Degree in Biomedical Laboratory Technician

Course: Clinical Biochemistry and Pharmaceutical Toxicology
SSD: BIO/12, BIO/14
Number of CFU: 5
Responsible Teacher: Costanza Montagna
Email: costanzamontagna@unicamillus.org

Module: **Pharmacotoxicology and Pharmaceutical Galenics**
SSD: BIO/14
CFU Number: 3
Teacher: Savina Apolloni
Email: savina.apolloni@uniroma2.it

MODULE: Special Clinical biochemistry
CFU: 2
SSD: BIO/12
PROFESSOR: Costanza Montagna
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Student's reception hours via e-mail

PREREQUISITES
Basic concepts in chemistry, biochemistry, molecular and cellular biology, genetics, general physiology, and pathology are required to better understand the course content. In order to learn the contents of the Special Clinical Biochemistry module, it is necessary to have mastered the fundamental concepts acquired in the teaching General Biochemistry, Clinical Biochemistry and Physiology.

LEARNING OBJECTIVES
The course aims to acquire the fundamental principles of pharmacokinetics, pharmacodynamics, toxicology, and pharmaceutical galenics, which form the basis for conducting biochemical and pharmacogenetic tests in diagnostic and research laboratories, as well as the theoretical foundations for the preparation of galenic drugs. Students should be familiar with the scientific rigor and methodological approach underlying the development of new drugs. They should also learn the fundamental aspects related to the therapeutic use of the most frequently used drug classes. These objectives will be achieved through lectures, seminars, and interactive educational activities designed to facilitate learning and enhance the ability to address and resolve key issues in the pharmaceutical, toxicological, and pharmaceutical galenic industries. The educational objectives of the module of **Special Clinical Biochemistry** are aimed at acquiring knowledge of the main methodologies used in clinical biochemistry; understanding the significance of alterations in biochemical-clinical relevant profiles.

LEARNING OUTCOMES
The expected learning outcomes align with the European Qualifications Framework (Dublin

Descriptors) as follows:

Knowledge and Understanding
By the end of the module, the student should demonstrate knowledge and understanding of the mechanisms of action, adverse effects, relevant pharmacological interactions of the drug classes studied, and the ability to connect the acquired knowledge of pharmacokinetics and pharmacodynamics with the toxic and therapeutic effects of various drug classes. The student should understand drug activity in relation to their interactions with specific targets, both at the cellular and systemic levels. Additionally, the student should have developed the ability to stay updated through critical reading and comprehension of scientific articles published in international journals. Finally, the student should demonstrate knowledge and understanding of laboratory analytical techniques, particularly those used in pharmacology laboratories. At the end of the **integrated course**, the student should be able to communicate clearly and unequivocally the scientific and applied contents covered in the two modules, using appropriate technical language, including with independent judgment to make broad assessments related to the topics covered. He/she should know the steps from biological sample collection to the reports; know the analytical groupings and profiles of biochemical-clinical relevance.

Ability to apply knowledge and understanding
By the end of the module, the student should be able to use the acquired knowledge for independent further study of the aspects related to their professional activities. The student should be able to use the knowledge acquired during the integrated course, for the autonomous in-depth study of aspects related to the specific field to which he/she will devote himself/herself in the context of professional activity. This should also be done with autonomy of judgment that will enable them to make broad assessments related to the topics covered, regarding the biochemistry and its links with other fundamental disciplines such as clinical biochemistry and physiology. In addition, the student will need to: Know the steps from biological specimen collection to the final reporting; Know the analytical groupings; Know The biochemical-clinical relevance profiles.

Communication Skills
The student should be able to present acquired knowledge clearly and with appropriate technical language, using specific scientific terminology.

Judgment Skills
At the end of the module, the student should be able to make preliminary evaluations regarding the topics covered.

