IV year (1st – 2nd semester) A.Y. 2025-2026	Scientific Field	**PHARMACOLOGY**	TUTOR	CFU
GRAZIANI GRAZIA. **COORDINATOR**	BIOS-11/A (BIO/14)	Pharmacology 1	Grazia Graziani	1
	BIOS-11/A (BIO/14)	Pharmacology 1	Maria Luisa Barbaccia	1
	BIOS-11/A (BIO/14)	Pharmacology 1	Ornella Franzese	1
	BIOS-11/A (BIO/14)	Pharmacology 1	Claudia Ceci	2
	BIOS-11/A (BIO/14)	Pharmacology 2	Grazia Graziani	3
	BIOS-11/A (BIO/14)	Informatics	Grazia Graziani	1
	BIOS-11/A (BIO/14)	Medical Statistics	Grazia Graziani	1
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SPECIFIC AIMS	The course of pharmacology will cover the most important topics of modern pharmacology through formal lectures, seminars and lectures on specific topics. At the end of the course, the students should demonstrate knowledge on: a) the principles of pharmacokinetics, pharmacodynamics and pharmacogenetics; b) the molecular/cellular mechanisms of action of different classes of therapeutic drugs; c) their therapeutic indications; d) their adverse effects/contraindications; e) the increasingly studied role of gender/sex in modulating the therapeutic and undesired effects of various classes of medicines. Students should also learn the principles of toxicology, the major and clinically important drug-drug interactions, methodology of clinical pharmacological research and of pharmacovigilance and how to critically read clinical study reports.

PROGRAM **PHARMACOLOGY**	PROGRAM OF THE PHARMACOLOGY EXAMINATION - Preclinical research and steps of clinical development of drugs. - Pharmacokinetics; - Pharmacodynamics; - Pharmacogenetics/Pharmacogenomics; - Drug side effects and basic principles of toxicology; - Drugs acting at the autonomic nervous system; - Drugs acting at the central and peripheral nervous system; - Drugs for pain, inflammation and fever; - Cardiovascular drugs; - Drugs for GI tract, lung, kidney and biliary tract diseases; - Drugs acting on the endocrine system; - Immunopharmacology; - Antimicrobial agents; - Anti-bacterial agents; - Anti-mycobacterial agents; - Antifungal agents; - Antiviral drugs; - Antiprotozoal drugs; - Anthelminthic drugs; - Anti-cancer agents; - Cytotoxic agents; - Differentiating agents; - Targeted therapies and other anticancer drugs; - Hormonal agents for cancer treatment.

TOPICS PHARMACOKINETICS	- Routes of drug administration, dynamics of drug absorption and distribution; - Drug metabolism; drug elimination; - Drug kinetics after single or repeated administration; - Bioavailability and bioequivalence.

TOPICS PHARMACODYNAMICS	- Mechanisms of drug action and relationships between drug concentration and effect; - On-target and off-target effects of drugs; - Drug-receptor interaction, structure-activity relationship (agonist, antagonist, partial agonist, allosteric modulator; inverse agonist; “biased ligands”); - Receptor modulation by repeated exposure to drugs; - Mechanisms of tolerance/dependence to drugs; - Drug-drug, drug-food, drug-microbiota interactions that may impact on medicine’s therapeutic and/or side effects;

TOPICS PHARMACOGENETICS	Genetically determined variability of drug metabolism and response to drugs.

TOPICS DRUG SIDE EFFECTS AND BASIC PRINCIPLES OF TOXICOLOGY	- Risk/benefit ratio of drugs – therapeutic index; - Adverse drug reactions (ADRs), suspected unexpected serious adverse reactions (SUSARs); - Tolerance and physical dependence, - Evaluation of drug and xenobiotic toxicity (dose-effect and time-effects relationships).

TOPICS DRUGS ACTING AT THE AUTONOMIC NERVOUS SYSTEM	- Cholinergic (muscarinic and nicotinic) agonists and antagonists; - Anticholinesterase agents; - Catecholamines, sympathomimetic drugs and adrenergic antagonists; - Agents active at autonomic ganglia.

