

COURSE OF STUDY Pharmacy

ACADEMIC YEAR 2023-2024

ACADEMIC SUBJECT Laboratory of Galenic Preparations and Medicinal Regulations

General information	
Year of the course	<i>IV year</i>
Academic calendar	<i>I semester (09-2023 - 01-2024)</i>
Credits (CFU/ETCS):	9
SSD	<i>CHIM 09</i>
Language	<i>Italian</i>
Mode of attendance	<i>Obligatory</i>

Professor/ Lecturer (A-E)	
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Virtual room	-
Office Hours (by appointment)	Monday, Wednesday, Friday (3 – 4,30 pm)

Professor/ Lecturer (F-N)	
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Professor/ Lecturer (O-Z)	
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Work schedule			
Hours			
Total	Lectures	Hands-on (laboratory, and exercise)	Out-of-class study hours/ Self-study hours
225	50	<i>55 (45+10)</i>	120
CFU/ETCS			
9	5	4 (3+1)	
Learning Objectives		<i>The course aims to provide the theoretical and practical bases for a valid and modern approach to the creation and dispensing of galenic products, as well</i>	

	<i>as to deepen the main rules on medicines. Particular attention will be paid to the preparation of pharmaceutical forms that can be produced in pharmacies and the professional responsibility of the pharmacist in this area, as well as the regulatory aspects of the pharmacist's professional activity.</i>
Course prerequisites	<i>General and Inorganic Chemistry, Mathematics, Physics, Organic Chemistry, Pharmaceutical Technology and Pharmacoeconomics.</i>
Teaching strategie	Lectures in the classroom with the aid of presentations in electronic format, projection of films. Any seminars conducted by experts from the pharmaceutical industry. Classroom discussions on the topics covered.
Expected learning outcomes in terms of	<i>The course aims to provide the theoretical and practical bases for a valid and modern approach to the creation and dispensing of galenic products, as well as to deepen the main rules on medicines. Particular attention will be paid to the preparation of pharmaceutical forms that can be produced in pharmacies and the professional responsibility of the pharmacist in this area, as well as the regulatory aspects of the pharmacist's professional activity.</i>
Knowledge and understanding on:	<p>Ability to express the notions acquired with mastery of scientific language, demonstrating logical and consequential skills in connecting the proposed topics. In particular, the student must:</p> <ul style="list-style-type: none"> • know the fundamental principles for the formulation and preparation of the different dosage forms; • have become aware of the pharmacist's responsibilities within the galenic laboratory; • understand the correct procedures for compiling the documentation accompanying the shipment of a galenic; • apply the current legislation for the correct pricing of magistral galenic, • recognize the mandatory formal aspects in the magistral prescription for the purposes of prescription and dispensing, • know the most commonly used methods for the characterization of the final formulation; • evaluate the checks to be carried out on the magisterial and officinal formulations, • knowing how to prepare the main pharmaceutical forms and organize activities within the galenic laboratory in compliance with the NBP; • know the main laws on the medicine; <p>• know the differences between a medicine, medical device, food supplement, health product, cosmetic.</p>
Applying knowledge and understanding on:	<p>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. In particular, the student must be able to:</p> <ul style="list-style-type: none"> • Understand and explain the content of any pharmaceutical formulation; • Identify, design and prepare galenic pharmaceutical formulations; • Perform pharmaceutical calculations; • Tariff and label galenic preparations; • Correctly fill in the documentation available in the Pharmacy; • Check the formalities of the prescription: and dispense medicines; • Knowing how to prepare medicinal and masterful pharmaceutical forms by identifying the appropriate excipients and adequate techniques.
Soft skills	<ul style="list-style-type: none"> • <i>Making informed judgments and choices</i>

	<ul style="list-style-type: none"> • <i>Critical spirit in the analysis of the proposed topics</i> • <i>Communicating knowledge and understanding</i> • <i>Expressive skills;</i> • <i>Appropriate use of the specific language of the discipline;</i> • <i>Logical skills and consequentiality in the connection of contents;</i> • <i>Ability to connect different topics studied by finding common points;</i> • <i>Organization and logical connections of the expository discourse.</i> • <i>Ability to synthesize also through the use of the symbolism of the</i> • <i>matter and the graphic expression of notions and concepts, in the form of formulas, schemes, equations.</i> • <i>Capacities to continue learning</i> • <i>Ability to use basic knowledge and information for practicing the profession of pharmacist and / or pharmaceutical technologist.</i> • <i>Ability to update, with the consultation of codes and scientific publications in the field of pharmaceutical technological-application disciplines.</i>
Syllabus	
Content knowledge	<p><i>Laboratory of Galenic Preparations and Medicinal Regulations</i></p> <p>Medicines legislation:</p> <p><i>Categories of products sold in pharmacies: medicines for human use (Legislative Decree 219/2006), veterinary medicines (Legislative Decree 6 April 2006, no. 193), medical devices, food supplements, cosmetics, health-promoting vegetable products.</i></p> <p><i>Medicines definition, medicinal products of industrial origin and path for marketing authorization. Primary, secondary and label packaging. AIC, AP. Bioequivalent and biosimilar drugs. Officinal and magister galenics. Rules of good preparation, simplified rules of good preparation (DM 18-11-03). The Italian Official Pharmacopoeia: structure, monographs, tables 1-8. Supranational pharmacopoeias with particular reference to the European Pharmacopoeia.</i></p> <p><i>prescriptions: formalisms and obligations of the pharmacist. Case studies of repeatable prescriptions, non-repeatable prescriptions, restrictive prescriptions, ministerial prescription tracing, prescriptions of the National Health Service, doping legislation. Documents compulsorily present in the pharmacy, "bollettario buono-acquisti", drug entry-exit register.</i></p>

