UNIVERSITÀ DEGLI STUDI DI PALERMO

DEPARTMENT	Scienze e Tecnologie Biologiche, Chimiche e Farmaceutiche
ACADEMIC YEAR	2019/2020
MASTER'S DEGREE (MSC)	CHEMISTRY AND PHARMACEUTICAL TECHNOLOGIES
INTEGRATED COURSE	PHARMACEUTICAL TECHNOLOGY, SOCIOECONOMICS AND REGULATIONS AND TECHNOLOGY OF PHARMACEUTICAL FORMULATIONS - INTEGRATED COURSE
CODE	13181
MODULES	Yes
NUMBER OF MODULES	2
SCIENTIFIC SECTOR(S)	CHIM/09
HEAD PROFESSOR(S)	CAVALLARO GENNARA Professore Ordinario Univ. di PALERMO
OTHER PROFESSOR(S)	FIORICA CALOGERO Professore Associato Univ. di PALERMO DE CARO VIVIANA Professore Associato Univ. di PALERMO CAVALLARO GENNARA Professore Ordinario Univ. di PALERMO
CREDITS	12
PROPAEDEUTICAL SUBJECTS	01874 - PHYSICAL CHEMISTRY
MUTUALIZATION	
YEAR	3
TERM (SEMESTER)	Annual
ATTENDANCE	Mandatory
EVALUATION	Out of 30
TEACHER OFFICE HOURS	**CAVALLARO GENNARA** Tuesday 9:30 11:00 Via Archirafi, 32 - Scala A, 2^ piano **DE CARO VIVIANA** Tuesday 12:00 13:30 Studio docente, via Archirafi, 32 - 2 piano Thursday 12:30 13:30 Studio docente, via Archirafi, 32 - 2 piano **FIORICA CALOGERO** Tuesday 11:30 13:30

DOCENTE: Prof.ssa GENNARA CAVALLARO

PREREQUISITES	Basic concepts of general chemistry, inorganic chemistry and organic chemistry.
LEARNING OUTCOMES	Knowledge and understanding Acquisition of advanced tools for the development of Dosage Forms both classical and advanced. Ability to use the technical language of this discipline. Applying knowledge and understanding Capacity to recognize the required methodologies to develop a dosage form, and applying these methodologies independently. Making judgements Being able to evaluate implications and results of investigations about the influence a dosage form can have on the activity of an active ingredient. Communication Capacity to expose studies' results even to an inexpert public. Being able to support the importance of studies on the development of Dosage Forms in the pharmaceutical field, and highlight their implications. Lifelong learning skills Ability to update their knowledge through consultation of scientific publications in the Pharmaceutical Technology sector. Using the knowledge acquired in the course, capacity to attend third cycle Masters and advanced courses about dosage forms both classical and advanced.
ASSESSMENT METHODS	Learning will be evaluated through a practical test and an oral examination. The practical test consists in the formulation of a galenic praparation in the laboratory, in the filling in the worksheet, in the charging and the preparation of the label according with law in force. The evaluation is expressed in thirtieths. Oral examination aims to assess the skills and disciplinary knowledge possessed by student; the evaluation is expressed in thirtieths. The final evaluation will be the average of the practice test and the oral examination evaluations The questions will be specifically designed to test the learning outcomes and to verify: a) the knowledge of topics; b) the ability to process the knowledge, c) the mastery of scientific language and presentation skills. The assessment has a final grade included in the following range: 30-30 with honors (excellent), corresponding to “excellent knowledge of topics, excellent use of language, good analytical skills, the student can implement his\her knowledge to solve the posed problems”; 26-29 (very good), corresponding to “good mastery of topics, very good use of language, the student can implement his\her knowledge in order to solve the posed problems”; 24-25 (good), corresponding to “basic knowledge of the main topics, fair use of language, with moderate capability to independently implement knowledge to solve the posed problems”; 21-23 (satisfactory), corresponding to“the student doesn't possess full mastery of the main teaching topics but s\he possesses knowledge of them, satisfactory use of language, poor ability to independently implement the acquired knowledge”; 18-20 (passing grade), corresponding to “poor basic knowledge of main teaching topics and scarce technical language, very poor ability to independently implement the acquired knowledge”; unsatisfactory when the student doesn't possess an acceptable knowledge of the contents of the topics dealt during the course.
TEACHING METHODS	The course will provide frontal lectures and individual laboratory practice exercises , for 2 CFUS, that will be given during the Module of Technology of Pharmaceutical Forms.

