
COURSE: PHARMACEUTICAL TECHNOLOGY AND LEGISLATION I

ACADEMIC YEAR: 2019-2020

TYPE OF EDUCATIONAL ACTIVITY: Characterizing

TEACHER: Dott. Antonio Vassallo

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Language: **ITALIAN**

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: **II**
(from 2 March 2020 to
20 June 2020)

EDUCATIONAL GOALS AND EXPECTED LEARNING OUTCOMES

The course aims to provide a comprehensive knowledge on the pharmaceutical forms and regulations governing the pharmaceutical sector, in particular the conventional pharmaceutical forms.

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

- Recognize and classify the conventional pharmaceutical forms;
 - Handle and recognize the raw materials in the formulation of therapeutic formulations;
 - Send medical prescriptions of medicinal and galenic formulations;
 - Consult the tariff national;
 - Know the laws and ethics inherent in the exercise of professional activity;
 - Know some elements of the pharmacoconomics.
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PRE-REQUIREMENTSPhysics, Organic Chemistry

SYLLABUS

Pharmaceutical forms: drug, excipient and pharmaceutical form. Main excipients used for the production of medicines.

Pharmaceutical and mechanical operations applied to the preparation of medicines.

Immediate release pharmaceutical forms: definition

Solid pharmaceutical formulations: The powders. The granulation. Effervescent granules. The tablets. Excipients for tablets. Types of tablets according to the FUI XII ed. The coverage of the tablets. The capsules. Pills and tablets.

Corrective of taste: aromatics. Sweeteners. Preservatives. Dyes. (16 hours)

Liquid preparations for skin application and oral use: Solutions. Hydrolate. Purified water FUI. Drug delivery in solution. Solubilization. Potions. Simple syrup. Preservatives. Flavoring syrup. Medicated syrups. Conservation and labels. Elixir. Alcoholate. Calculating the volumetric and gravimetric alcohol. Glycerite. Oil Solutions. (16 hours)

Rectal and vaginal preparations. (4 hours)

Formulations for parenteral use and Ophthalmic preparations. Routes of administration. Vehicles for injection (aqueous and non-aqueous). Sterility. Sterilization methods. Formulation of apyrogenic solutions. Powders for injections. (12 hours)

Drug stability: lipids and antioxidants (4 hours)

Pharmaceutical Legislation. National and supranational health organizations. The National Health Service (SSN). Laws affecting the pharmaceutical industry. The administrative classification of pharmacies. The Code of Ethics of the Pharmacist. Staffing plan. Ownership and direction of the pharmacy, replacement and provisional management. Mandatory records and texts in pharmacies. Pharmacy inspections. (8 hours) Drugs, pharmaceutical forms and pharmacopoeias. The International Pharmacopoea and the European Pharmacopoeia. The Italian Official Pharmacopoeia. Rules and Guidance for A good manufacturing practice (NBP-GMP). Marketing Authorisation Holder (A.I.C-M.A.H.). Notes on labeling, pharmaceutical label, plaque. Package insert. Classification of medicines for the purpose of supply and dispensing regime: medicines subject to medical prescription (RR), medical prescription to be renewed from time to time (RNR), limitative prescription (RL), special prescription (RMR), medicines not subject to

medical prescription : OTC and SOP. Pharmaceutical socio-economics (12 hours).

Laboratory tutorials/practice. Galenic Formulations: powders (3 hours), capsules (3 hours) and syrup (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).

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)

EVALUATION METHODS

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

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 12:30 am to 13:30 pm in the teacher’s office.

EXAMINATION SESSIONS (FORECAST)¹

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

SEMINARS BY EXTERNAL EXPERTS YES X NO

FURTHER INFORMATION

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

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