

COURSE OF STUDY PHARMACY

ACADEMIC YEAR 2024-2025

ACADEMIC SUBJECT *Advanced pharmaceutical technology and medical devices (Tecnologia farmaceutica avanzata e dispositivi medici)*

General information	
Year of the course	IV
Academic calendar (starting and ending date)	February 24, 2025-June 13, 2025
Credits (CFU/ETCS):	9
SSD	<i>CHEM 08- Technology, socioeconomy and drug law</i>
Language	ITALIAN
Mode of attendance	In accordance with the didactic regulations of Course of Pharmacy

Professor/ Lecturer	
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Virtual room	<i>Prof. Cutrignelli's Team Platform: tj3jfsj (Canale A-E); istf82r (Canale F-N)</i>
Virtual room	<i>Prof. Trapani's Team Platform: woufeu2</i>
Office Hours (and modalities: e.g., by appointment, on line, etc.)	<i>Please, contact the professors Cutrignelli and Trapani by email</i>

Work schedule			
Hours			
Total	Lectures	Hands-on (laboratory, workshops, working groups, seminars, field trips)	Out-of-class study hours/ Self-study hours
225	80	10	135
CFU/ETCS			
9	8	1	

Learning Objectives	Acquisition of formulation knowledge regarding the so-called innovative pharmaceutical dosage forms and preformulation issues. Acquisition of legislative and structural contents of selected examples of biomedical devices
Course prerequisites	Basic knowledge concerning the following disciplines: General and Inorganic Chemistry, Mathematics, Physics, Organic Chemistry, Pharmaceutical and Toxicological Chemistry I, Pharmaceutical and Toxicological Chemistry II, Pharmaceutical Technology.

Teaching strategies	The course is delivered in presence mode for the 9 ECTS of competence
Expected learning outcomes in terms of	
Knowledge and understanding on:	<ul style="list-style-type: none"> At the end of the course the student must have acquired knowledge of pharmaceutical technology skills essential for the design and development of advanced pharmaceutical forms in the industrial field. Furthermore, the student must know the classification of medical devices and the related legislation.
Applying knowledge and understanding on:	Ability to express the acquired knowledge with mastery of scientific language. Attitude to synthesis through the use of the symbolism of matter and the graphic expression of notions and concepts, in the form of formulas, schemes, equations
Soft skills	<ul style="list-style-type: none"> Making informed judgments and choices <ul style="list-style-type: none"> Critical spirit in the analysis of the proposed topics Communicating knowledge and understanding <ul style="list-style-type: none"> Expressive skill Appropriate use of the specific language of the discipline Logical skills and consequentiality in the connection of contents Organization and logical connections of the expository discourses Capacities to continue learning <ul style="list-style-type: none"> Mastery of the covered topics and ability to use them in a future work context.
Syllabus	
Content knowledge	<p>Pharmaceutical preformulation: Development path of a new drug from its discovery to its introduction on the market. Pharmaceutical preformulation fundamental properties; derived properties; analytical methods. Improvement of the solubility of a drug: chemical, physical and technological interventions; drug-cyclodextrin inclusion complexes, cosolvency, micellar solubilization. The diffusion of drugs, Fick's laws. The Dissolution of Drugs, Noyes-Whitney Law. Partition coefficient. Physical properties of solid pharmaceutical substances, polymorphism in the pharmaceutical field and its implications. Stability and stabilization of drugs: Main mechanisms of degradation of the active principles and kinetics of alteration. Shelf life of the pharmaceutical form. Stability test. General principles of biopharmaceuticals: In vitro and in vivo studies for the determination of intestinal permeability of drugs. Biopharmaceutical Classification System (BCS). Therapeutic effect and bioavailability. Routes of administration. Dissolution, absorption, distribution, biotransformation and elimination of drugs. Absorption mechanisms. Trend in blood levels. Pharmacokinetic parameters and their determination. Apparent volume of distribution. Drug-plasma protein interaction. Clearance. Sterilization of pharmaceutical forms: sterilization techniques and parameters (LAS, D</p>