MODULE
PHARMACEUTICAL TECHNOLOGY, SOCIOECONOMICS AND REGULATIONS

Prof. CALOGERO FIORICA

SUGGESTED BIBLIOGRAPHY

•P. Colombo et al. “Principi di Tecnologie Farmaceutiche” Ambrosiana - Bologna
•A. Martin. “Physical Pharmacy” Lea & Febiger, Philadelphia.
•T. Florence, D. Attwood. “Le Basi Chimico-Fisiche della Tecnologia Farmaceutica” EdiES-Napoli.
•M. E. Aulton. "Pharmaceutics: The science of dosage form design" - Churcill Lingstone - New York.

AMBIT	50323-Discipline Chimiche, Farmaceutiche e Tecnologiche
INDIVIDUAL STUDY (Hrs)	102
COURSE ACTIVITY (Hrs)	48

EDUCATIONAL OBJECTIVES OF THE MODULE

The goal of the Course is that to give to the students basic information concerning preformulation and specific knowledge concerning the preparation of pharmaceutical dosage forms. Students receive also information and knowlege about Italian Official Pharmacopea.

SYLLABUS

Hrs	Frontal teaching
1	Organization of the course
6	Development stages of a new chemical entity (NCE). Testing for new drugs characterization. Background concepts on gaseous state, liquid state, solid state (Amorphous state and crystalline state. Polymorphism and pseudopolymorphism. Enantiotropy and monotropy. Practical aspects of drugs' polymorphism).
2	Thermal analysis. Differential thermal analysis and differential scanning calorimetry. Main applications in pharmaceutical field
8	Dissolution. Physical basis of the dissolution process. Solubility, i.e. gases in liquids, of liquids in liquids, solids in liquids, solids in solids. Practical matters on the solubility of drugs. The different ways to increase solubility of drugs. (Two-component systems containing solid and liquid phase. Eutectic. Salt production for weak electrolytes; precipitation pH. Three-component systems, triangular diagrams, use of cosolvents, using direct and inverse micelles. Formation of complexes. Cyclodextrins, Chemical Derivatives). Partition Coefficient. The effect of association and dissociation phenomena on the partition coefficient. Transport's properties.
5	Diffusion Phenomena. First Fick's Law. Stationary and “quasi-stationary” state. Diffusion through membranes. Rate of solid dissolution in a liquid. Noyes and Whitney's Law. Factors affecting the dissolution rate. Influence of dissolution rate on the absorption. Pharmaceutical Applications.
7	Interfacial phenomena. interfacial and surface tension. Gibbs' adsorption equation. Surfactants. Selfassociation phenomena. Critical micelles' concentration. Micelles. Outline on HLB and calculating its value. Surfactants' properties in relation to the HLB values. Classification of surfactants. Surfaces' contact angle and wetting. Physical and chemical adsorption. Adsorption to the solid-gas and solid-liquid interfaces. Langmuir's isotherm. B.E.T. isotherm. Pharmaceutical use of the adsorption phenomena.
7	Stability and stabilization of drugs and causes of their possible structural changes. Measuring alteration speed. Order zero and higher orders reactions. Half-life time. Determination of dosage form's expiring date. Arrhenius' equation. Accelerated stability tests. Hygroscopicity. Dew point hygrometer. Determination of humidity fluctuations of an environment. Evaluation criteria about hygroscopicity of pharmaceutical substances. Determination of the water content of pharmaceutical substances. Protection of dosage forms substances against hydrolytic alteration. Microbial contamination, oxidative and self-ossidative alterations. Sterilization. Antimicrobials frequently used in the pharmaceutical sector. Antioxidants. Adjuvant substances. Determination of hydroperoxides' index.
10	Pharmaceutical dispersions. Definition and classification. Solid and liquid pharmaceutical solutions. Solvents and cosolvents, their characteristics depending on the site of administration of dosage form. Isotonic. Pharmaceutical isotonic solution preparation. Lyophilization. Advantages and drawbacks of using solutions as dosage forms. The Colloidal systems. lyophilic colloids, lyophobic colloids, association and protective colloids. Properties of colloidal systems (Tyndall effect, Brownian motions, diffusion, sedimentation). Stability of colloidal systems. The z potential. How to affect stability of colloidal systems. Coacervation. Protective colloids. Their usage in pharmaceutical field. Pharmaceutical emulsions. Emulsifying agents. Instability of emulsions. How to stabilize an emulsion. Preparation methods. Properties of parenteral emulsions. Stability test for an emulsion. Pharmaceutical suspensions, definition and features. Sedimentation. Flocculated and deflocculated suspensions. Controlled flocculation. Instability of the suspensions. How to stabilize a suspension. Pharmaceutical semi-solids. Classification. Ointments. Creams. Pastes. Gels. Definitions, properties, structure and preparation methods.
2	Rheology. Reynolds number. Newtonian and non-Newtonian fluids (plastic, pseudo-plastic, dilatant and thixotropic). Viscosity's dependence on temperature. Experimental determination of fluids' viscosity. Pharmaceutical applications.

