
COURSE: PHARMACEUTICAL TECHNOLOGY AND LEGISLATION I

ACADEMIC YEAR: 2017-2018

TYPE OF EDUCATIONAL ACTIVITY: Characterizing

TEACHER: Antonio Vassallo

e-mail: **antonio.vassallo@unibas.it**

website:

phone: **+39 0971205624**mobile (optional):

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
Science**
Program: **PHARMACY (LM-13)**Semester: **II**
**(from 5 March 2018 to
31 June 2018)**

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 pharmacoeconomics.
-

PRE-REQUIREMENTSPhysics, Organic Chemistry

SYLLABUS

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 pharmaceutical formulations: 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)

Suppositories. (4 hours)

Formulations for parenteral use: Eye drops. 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. The National Health Service. Laws affecting the pharmaceutical industry. The administrative classification of pharmacies. The Code of Ethics of the Pharmacist. Staffing plan. (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.). The wholesale distribution of medicinal products. Pharmaceutical socio-economics (12 hours).

Laboratory tutorials/practice. Galenic Formulations: powders (3 hours), capsules (3 hours) and syrup (3 hours). The Medical prescription: Standards for the delivery of the Medical prescription. Charging (3 hours).

TEACHING METHODSNumbers of hours: 84 (72 h lessons and 12 h Classroom tutorials/Laboratory tutorials)

EVALUATION METHODSIntermediate 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.
- 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

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

22/01/2018, 12/02/2018, 21/05/2018, 18/06/2018, 09/07/2018, 10/09/2018, 26/11/2018

SEMINARS BY EXTERNAL EXPERTS YES NO

FURTHER INFORMATION

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

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