**Degree in Biomedical Laboratory Techniques**

**Teaching: CLINICAL BIOCHEMISTRY AND PHARMACEUTICAL TOXICOLOGY**
**SSD: BIO/14, BIO/12**
**Number CFU: 5**
**Responsible Teacher: GAETANO BARBATO**
**e-mail: gaetano.barbato@unicamillus.org**

Module: Pharmaceutical toxicology and galenic pharmacology
SSD: BIO/14
CFU number: 3
Teacher: Isabella Faraoni E-mail: isabella.faraoni@unicamillus.org

Module: Special Clinical Biochemistry
SSD: BIO/12
CFU number: 2
Teacher: Gaetano Barbato E-mail: gaetano.barbato@unicamillus.org

ATTENDANCE MODE: ATTENDANCE OBLIGATORY WITH AT LEAST 75% PRESENCES TO THE INTEGRATED COURSE

**PREREQUISITES**
Although there are no prerequisites, basic concepts of chemistry, biochemistry, molecular biology, cell biology, genetics, physiology and general pathology are required.

**LEARNING OBJECTIVES**
The Teaching of Pharmaco Toxicology Module aims at acquiring the fundamental principles of pharmacokinetics, pharmacodynamics, toxicology and pharmaceutical galenic that underlie the execution of biochemical and pharmacogenetic tests carried out in the analysis and research laboratories and the theoretical bases for the preparation of galenic drugs. The Students must know the scientific rigor and methodological approach underlying the development of new drugs. They will also have to learn the fundamental aspects connected with the therapeutic use of the most frequently used classes of drugs. These objectives will be achieved through lectures, seminars and interactive teaching activities, designed to facilitate learning and improve the ability to address and resolve the main questions of the pharmaceutical industry, toxicology and pharmaceutical galenics.
During the Special Clinical Biochemistry Module the student will be provided with a theoretical-practical preparation on some commonly used metodologies in Clinical Biochemistry Laboratory activities for both Clinical and Research Analysis leading to diagnostic data.
Objectives will be reached by front lessons and verifications at given time points, with the objective of facilitating comprehension, learning and improve the ability to confront and solve some main questions of Applied Clinical Biochemistry.

**LEARNING OUTCOMES**
Expected learning outcomes are conform with the general dispositions of the Bologna Process and the specific dispositions of the 2005/36/CE directive. They are within the scope of the European Framework of qualification (Dublin descriptors) as follows :

**Knowledge and understanding**

- At the end of this integrated course the student must demonstrate the knowledge and understanding of:
- the mechanisms of action, adverse effects, relevant drug interactions of main classes of drugs and demonstrate the ability to link the acquired knowledge on pharmacokinetics and pharmacodynamics with the toxic and therapeutic effects of the various classes of drugs.
- The students must demonstrate the fundamental multi-disciplinary knowledge for understanding the activity of drugs in relation to their interaction with targets at the cellular and systemic level.
- The must also have developed the ability to keep up to date by critically reading and understanding scientific articles published in reviewed international journals.
- The student must also demonstrate knowledge and understanding of laboratory analytical techniques, with particular reference to the techniques used in pharmacology and pharmacy laboratories.
- Knowledge of the role of the main enzymes in diagnosis, action models, main effectors of quality of an enzymatic analysis, factors affecting the analysis.
- Knowledge of the role of relevant diagnostic tumor markers, the more relevant methodologies in their quantification, the main effectors of quality of analysis of tumor biomarkers
- Knowledge of the role of some of the more important allergenes and the main methodologies in the quantification of the immunoresponse against them; the main effectors of quality of analysis of allergenes
- To Explain/Describe the rationale and architecture of Case Studies
- To explain possible deviation and anomalies within the analysis
- To know how to perform an on-line search query on reference web sites

**Applying knowledge and understanding**

At the end of the Integrated course the student will be able:

- to use the acquired knowledge for an in-depth study of aspects related to the professional activity to which he will devote himself.
- Use the acquired knowledge to delineate an approach to analyze biological samples using enzymatic analysis, analysis of tumor biomarkers or allergy analysis to provide data to contribute to the formulation of a diagnosis.
- Use the databases of on-line reference sites to verify/compare results obtained and the corresponding diagnosis

