UNIVERSITÀ DEGLI STUDI DI BARI ALDO MORO

dipartimento di farmacia-scienze del farmaco

General information	
Academic subject	**Pharmaceutical Technology and Legislation**
Degree course	**Pharmaceutical Chemistry And Technology**
Year of study	*III*
European Credit Transfer and Accumulation System (ECTS)	09
Language	*Italian*
Academic Year	*2021-2022*
Academic calendar (starting and ending date)	
Attendance	*Compulsory attendance*

Professor/ Lecturer	
Name and Surname	MASSIMO FRANCO
E-mail	massimo.franco@uniba.it
Telephone	+390805442154
Department and address	*Department of Pharmacy Drug Sciences Orabona street BARI*
Virtual headquarters	*Microsoft office teams ndc0nec*
Tutoring (time and day)	every day by appointment

Syllabus	
Learning Objectives	
Course prerequisites	Basic knowledge concerning the following disciplines: General and Inorganic Chemistry, Mathematics, Physics, Physical Chemistry, Organic Chemistry I, Organic Chemistry II, Pharmaceutical and Toxicological Chemistry I.
Contents	**Pharmaceutical Technology**: Drugs and the Pharmaceutical dosage form concept. Bioavailability and bioequivalence of pharmaceutical dosage forms and determination methods. Definition, classification criteria, sources and requirements of the main excipients. Powders: solid state characteristics , preparation methods. Particle size analysis. Powder density. Porosity. Adsorption phenomena. Powder mixing and granulation. Evaluation methods of powders and granulates. Tablets: preparation methods, excipients. Quality assurance. Disintegration, disaggregation and dissolution phenomena. Coating: aim, materials and instrumentation required. Checks on coated tablets. Hard and soft capsules, microcapsules. Technological and biopharmaceutical features. The features of water as solvent: preparation of deionized and distilled water. Water and Italian Pharmacopeia. Solid solubility and solubilization; rate of dissolution, pH and isotonic solutions. Solution colligative properties. The colloid state. Colloidal systems of pharmaceutical interest. Z potential. Emulsions. Stability of emulsions. Surfactants. The HLB system and the HLB determination. Chemical and physical characteristics of surfactants. Surface phenomena. Pharmaceutical suspensions. Settling of suspended particles. Suspension stability. Application of suspensions in pharmaceutical field. Rheological properties of the fluids of pharmaceutical interest. Dermatological preparations; Drug percutaneous absorption. Formulation strategies. Penetration enhancers. Main features of the vehicles and excipients. Suppositories: Biopharmaceutical aspects of rectal absorption. The choice and the control of excipients. Preparation and control of suppositories. Parenteral formulations. Vehicles; sterile containers and quality assurance; chemical, physico-chemical and biological requirements of parenteral formulations. Powders for parenteral injections. Nasal and pulmonary

	preparations: anatomical-physiological aspects, administration devices. Pressurized preparations, propellant gases and aerosol formulations. **Pharmaceutical regulations** Pharmacopoeia: F.U.I. XII edition and Supranational Pharmacopoeias. Definition of medicinal product: Legislative Decree no. 219/2006 and 193/2006. Administrative classification of medicinal products. Regulation on medicinal selling. DPR n. 309/1990. Health professions and pharmacy exercise. Administrative classification of pharmacies and territorial system.
Books and bibliography	• P. Colombo e coll. "Principi di Tecnologie Farmaceutiche" - Casa Editrice Ambrosiana • Howard C. Ansel, Shelly J. Stockton "Principi di Calcolo farmaceutico", XV Ed Edra, 2017. • P. Minghetti e coll."Legislazione Farmaceutica"- Casa Editrice Ambrosiana • Farmacopea Ufficiale Italiana in vigore • Martin, J. Swarbrick, A. Cammarata - Physical Pharmacy - Lea & Febiger, Phil., USA. • M.E. Aulton «Tecnologie Farmaceutiche: Progettazione e allestimento dei medicinali». Edra Edizioni 2015. M. Amorosa "Principi di tecnica farmaceutica" VI ED. Piccin
Additional materials	

Work schedule			
Total	Lectures	Hands on (Laboratory, working groups, seminars, field trips)	Out-of-class study hours/ Self-study hours
Hours			
225	*90*		*135*
ECTS			
09			

Teaching strategy	
	Lectures in the classroom with the aid of presentations in electronic format, projection of films. Any seminars conducted by experts from the pharmaceutical industry.
Expected learning outcomes	
Knowledge and understanding on:	○ Ability to express the knowledge acquired with mastery of scientific language, demonstrating logical and consequential skills in connecting the proposed topics.
Applying knowledge and understanding on:	○ 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. ○ Ability to independently apply the theoretical concepts acquired to solve some problems related to the pharmaceutical forms studied.
Soft skills	• *Making informed judgments and choices* ○ Critical spirit in the analysis of the proposed topics ○ Ability to autonomously suggest resolutions to the problems presented. • *Communicating knowledge and understanding* ○ Expressive skills ○ Appropriate use of the specific language of the discipline ○ Logical skills and consequentiality in the connection of contents

	○ Ability to connect different topics by finding common points ○ 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, in the form of formulas, schemes, equations. • *Capacities to continue learning* ○ Ability to use basic knowledge and information for exercising the profession of pharmaceutical technologist. ○ Ability to update, with the consultation of codes and scientific publications in the field of pharmaceutical-technological-application disciplines.

Assessment and feedback	
Methods of assessment	To achieve the final mark, expressed out of thirty, the student must demonstrate that he has understood and is able to apply the fundamental concepts of each topic dealt with. In particular, during the examination session, he will have to take a written test lasting about two hours, preparatory to the interview, divided into six problems, five of which are numerically answered and one concerning the comment of a pharmaceutical form.
Evaluation criteria	• *Knowledge and understanding* ○ 20% • *Applying knowledge and understanding* ○ 20% • *Autonomy of judgment* ○ 20% • *Communicating knowledge and understanding* ○ 20% • *Communication skills* ○ 10% • *Capacities to continue learning* ○ 10%
Criteria for assessment and attribution of the final mark	To pass the test and access the interview it is necessary to acquire a minimum score of 18 out of 30. This test will constitute 50% of the final grade. The oral exam will consist in the proposition of three questions on topics of technology and legislation in the program. The final grade will take into account various factors such as: appropriateness, correctness and congruence of the knowledge, skills and competences possessed and / or manifested.
Additional information	
	If due to the persistence of the health emergency the teaching is given in mixed or remote mode, the completion of the exams for the written and oral tests will take place remotely.