

BSc Biomedical Laboratory Techniques

Integrated Course: CLINICAL BIOCHEMISTRY AND PHARMACEUTICAL TOXICOLOGY SSD: BIOS-09/A, BIOS-11/A CFU: 5 Course Coordinator: <u>Prof. LUISA PIERONI</u>

Teaching: <u>Special Clinical Biochemistry</u> SSD: BIOS-09/A <u>Prof. LUISA PIERONI</u>, email: <u>luisa.pieroni@unicamillus.org</u> CFU: 2

Teaching: <u>Pharmaceutical Toxicology and galenic Pharmacology</u> SSD: BIOS-11/A <u>Prof. SAVINA APOLLONI</u>, email: <u>savina.apolloni@unicamillus.org</u> CFU: 3

PREREQUISITES

Although there are no prerequisites, for a correct understanding of the notions of the integrated teaching, it is necessary to have mastery of the acquired fundamental concepts of chemistry, biochemistry, molecular and cellular biology, genetics, physiology and general pathology.

LEARNING OBJECTIVES

The integrated teaching of Clinical Biochemistry and Pharmacotoxicology aims to acquire the fundamental principles of pharmacokinetics, pharmacodynamics, toxicology and pharmaceutical galenics, at the basis of the execution of biochemical and pharmacogenetic tests, carried out in diagnostic and research laboratories as well as the theoretical bases for the preparation of galenic drugs. Student will be taught the scientific precision and methodological approach underlying the development of new drugs and the fundamental aspects connected with the therapeutic use of the most frequently used drug classes. The activity of the clinical biochemistry laboratory in the diagnostic process will be presented, from the preparation of samples to the understanding of the meaning of the alterations of the most relevant biochemical-clinical profiles, and some methodologies used in biochemical diagnostics and for therapeutic monitoring of drugs. At the end of the Integrated Teaching, the student will have acquired the ability to deal with the main technologies of the pharmaceutical, toxicological and galenic pharmaceutical industry, to use the procedures of the clinical laboratory, to correctly analyze and interpret the diagnostic data and to cooperate in clinical reasoning.

LEARNING OUTCOMES

The learning outcomes expected from the integrated teaching Molecular Biology and Clinical Pathology are consistent with the provisions from the Bologna Process and are found within the Dublin descriptors as follows:



Knowledge and understanding

At the end of the course, the student must demonstrate:

- know and understand the mechanisms of action, adverse effects, relevant pharmacological interactions, of the drug classes treated
- demonstrate the ability to link the knowledge acquired in pharmacokinetics and pharmacodynamics with the toxic and therapeutic effects of the various drug classes treated
- understand the activity of drugs in relation to their interactions with specific targets, both at cellular and systemic level
- know the organization of the clinical laboratory throughout the diagnostic process
- demonstrate knowledge and understanding of laboratory analytical techniques, with particular reference to those used in pharmacology laboratories
- know the importance of alterations in biochemical processes as a cause of various relative pathological states
- know the technologies used for the analysis of drug response

Applying knowledge and understanding

- At the end of the integrated teaching, the student must be able to use the knowledge acquired for an autonomous application of the aspects related to the activity to which he will dedicate himself in his professional field, whether in the pharmaceutical industry or in the healthcare field and therefore:
- Know and understand the toxic and therapeutic effects of the pharmacological classes treated
- Know and understand the technologies for the analysis of drugs and be able to adequately identify and select them based on the specific case
- Know and understand the methods of preparation and conservation of the clinical sample for pharmacodynamic and pharmacokinetic analyses and be able to appropriately identify them based on the need
- Know and understand how to interpret the importance of alterations in biochemical processes as a cause of various relative pathological states
- must also have developed the ability to update themselves through critical reading and understanding of scientific articles published in international journals

Communication

At the end of the integrated teaching, the student must be able to communicate the scientific and applicative contents studied in a clear and unequivocal way, using the specific scientific terminology and using an appropriate technical language. Students should also able to independently elaborate a clinical/diagnostic reasoning in the pharmacological field.

Making judgements



At the end of this teaching, the student will be able to:

- Carry out assessments of the topics covered.
- Autonomously interpret the data pertaining the topics covered by the course

Lifelong learning skills

At the end of the course the student must be able to deepen and keep their knowledge and skills up-to-date by consulting scientific literature, databases and specialist websites, grasping the fundamental and relevant aspects for their professional context

SYLLABUS

PHARMACOTOXICOLOGY AND PHARMACEUTICAL GALENICS

• Principles of general pharmacology: definition of drug; classification and nomenclature of drugs; desired and undesired effects of drugs.

- General principles of pharmacokinetics: routes of administration, absorption, distribution, metabolism, elimination of drugs.
- Pharmacogenomics: individual variability and response to drugs, variations in target proteins, variations in enzymes responsible for drug metabolism.
- Principles of toxicology; toxicokinetics; mechanisms of intoxication and detoxification; main sources of toxicity; toxic effects of drugs
- General principles of pharmacodynamics: receptors and mechanisms of action of drugs.
- Development of new drugs: general principles of pharmacological sensitivity tests conducted in vitro; preclinical studies, experimental models of pathologies and clinical trials.
- Pharmacology of the autonomic nervous system (parasympathomimetics and cholinergic antagonists; sympathomimetics and adrenergic antagonists).
- Pharmacology of the central nervous system (anxiolytics, antipsychotics, antidepressants, drugs for neurodegenerative diseases)
- Special Pharmacology; general characteristics of the following classes of drugs: anti-

inflammatories, antihistamines, opioid analgesics, immunosuppressants, antimicrobial agents, and antitumor agents, notes on gastrointestinal, pulmonary, and cardiovascular pharmacology.