**Learning skills**

At the end of the integrated course the student will be able to:

- Produce a macro-level flow-chart for an analysis process suitable for specific diagnostic purposes
- Use appropriately measure units for each analsyis modality examined
- Use on-line database searches/queries as reference and comparison

**Communication skills**

The student must be able to

- present the knowledge acquired during the course in a clear and appropriate technical language.
- Use specific scientific terminology in a suitable manner

- Express concepts dividing in logical steps the different moments of the analytical investigation to contribute to a diagnosis formulation

**Making judgements**
At the end of the Teaching, the student will:

- Know how to carry out rough assessments concerning the topics covered.
- Make general assessments relatively to the dealt topics.
- Use the comprehension of the factors affecting the dosing analysis examined to provide a critical reading of the result.

**Such expected learning results, are measurable within the final evaluation**

**COURSE SYLLABUS**

Pharmaceutical Toxicology and galenic pharmacology
• Definition of drug.
• Main pharmacokinetic parameters: routes of administration, absorption, passage through the membranes, distribution, biotransformation, elimination of drugs.
• General principles of pharmacodynamics: receptors, mechanism of action of drugs.
• Development and discovery of new drugs: general principles of in vitro drug sensitivity tests, preparation of a pharmacological experiment.
• Drug testing: preclinical experimentation; Phases I, II, III and IV of the clinical trials.
• Drugs and food-drug interactions.
• Branded medicines, equivalents and biosimilars.
• General characteristics of the main classes of drugs.
• Pharmacogenomics: individual variability of drug response, variation of target proteins, variation in enzymes responsible for drug metabolism.
• Biotechnological drugs and targeted therapies: anti-sense oligonucleotides, monoclonal antibodies; chimeric proteins, kinase inhibitors.
• Principles of toxicology; toxicokinetics; toxication and detoxification mechanisms; main sources of toxicity; toxic drug effects.
• Principles of pharmaceutical galenic, magisterial and officinal galenic, auxiliary substances in galenic preparations: solvents, excipients, preservatives.
• Operation in a confined environment with reference to the Official Pharmacopoeia; calculation of the molarity of the solutions and their preparation.

Special Clinical Biochemistry:

- FLOW CHARTS METHODOLOGY : High level road map to fractionate in logical steps a laboratory analysis pathway leading to diagnostic data. Intermediate level actions road maps. Timing and resources critical evaluation to reach the analysis objectives.
- CLINICAL ENZYMOLOGY : Enzyme's role in clinical diagnosis. Early markers and late markers. Basics of enzymatic catalysis: ezyme kinetics, action models (lock and key, induced fit, Michaelis and Menten) and their use, influence of ambient factors. Mechanisms of action, regulation, allostery, feedback. Inibition: competitive and non competitive.
- Enzymatic dosing methodologies: Critical evaluation of results: sensitivity, specificity, predictive value, accuracy, precision.
- Continuous and discrete measure dosing. Substrate, product and co-factors dosing.
- Diagnostic dosing "Case Studies" in the Clinical Laboratory practice: Creatin Kinase

(CK), Lactic DeHydrogenase (LDH), Transaminases (GOT, GPT), Alkaline and Acidic Phosphatases, Amilases.

- TUMORAL MARKERS: Definition of sensitivity, specificity, diagnostic effectiveness, predictive value and cut-off value.
- Classification and description of the main serologic markers : «case studies» of tumoral markers in organs such as colon, pancreas, liver, breast, ovary, prostate, thyroid.
- Dosage methods of tumor markers in the « case studies ». Main analytical interferences and diagnostic outcome validity of interpretation.
- ALLERGOLOGY: Hypersensitivity reactions (type I-IV). Serologic investigation for total and specific IgEs. New multiparametric methodologies. Recombinant allergens. Single components diagnosis.
- «Case studies» of common allergens and their diagnosis based on analytical data.
- Dosing methods of immunoresponse, immunofluorescence, immunoenzymatic methodologies. Main analytical interferences, diagnostic outcome and validity of interpretation.