	<p>Pharmaceutical calculation, theoretical aspects and classroom practice on:</p> <p><i>Units of measure, percentages, ratios and proportions, calculations with units of measure; the international system of measurement measures of length, weight, special considerations on the SI in pharmacies, fundamental conversions; measurement operations in pharmacies; volume measurement, weight measurement, rate method for weight and volume measurements, weighed by the method of the minimum weighable quantity, percentage of errors; interpretations of medical prescriptions; case studies; density and relative density, pycnometer, use of relative density in weight and volume calculations; concentration in percentage, in part ratios and other expressions of concentration; isotony and buffer solutions: clinical considerations on tonicity, chemical-physical consideration in the preparation of isotonic solutions, buffers and buffer solutions; problem solving; electrolytic solutions: milliequivalents, millimoles and milliosmoles, osmolarity; variations in concentration, use of stock solutions and alloying rules: troubleshooting; relationship between concentration and total quantity, dilutions of liquids, increase in the concentration of a pharmaceutical product, stock solution, dilutions and concentration of semisolids, alloying, relative density of mixtures. Solving problems associated with pharmaceutical forms such as: powders, granules, tablets, capsules, syrups, solutions, emulsions, suspensions, semi-solid preparations for dermatological use, suppositories and ovules.</i></p> <p>Galenic preparations:</p> <p><i>Simulation of prescription and dispensing of a magister and officinal prescription: control of the prescription, preparation of pharmaceutical form, label, pricing galenic preparation and compilation of the worksheet on:</i></p> <p><i>Powders for topical use, Papers, Granules, Tablets (Tablet press and assays), Capsules, Syrups, Emulsions, Suspensions, O / A and A / O creams, Gels, Pastes and ointments, Suppositories and ovules.</i></p>
<p>Texts and readings</p>	<ol style="list-style-type: none"> 1. <i>Paolo Colombo Franco Alhaique, Carla Caramella, Bice Conti, Andrea Gazzaniga, Elena Vidale "Principi di Tecnologie Farmaceutiche" Edizioni Zanichelli II ed.</i> 2. <i>Howard C. Ansel, Shelly J. Stockton «Principi di calcolo farmaceutico» Edra edizioni</i> 3. <i>Minghetti P. «Legislazione farmaceutica» X ed</i> 4. <i>F.U. XII edizione Istituto Poligrafico e Zecca dello Stato</i> 5. <i>Enrico Ragazzi "Galenica pratica" Edizioni Libreria Cortina Padova 2006.</i> 6. <i>Franco Bettiol "Manuale delle preparazioni galeniche" IV ed. Tecniche nuove</i> 7. <i>Francesca Baratta et al. Manuale di galenica a uso umano e veterinario. Zanichelli 2019</i> 8. <i>Barberini, Casettari, "Legislazione farmaceutica nella pratica professionale". Piccin 2021</i>
<p>Notes, additional materials</p>	<p><i>websites linked to some reference texts</i></p>
<p>Repository</p>	<p>-</p>

Assessment	
Assessment methods	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 / she will have to take a written test lasting about two hours, preparatory to the interview, divided into five numerically answered problems and inherent in the commentary on a pharmaceutical form. 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 pharmaceutical technology, galenic preparations and drug regulations. The final grade will take into account various factors such as: appropriateness, correctness and congruence of knowledge, skills and competences possessed and / or manifested.
Assessment criteria	<ul style="list-style-type: none"> • <i>Knowledge and understanding</i> • <i>ability to discursively organize knowledge</i> • <i>Applying knowledge and understanding</i> • <i>critical reasoning skills on the study carried out</i> • <i>Autonomy of judgment</i> • <i>Communicating knowledge and understanding</i> • <i>Communication skills</i> • <i>quality of exposure</i> • <i>competence in the use of specialized vocabulary, effectiveness, linearity</i> <i>Capacities to continue learning</i>
Final exam and grading criteria	<ul style="list-style-type: none"> • Knowledge and understanding 20% • Applying knowledge and understanding 20% • Autonomy of judgment 20% • Communication skills 20% • Capacities to continue learning 20%
Further information	<i>FINAL REMARKS FROM THE TEACHER: The subject prepares students for practical training in a pharmacy for which it is recommended to take and pass the exam before carrying out this activity.</i>

Bari, 17 November 2023

Signature Professor/Lecturer

(Prof. Angela Assunta Lopedota)

(Prof. Nunzio Denora)

(Prof. Antonio Lopalco)