterile products.
- The GMP rules applicable to the production of liquids and semi solids (sterile or not)
- About stability of liquid and semi-solid dosage forms

Course Contents:

Solutions: Solvents for liquid pharmaceutical preparations, stability considerations, aqueous solutions, enemas, gargles, mouthwashes, nasal solutions, ear solutions and preparations of them. Emulsions: theory of emulsification, formulation and preparation, process equipment. Suspensions: physical characteristics, ingredients, preparation of suspensions, quality considerations, sustained release suspensions. Extracts: preparations. Sterilization: methods, process, chemical sterilization, radiation and filtration, mechanism of killing microorganisms. Antimicrobial compounds used in the pharmaceutical technology along with sterilization techniques are elaborated. Microbial load and contamination is determined in various cases. Pharmaceutical manufacture and microbiology: sterilization kinetics, D and Z values, microbial contamination, hygiene, cross contamination and GMP. Sterility testing and pyrogenic materials testing. Parenteral preparations: formulation, principles, vehicles, manufacturing process, containers, pyrogenic materials, clean room classification, sterilization, sterility and pyrogenic materials test. Intravenous fluids. Ophthalmic Preparations: anatomy of the eye, bioavailability, types of ophthalmic dosage forms, preparation and sterilization. Medicated topical formulations: epidermal and transdermal drug delivery, in vivo and in nitro studies, drug absorption from the skin, rectal absorption, vaginal absorption. Topical dosage forms such as ointments and creams and their preparation.
In all cases the following will be discussed: necessity of a particular dosage form, bioavailability, patient compliance, stability study of open product and closed product, solubility of products, effectiveness, risk assessment during manufacturing, GMP procedures. Design of GMP plant for sterile products and liquids. Risk assessment of production of highly toxic carcinogenic and related products such as hormones, penicillin etc.

Indicative Lab Exercises:
Exercise 1:Disinfection and disinfectants
Exercise 2: Process validation of critical processes and its importance.
Exercise 3:Stability of injectable preparations and/or other liquids
Exercise 4: Emulsification process.
Exercise 5:Design of a plant in detail and to scale for sterile products
Exercise 6: Risk analysis of Out Of Specification products (OOS). Simulation OOS
Exercise 7: Simulation manufacturing.

Learning Activities and Teaching Methods:

Lectures, class discussion, assignments, laboratory

Teaching Methods

Lectures, laboratory exercises, written exams, guiding homework

Assessment Methods:

Midterm examination, final examination, laboratory work as shown below

Assessment

Midterm Examination	25%
Laboratory Exercises	25%
Final Examination	50%

Required Textbooks/Reading:

Authors	Title	Publisher	Year	ISBN
M. E. Aulton	Pharmaceutics: The Science of Dosage Form Design	Churchill & Livingston	2nd Edition	9780443055171
Editor : David B Troy	Remington: The Science and Practice of Pharmacy	Lippincott, Williams & Wilkins	21st Edition of 1995 or later	0-7817-4673-6

Recommended Textbooks/Reading:

Authors	Title	Publisher	Year	ISBN
Σ. Μαλαματάρης	Τεχνολογία Υγρών και Στείρων Φαρμακευτικών Μορφών	Αριστοτέλειο Πανεπιστήμιο Θεσσαλονίκης	2004	