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**COURSE: PHARMACEUTICAL TECHNOLOGY AND LEGISLATION II**

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**ACADEMIC YEAR: 2019-2020**

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**TYPE OF EDUCATIONAL ACTIVITY: Characterizing**

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**TEACHER: Dott. Antonio Vassallo**

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phone: **0971205624**mobile (optional):

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Language: **ITALIAN**

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ECTS: **10 (9 lessons  
and 1  
tutorials/practice)**n. of hours: **84 (72  
lessons and 12  
tutorials/practice)**Campus: **Potenza**  
Dept./School: **Department of  
Sciences**  
Program: **Pharmacy (LM-13)**Semester: **I**  
(from 1 october 2019 to -  
20 January 2020)

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**EDUCATIONAL GOALS AND EXPECTED LEARNING OUTCOMES**

The course aims to provide a comprehensive knowledge for the formulation, preparation and control of medicinal products in the industry and in galenic formulations. In particular, the course aims to provide the basic elements for the implementation of innovative pharmaceutical forms.

The students at the end of the course have to demonstrate that they are able to:

- Know the basics of pharmacokinetics;
  - Know the chemical, physical and technological conditions for the drugs phase LADME, with special reference to pharmaceutical forms and controlled-release systems;
  - Knowing the principles of conveyance and drug targeting;
  - To recognize and classify pharmaceutical forms ;
  - Handle and recognize the raw materials in the formulation of therapeutic preparations;
  - Send medical prescriptions of medicinal and galenic preparations;
  - Consult the national tariff;
  - Know the rules relating to the exercise of legal and ethical professional;
  - Know some elements of pharmacoconomics.
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**PRE-REQUIREMENTS**Technical and pharmaceutical legislation I

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**SYLLABUS**Suspensions and colloidal dispersions. (4 hours)Semi-solid preparations for skin application. Rheology. Transdermal absorption principles. Percutaneous absorption and formulation. Unguent. Creme. Gels. Multiple emulsions. Microemulsion. Tests for Identification of Emulsion types W/O and O/A. Lotions. Auxiliary ingredients. (8 hours)The plant -derived drugs. Homeopathic preparations. (4 hours)Inhalation formulations: liquid and solid preparations. Liquid preparations dispensed through pressurized inhalers with metering valve. (4 hours)Modified release dosage forms (delayed, prolonged, repeated): definitions and mechanisms. General principles, speed and mechanism control of release, formulation methods, in vitro measure of bioavailability. (8 hours)Polymers of pharmaceutical interest : preparation, classification and properties. (4 hours)Micro and nanoparticles for drug delivery: Microparticles, Nanoparticles, Liposomes, Dendrimers. The microcapsules: introduction, aims and release mechanisms. Reservoir systems, matrix systems (monolithic, erodible, swellable), ion exchange systems, osmotic systems. Oral modified release dosage forms. Parenteral dosage Forms for sustained release systems, or "depot systems". Transdermal systems. (16 hours)Subcutaneous implants: Therapeutic systems for ophthalmic use, Intravaginal and intrauterine systems. Radiopharmaceuticals. (8 hous)Incompatibility: physical, chemical and technological properties. The pharmacist's advice in dispensing various pharmaceutical forms. (2 hours)

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Principles of biopharmaceutical (2 hours).

Pharmaceutical legislation. Custody and sale of poisons: Table 3. Rules concerning purchase, storage and sale of narcotics (DPR 309/90): coupon voucher and entry / exit register. Dispensing mode. Pain therapy. Table 7 FU XII ed.

Definition of veterinary medicinal product and of the different types of medicines. Prescription and dispensation methods. Generic and Biosimilars: analogies, differences and hints on the patent patent in the pharmaceutical field. Medication delivery without prescription in urgent cases. Off-label prescription of medicines. Direct distribution and distribution on behalf (DPC). LASA drugs. Pharmacovigilance: the role of the pharmacist. Professional association of pharmacists. National Federation of Professional Associations of Pharmacists (FOFI), Trade Associations, ENPAF. Code of ethics of the pharmacist and disciplinary power of the Order of Pharmacists. Food legislation, food supplements and food for special medical purposes: obligations for the pharmacist. HACCP. Medical devices. Socioeconomy pharmaceutical. (12 hours)

Laboratory tutorials/practice. Galenic Formulations: suppositories (3 hours), unguents (3 hours) and gels (3 hours). Preformulation and galenic development for the preparation of medicines in the pharmacy laboratory. Prescription and method of dispensing galenic preparations. National tariff for the sale of galenic preparations to the public (3 hours).

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#### TEACHING METHODS

Numbers of hours: 84 (72 h lessons and 12 h Classroom tutorials/Laboratory tutorials with final written reports of each exercise, recommended frequency)

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#### EVALUATION METHODS

Intermediate verifications or Written examination, Practical test, and Oral examination.

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#### TEXTBOOKS AND ON-LINE EDUCATIONAL MATERIAL

Slides and study materials provided by Teacher.

Suggested textbooks:

- P. Colombo ed altri :” Principi di tecnologie farmaceutiche”- Casa Editrice Ambrosiana – Milano.
- Aulton Michael E., Kevin M.G. Taylor. TECNOLOGIE FARMACEUTICHE Progettazione e allestimento dei medicinali. Casa Editrice Edra, Milano.
- M. Amorosa - Principi di Tecnica Farmaceutica – Libreria Universitaria Tinarelli – Bologna.
- Florence A. T., Attwood D.: " Le basi chimico-fisiche della Tecnologia farmaceutica " Ed. Edises
- F. Bettiol : “Manuale di preparazioni galeniche” Ed. Tecniche nuove
- E. Ragazzi: “Galenica pratica” Ed.Cortina
- P. Brusa, A. Germano –“Prontuario pratico di galenica” Casa Editrice Ambrosiana – Milano.
- Paola Minghetti, Marcello Marchetti - “Legislazione farmaceutica”. Casa Editrice Ambrosiana – Milano.
- M. Cini, P. Rampinelli - Compendio di Legislazione Farmaceutica - Edizioni Minerva Medica – Torino

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#### INTERACTION WITH STUDENTS

At the beginning of the course, after having described the programme and the valuation’s methods, the teacher gives to students the studying material. In the same time, the teacher takes a paper with the names and emails of the students, who want to participate to the lessons/lab.

Teacher’s meetings: Monday from 11:30 am to 12:30 in the teacher’s office.

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#### EXAMINATION SESSIONS (FORECAST)<sup>1</sup>

10/02/2020; 4/03/2020; 15/06/2020; 13/07/2020; 14/09/2020; 7/10/2020; 2/12/2020

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SEMINARS BY EXTERNAL EXPERTS    YES X    NO

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#### FURTHER INFORMATION

Lab activities in preparation and control of medicinal products in galenic formulations.

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<sup>1</sup>Subject to possible changes: check the web site of the Teacher or the Department/School for updates.