**COURSE STRUCTURE**

The Module Pharmaceutical toxicology and galenic pharmacology is structured in 30 hours of frontal teaching, divided into lessons of 2-4 hours according to the academic calendar. Lectures will include theoretical lessons and supplementary seminars on the topics covered.
The Module Special Clinical Biochemistry is structured in 20 hours frontal lessons, and makes use also of multimedia platform (short movies and on-line databases consultation). It is divided in 2 hours lessons, frequency determined by the academic calendar. Frontal lessons include also practical verification check points using tests designed to assert the degree of comprehension and learning of students (learning skills).

**COURSE GRADE DETERMINATION**

The exam of the integrated course Pharmaceutical toxicology and galenic pharmacology – PTGP, Special Clinical Biochemistry – SCB consists in an evaluation test of PTGP and and evaluation test of SCB, whose marks will constitue part of the integrated course evaluation.
The student may take the PTGP and the SCB test on the same date or on different dates of the academic year according to the modality below reported.

**The final evaluation of the integrated course will be made with a weighted average on the CFU of the respective modules.**

**Evaluation of Pharmaceutical toxicology and galenic pharmacology:**

The verification will take place with a written exam followed by an oral exam. There are exemptions during the Teaching to highlight any topics. The written test will consist of 30 questions with multiple-choice answers, for each correct answer, a point will be assigned. The final score of the written test will be given by the sum of the partial scores assigned to each question answered correctly. To access the oral exam the student must have totalled at least a minimum of 18 points. During the oral exam, the student will have to demonstrate adequate skills related to the Teaching.
In particular, the student will have to demonstrate: i) understanding of the topics learned; ii) appropriate use of the technical terms related to pharmacology iii) clarity of exposition; iv)

ability to link together the acquired knowledge; v) in-depth study of the topics studied.

In the evaluation mark knowledge and understanding represents up to 40%, applying knowledge and understanding represents up to 40% and making judgements represents up to 20% of the final mark.

**Evaluation of Special Clinical Biochemistry**
Final test of student's preparation is with a written test followed by an oral part.
The written test is divided in two sections : i) 15 questions with multiple choice, answer score : exact +1, wrong -0.5 points; ii) 3 questions with free text elaboration (20 rows limit), each question 5 points. Written final test score is given by the sum of the partial scores given per each question. To access the oral exam the student should have totalized a minimum score of 18 points.
During the oral part the Exam Commission will evaluate Student's ability : to apply knowledge, proper technical language, and will explore student's capacity to solve laboratory problems taken from the developed program choosing the suitable methodologies for the scope.
Will be evaluated : knowledge and comprehension, applying knowledge and understanding, communication skills, thought decision making.

In the evaluation mark knowledge and understanding represents up to 40%, applying knowledge and understanding represents up to 40% and making judgements represents up to 20% of the final mark.

**OPTIONAL ACTIVITIES**
**Pharmaceutical toxicology and galenic pharmacology:**
In addition to teaching activities, the student will be given the opportunity to participate in seminars and research internships. The topics of the activities are not subject to examination.
**Special Clinical Biochemistry: N.A.**

**READING MATERIALS**

**Pharmaceutical toxicology and galenic pharmacology:**

1) Moini J. Focus on Pharmacology: Essentials for Health Professionals. 3rd Edition PEARSON, 2018.

2) Other material and scientific articles indicated from time to time by the teacher.

**Special Clinical Biochemistry:**

1) « TIETZ FUNDAMENTALS OF: Clinical Chemistry and Molecular Diagnostics », 2019, Elsevier, 8th edition, Nader Rifai, Andrea Rita Horvath, Carl T. Wittwer, ISBN-13: 978-0323530446
2) « Laboratory Medicine Diagnosis of Disease in Clinical Laboratory », McGraw Hill, Laposata Michael, ISBN-13: 978-1259255137

**Responsible Availability**

Students will be received by previous appointment by writing to:

Prof. Gaetano Barbato
e-mail: gaetano.barbato@unicamillus.org

Prof. Isabella Faraoni
e-mail: isabella.faraoni@unicamillus.org