MODULE
TECHNOLOGY OF PHARMACEUTICAL FORMULATIONS

Prof.ssa GENNARA CAVALLARO - Lettere A-L, - Lettere A-L

SUGGESTED BIBLIOGRAPHY

• P. Colombo et al. “Principi di Tecnologie Farmaceutiche” Ambrosiana - Bologna
• A. Martin. “Physical Pharmacy” Lea & Febiger, Philadelphia.
• T. Florence, D. Attwood. “Le Basi Chimico-Fisiche della Tecnologia Farmaceutica” EdiES-Napoli.
• M. E. Aulton and K. M. G. Taylor. Tecnologie farmaceutiche. Progettazione e allestimento dei medicinali.

AMBIT	50323-Discipline Chimiche, Farmaceutiche e Tecnologiche
INDIVIDUAL STUDY (Hrs)	88
COURSE ACTIVITY (Hrs)	62

EDUCATIONAL OBJECTIVES OF THE MODULE

Target of the module is to provide knowledge on the preparation, the technological properties, the excipients main dosage forms. Moreover, objective of the module is to provide knowledge about the procedures for registering and dispensing of medicinal products.

SYLLABUS

Hrs	Frontal teaching
2	Powders: Property of individual dust. Particle sizes and measuring methods. Size distribution. Bulk propertes of powders. Volume. Porosity. Packing. Density. Scrolling. Capacity 'absorption. Examples of powder formulations.
2	Granules and granulation: Types of granules according to F.U. Granulation. Technological tests.
3	Tablets: types of tablets according to F.U. XII. Main requirements of the tablets. Excipients for tablets. Methods of preparation. Tablet formulation. Technological controls accordingto Pharmacopoeia.
3	Capsule: types of capsules according F.U. XII. Involucre components and manufacturing methods. Filling and sealing of hard capsules. Soft capsules. Technological controls.
3	Rectal and vaginal preparations: preparations for rectal applications. Factors that influence the absorption: Physiological aspects, chemical-physical characteristics of the drug and of the formulation. Excipients. Methods for preparation of suppositories. Vaginal preparations. Technological controls.
2	Parenteral pharmaceutical preparations: routes of administration. Preparation and requirements. Powders for injectable preparations. Perfusion liquids. Water for injectable preparations. Oils for injectable preparations. Containers.
2	Ophthalmic pharmaceutical preparations: physiology of the eye (notes). Preparation and requirements.
3	Pharmaceutical preparations for dermatology: tegumentary system. The skin barrier function. Excipients for dermatological use. Preparation techniques. Transdermal Therapeutic Systems. Percutaneous absorption. Factors affecting percutaneous absorption. Absorption promoters. Effectiveness of a transdermal patch. A transdermal system design. The drug release tests.
2	The Italian Pharmacopoeia
3	Standards of good preparation of medicines in pharmacies. Pharmaceutics laboratory. Staff and equipment. Preparation operations.
1	Role of regulatory affairs in the pharmaceutical industry. Classification of medicinal products. Manufacturing Authorisation (A.P.).
2	Marketing authorization of a product of industrial origin (A. I. C.). Registration dossier.
3	Discipline dispensing of medicines to the public. Recipe. Mode 'of prescription and dispensation. Discipline of drugs.
1	Administrative classification of pharmacies. Staffing plan.