	<p>value, Z index).</p> <p>Modified Release Pharmaceutical Forms: Definition. The Polymers used for the preparation of modified release pharmaceutical forms. Matrix and reserve systems. Modified-release pharmaceutical forms for dermatological use: Principles of diffusion through membranes. Transport through the skin. Transdermal Therapeutic Systems (TTS). Excipients for dermatological use. Methods for studying percutaneous absorption. Modified release pharmaceutical forms for ophthalmic use: "In situ" gellable systems. Ophthalmic inserts. Modified release pharmaceutical forms orally: matrix systems (monolithic, swellable, erodible), reservoir systems, osmotic systems, bioadhesive systems, Geomatrix, Chronotopic® System. Pharmaceutical forms for specific drug targeting: Micro and nanoparticulate systems as drug carriers. Methods of preparation of microspheres and microcapsules. Methods of preparation of nanospheres and nanocapsules. Liposomes: generalities, characteristics, composition, preparation, in vitro and in vivo interactions, current uses in therapy. Niosomes. Polymeric and oligomeric prodrugs; definitions, characteristics and preparation. Gene therapy.</p> <p>Medical devices: National classification of medical devices. Evolution of the legislation: the new regulation. Marketing and post-marketing phase: supervisory and post-marketing surveillance system. Various examples of medical devices.</p>
Texts and readings	<ul style="list-style-type: none"> • P. Colombo e coll. "Principi di Tecnologie Farmaceutiche" - Casa Editrice Ambrosiana • P. Minghetti ."Legislazione Farmaceutica"- Casa Editrice Ambrosiana X edizione • A.Ferraioli- Manuale ingegneria biomedicale. Dispositivi medici, normative, apparecchiature elettromedicali e nozioni fondamentali- DF Editore
Notes, additional materials	Teams platforms
Repository	

Assessment	
Assessment methods	The exam consists of an oral test.
Assessment criteria	<ul style="list-style-type: none"> • Knowledge and understanding (30%) <ul style="list-style-type: none"> ○ appropriateness, correctness, and congruence of knowledge acquired during the course • Applying knowledge and understanding (20%) <ul style="list-style-type: none"> ○ Illustrating methodological interconnections between the various topics of the course • Autonomy of judgment (10%) <ul style="list-style-type: none"> ○ The student must be able to rationally interpret and illustrate case studies in the development of drugs • Communicating knowledge and understanding (10%) <ul style="list-style-type: none"> ○ Expressive capacity ○ Appropriate use of the specific language of the discipline ○ Logical skills and consequentiality in the connection of contents

	<ul style="list-style-type: none"> • Communication skills (10%) <ul style="list-style-type: none"> ○ Ability to connect different topics by finding common points and to establish a coherent general design, taking care of the structure, organization, and logical connections of the expository discourse ○ Ability to synthesize also through the use of the symbolism of the material and the graphic expression of notions and concepts, for example in the form of formulas, schemes, equations. • Capacities to continue learning (10%) <ul style="list-style-type: none"> ○ Development of the necessary learning capacities for practical application of knowledge and skills acquired during the course
Final exam and grading criteria	<p>The final grade is awarded out of thirty. The exam is passed when the grade is greater than or equal to 18. The grade is determined by an overall evaluation concerning the clarity of the presentation, the completeness of the acquired knowledge, the property of the specific vocabulary of the subject, the depth of knowledge, and the ability to analyze questions and provide suitable answers.</p> <p>In particular, the grade breakdown is as follows:</p> <p>Insufficient: 0-17 Lack of, incomplete, and inadequate knowledge of the topics contained in the syllabus, use of non-technical vocabulary</p> <p>Sufficient: 18-20 Sufficient knowledge of the topics contained in the syllabus and overall adequacy of the technical vocabulary used</p> <p>Adequate: 21-23 Adequate knowledge of the topics contained in the syllabus, adequate ability to argue and make connections between the various topics, use of appropriate technical vocabulary</p> <p>Good: 24-26 Good knowledge of the topics contained in the syllabus, good capacity for in-depth analysis and criticism through the use of an adequate technical vocabulary</p> <p>Distinguished: 27-28 More than good knowledge of the topics contained in the syllabus, more than good capacity for in-depth study, for linking the various topics, for critique and mastery of technical vocabulary</p> <p>Excellent: 29-30 Excellent knowledge of the topics contained in the syllabus, excellent ability to deepen and link between the different topics, as well as criticism and mastery of the technical vocabulary</p> <p>Excellent: 30L Excellent knowledge of the topics contained in the syllabus, outstanding capacity for in-depth study, for linking the various topics, for critique and mastery of the technical vocabulary</p>
Further information	