COURSE SYLLABUS

PHARMACOTOXICOLOGY AND PHARMACEUTICAL GALENICS
General principles of pharmacology: drug definition, drug classification, and nomenclature; desired and undesired effects of drugs.
General principles of pharmacokinetics: routes of administration, absorption, distribution, metabolism, elimination of drugs.
Pharmacogenomics: individual variability and drug response, variations in target proteins, variations in drug-metabolizing enzymes.
General principles of toxicology; toxicokinetic; mechanisms of intoxication and detoxification; main

sources of toxicity; toxic effects of drugs.

General principles of pharmacodynamics: receptors and mechanisms of drug action.

Development of new drugs: general principles of in vitro pharmacological sensitivity tests, preclinical studies, experimental models of diseases, 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 drug classes: anti-inflammatories, antihistamines, opioid analgesics, antimicrobial agents, antitumor drugs, brief overview of 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 CAR-T therapies.

SPECIAL CLINICAL BIOCHEMISTRY
From biological sample collection to reporting
Pre-pre-analytical phase, pre-analytical phase, analytical phase, post-analytical phase, interpretation of results.
Analytical groupings
Blood, urine, feces, CSF, hair, and saliva.
Profiles of biochemical-clinical significance
Glucose profile, protein profile, lipid profile, profile. vitamin profile.

TEACHING METHODS
PHARMACOTOXICOLOGY AND PHARMACEUTICAL GALENICS
The module consists of 30 hours of frontal teaching, divided into 2-4 hour lectures based on the academic calendar. The lessons will cover theoretical topics and complementary seminars on the subjects discussed.
SPECIAL CLINICAL BIOCHEMISTRY
The module of special biochemistry is structured in 2 or 3 hours lessons (20 hours in total)

ASSESSMENT METHODS
Learning will be assessed through a written exam, followed by an oral examination. The written exam will consist of 30 multiple-choice questions, with one point awarded for each correct answer. The final score for the written exam will be the sum of the partial scores assigned to each correct answer. To access the oral exam, students must have a minimum of 18 points. During the oral exam, the student must demonstrate adequate competencies related to the course. Specifically, the student must demonstrate: i) understanding of the learned topics; ii) appropriate use of technical terms related to pharmacology; iii) clarity of presentation; iv) ability to connect acquired knowledge; v) in-depth understanding of the topics discussed.

For special biochemistry, final exams consist of a multiple-choice test.

The grade will be expressed in thirtieths, ranging from a minimum of 18 to a maximum of 30 cum laude.

In the final assessment, knowledge and understanding represent up to 40%, the application of knowledge and understanding represents up to 40%, and the ability to make judgments represents up to 20% of the final grade.

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

The examination will be graded overall according to the following criteria:

Unsuitable: major deficiencies and/or inaccuracies in knowledge and understanding of topics; limited analytical and synthesis skills, frequent generalizations

18-20: barely sufficient knowledge and understanding of topics, with possible imperfections; sufficient skills of analysis, synthesis and independent judgment.

21-23: routinized knowledge and understanding of topics; correct analysis and synthesis skills with coherent logical argumentation.

24-26: fair knowledge and understanding of topics; good analytical and synthesis skills with rigorously expressed arguments.

27-29: complete knowledge and understanding of topics; remarkable skills of analysis, synthesis. Good autonomy of judgment.

30-30L: excellent level of knowledge and understanding of topics. Remarkable analytical and synthesis skills and autonomy of judgment. Arguments expressed in an original way

OPTIONAL ACTIVITIES
Not specified.

RECOMMENDED TEXTBOOKS AND BIBLIOGRAPHY

Pharmacotoxicology and Pharmaceutical Galenics
- Di Giulio et al. "Farmacologia generale e speciale per le lauree sanitarie." Piccin, second edition
- Amico Roxas et al. "Compendio di farmacologia generale e speciale, second edition." 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.
- Other materials and scientific articles indicated by the teacher.

Special Clinical Biochemistry
- Biochimica clinica essenziale, dal laboratorio ai quadri di patologia clinica. Elisabetta Albi Tommaso Beccari Samuela Cataldi. Zanichelli 2019.