Hrs	Practice
30	Individual laboratory practice exercises, during which galenical preparation is planned, dispatched, charged and labeled. Both officinal and mastered recipes will be formulated.

MODULE
TECHNOLOGY OF PHARMACEUTICAL FORMULATIONS

Prof.ssa VIVIANA DE CARO - Lettere M-Z, - Lettere M-Z

SUGGESTED BIBLIOGRAPHY

• P. Colombo et al. “Principi di Tecnologie Farmaceutiche” Ambrosiana - Bologna
• A. Martin. “Physical Pharmacy” Lea & Febiger, Philadelphia.
• T. Florence, D. Attwood. “Le Basi Chimico-Fisiche della Tecnologia Farmaceutica” EdiES-Napoli.
• M. E. Aulton and K. M. G. Taylor. Tecnologie farmaceutiche. Progettazione e allestimento dei medicinali.

AMBIT	50323-Discipline Chimiche, Farmaceutiche e Tecnologiche
INDIVIDUAL STUDY (Hrs)	88
COURSE ACTIVITY (Hrs)	62

EDUCATIONAL OBJECTIVES OF THE MODULE

Target of the module is to provide knowledge on the preparation, the technological properties, the excipients main dosage forms. Moreover, objective of the module is to provide knowledge about the procedures for registering and dispensing of medicinal products.

SYLLABUS

Hrs	Frontal teaching
2	Powders: Property of individual dust. Particle sizes and measuring methods. Size distribution. Bulk propertes of powders. Volume. Porosity. Packing. Density. Scrolling. Capacity 'absorption. Examples of powder formulations.
2	Granules and granulation: Types of granules according to F.U. Granulation. Technological tests.
3	Tablets: types of tablets according to F.U. XII. Main requirements of the tablets. Excipients for tablets. Methods of preparation. Tablet formulation. Technological controls accordingto Pharmacopoeia.
3	Capsule: types of capsules according F.U. XII. Involucre components and manufacturing methods. Filling and sealing of hard capsules. Soft capsules. Technological controls.
3	Rectal and vaginal preparations: preparations for rectal applications. Factors that influence the absorption: Physiological aspects, chemical-physical characteristics of the drug and of the formulation. Excipients. Methods for preparation of suppositories. Vaginal preparations. Technological controls.
2	Parenteral pharmaceutical preparations: routes of administration. Preparation and requirements. Powders for injectable preparations. Perfusion liquids. Water for injectable preparations. Oils for injectable preparations. Containers.
2	Ophthalmic pharmaceutical preparations: physiology of the eye (notes). Preparation and requirements.
3	Pharmaceutical preparations for dermatology: tegumentary system. The skin barrier function. Excipients for dermatological use. Preparation techniques. Transdermal Therapeutic Systems. Percutaneous absorption. Factors affecting percutaneous absorption. Absorption promoters. Effectiveness of a transdermal patch. A transdermal system design. The drug release tests.
2	The Italian Pharmacopoeia
3	Standards of good preparation of medicines in pharmacies. Pharmaceutics laboratory. Staff and equipment. Preparation operations.
1	Role of regulatory affairs in the pharmaceutical industry. Classification of medicinal products. Manufacturing Authorisation (A.P.).
2	Marketing authorization of a product of industrial origin (A. I. C.). Registration dossier.
3	Discipline dispensing of medicines to the public. Recipe. Mode 'of prescription and dispensation. Discipline of drugs.
1	Administrative classification of pharmacies. Staffing plan.

Hrs	Practice
30	Individual laboratory practice exercises, during which galenical preparation is planned, dispatched, charged and labeled. Both officinal and mastered recipes will be formulated.