• Principles of pharmaceutical galenics, techniques for galenic and pharmaceutical preparations, auxiliary substances in galenic preparations: solvents, excipients, preservatives. Techniques applied in UFA laboratories and in CAR-T therapies.

SPECIAL CLINICAL BIOCHEMISTRY

• From the collection of the biological sample to the report: Pre-preanalytical phase, preanalytical phase, analytical phase, post-analytical phase, interpretation of the results.

• Analytical groupings: Blood, urine, feces, liquor, hair and saliva.

• Biochemical-clinical profiles of relevance: Glucose profile, protein profile, lipid profile, vitamin profile.

• Analytical techniques for Pharmacodynamic analysis: Mass spectrometry in the clinical laboratory. Potential and applications.



COURSE STRUCTIRE

The Integrated teaching will be organized in lectures, seminars and interactive teaching activities, aimed at facilitating learning.

PHARMACOTOXICOLOGY AND PHARMACEUTICAL GALENICS: The teaching is structured in 30 hours of lectures, divided into lessons of 2-4 hours, based on the academic calendar. The lessons will include theoretical topics and integrative seminars on the topics covered.

SPECIAL CLINICAL BIOCHEMISTRY: The teaching is structured in 20 hours of lectures, divided into lessons of 2-3 hours, based on the academic calendar. The lessons will include theoretical topics and integrative seminars on the topics covered.

COURSE GRADE DETERMINATION

The exam is a single one for the entire integrated course and it is not possible to take exams for individual courses.

The exam consists of a written test including multiple choice questions for each individual course. The score associated with the correct answer will be indicated on the test. No penalty will be assigned for unanswered questions or incorrect answers. Students will have 60 minutes to complete the test. The exam will be passed with a minimum score of 18/30. The total score obtained, even if sufficient, will not be considered valid for passing the test if the student has not answered sufficiently to the questions relating to even just one course.

Students who pass the written test may accept the grade or ask to complete the evaluation with an oral test.

During the oral exam, the student must demonstrate adequate skills relating to the Course. In particular, the student must demonstrate: I) understanding of the topics learned; ii) appropriate use of technical terms relating to both disciplines; iii) clarity of exposition; iv) ability to connect the knowledge acquired; v) in-depth analysis of the topics covered.

In the evaluation grade, knowledge and understanding represent up to 40%, the application of knowledge and understanding represents up to 40% and independent judgment represents up to 20% of the final grade

The final evaluation derives from the weighted average of the CFU of the two courses. The exam will be evaluated overall according to the following criteria:

Not suitable: Poor or lacking knowledge and understanding of the topics; limited capacity for analysis and synthesis, frequent generalizations of the requested contents; inability to use technical language.

18-20: Just sufficient knowledge and understanding of the topics, with obvious imperfections; just sufficient capacity for analysis, synthesis and autonomy of judgment; poor ability to use technical language.

21-23: Sufficient knowledge and understanding of the topics; sufficient ability to analyze and synthesize with the ability to reason with logic and coherence the required contents; sufficient



ability to use technical language.

24-26: Fair knowledge and understanding of the topics; discrete ability to analyze and synthesize with the ability to rigorously argue the required contents; good ability to use technical language

27-29: Good knowledge and understanding of the required contents; good ability to analyze and synthesize with the ability to rigorously argue the required contents; good ability to use technical language.

30-30L: Excellent level of knowledge and understanding of the required contents with an excellent ability to analyze and synthesize with the ability to argue the required contents in a rigorous, innovative and original way; excellent ability to use technical language

OPTIONAL ACTIVITIES

In addition to the frontal teaching activity, students can be received by individual teachers by requesting an appointment via email.

BIBLIOGRAPHY AND READING MATERIALS

PHARMACOTOXICOLOGY AND PHARMACEUTICAL GALENICS

- Di Giulio et al. Farmacologia generale e speciale per le lauree sanitarie. Piccin, seconda edizione
- Amico Roxas et al. Compendio di farmacologia generale e speciale, seconda edizione EDRA 2021
- Clementi F., Fumagalli G. FARMACOLOGIA GENERALE E MOLECOLARE 5a edizione EDRA 2018.
- C. Colombo, F. Alhaique, C. Caramella, B. Conti, A. Gazzaniga, E. Vidale. Principi di Tecnologia Farmaceutica. Zanichelli 2015.
- Teaching material provided by the teacher during the lessons

SPECIAL CLINIC BIOCHEMISTRY

- Biochimica clinica essenziale, dal laboratorio ai quadri di patologia clinica. Elisabetta Albi Tommaso Beccari Samuela Cataldi. Zanichelli 2019.
- Teaching material provided by the teacher during the lessons