TOPICS DRUGS ACTING AT THE CENTRAL AND PERIPHERAL NERVOUS SYSTEM	- Drugs acting at the neuromuscular junction; - Neurotransmitters, neuromodulators and neuro-hormones and their receptors; - Drugs for: anxiety (anxiolytics); hypnosis/sedation (sleep-inducers); psychosis (antipsychotics); mood disorders (antidepressants, lithium salts, mood stabilizers); epilepsy; Parkinson disease; Alzheimer's and non-Alzheimer's dementia; spasticity; - Antiemetic drugs; - Drug dependence (alcohol, opioids, barbiturates, psychostimulants, hallucinogens); - General and local anesthetics; - Drugs for appetite control, anti-obesity approaches;

TOPICS DRUGS FOR PAIN, INFLAMMATION AND FEVER	- Prostaglandins, thromboxanes, prostacyclins, leukotrienes; - Non-steroidal anti-inflammatory drugs (NSAIDs): COX-1 and COX-2 non-selective inhibitors; COX-2 selective inhibitors; - Steroidal anti-inflammatory drugs (glucocorticoids); - Drugs specific for migraine [triptans, ditans, CGRP-receptor antagonists/gepants, anti–CGRP and –CGRP-receptor monoclonal antibodies (mAbs)]; - Opioids (weak and strong agonists, antagonists); - Drugs for gout; - Anti-rheumatics (symptomatic, disease-modifying antirheumatic drugs or DMARDs, biologics).

TOPICS CARDIOVASCULAR DRUGS	- Anti-hypertensive drugs [diuretics (thiazides, loop, MRA, K-sparing), sympatholytic, direct vasodilators, calcium channel blockers, renin-angiotensin system inhibitors]; - Drugs for shock; - Drugs for myocardial infarction; - Drugs for heart failure (acute and chronic/pulmonary edema): diuretics, renin-angiotensin system inhibitors, ARNI (angiotensin antagonist-neprilisin inhibitor), SGLT2-inhibitors, ranolazine, ivabradine, digoxin, parenteral positive inotropic drugs; - Drugs for pulmonary hypertension (prostaglandin analogues, endothelin-R antagonists, NO and NO pathway activators, phosphodiesterase type 5 inhibitors) - Drugs for coronary artery disease (CAD); - Drugs for dyslipidemias (statins, anti-PCSK9 drugs [mAbs, si-RNA], bempedoic acid, ezetimibe, fibrates, resins, niacin/vit B3), microsomal triglyceride transfer protein (MTP) inhibitors, anti-Lp(a); - Inhibitors of platelet aggregation (aspirin, ADP-receptor antagonists, PAR antagonist); - Anticoagulants (parenteral, oral: indirect/direct acting and their antidotes); - Fibrinolytic drugs; - Anti-hemorrhagic (anti-fibrinolytic); - Drugs for anemia (erythropoietin, iron, folic acid, vitamin B12) - Antiarrhythmic drugs.

TOPICS DRUGS FOR GI TRACT, LUNG, KIDNEY AND BILIARY TRACT DISEASES	- Drugs for gastric acid control (anti-H2, antacids, proton pump inhibitors); - Prokinetics, drugs to treat diarrhea; - Drugs for ulcerative colitis, Crohn's disease, irritable bowel syndrome; - Drugs for gallstones; - Drugs for asthma.

TOPICS DRUGS ACTING ON THE ENDOCRINE SYSTEM	- Androgens, estrogens, progestins and their antagonists/synthesis inhibitors and receptor modulators; - Selective estrogen receptor modulators (SERMs); - Adrenal hormones and their antagonists/synthesis inhibitors; - Drugs for the thyroid; - Insulin, oral and parenteral hypo/anti-hyperglycemic drugs [metformin, sulphonylureas, glitazones, incretins (GLP1-RA, gliptins), sGLT2 inhibitors; acarbose]; - Drugs for uterine motility; - Anabolic steroids; - Drugs for osteoporosis [bisphosphonates, anti-RANK-L mAb (denosumab), teriparatide, anti-sclerostin mAb [romosozumab], strontium ranelate, estrogens, SERMs, SEEM (tibolone), calcitonin].

TOPICS IMMUNOPHARMACOLOGY	- Leukocytes stimulating factors; - Immunosuppressive drugs

TOPICS ANTIMICROBIAL AGENTS	General Principles of anti-microbial therapy (classification; drug resistance; pharmacokinetics; mechanism of action; rational basis for drug selection and drug association; empirical, definitive and prophylactic therapy). Antimicrobial resistance: a threat to public health. The antimicrobial resistance situation in Europe. Mechanisms of resistance to antimicrobial agents. Infections caused by methilcillin-resistant *Staphylococcus Aureus* (MRSA), vancomycin-resistant *Enterococcus faecium* (VRE), multi-drug-resistant Gram-negative bacteria [e.g., carbapenem-resistant *Enterobacteriaceae* (CRE), carbapenem-resistant *Acinetobacter baumannii* (CRAB), carbapenem-resistant *Pseudomonas aeruginosa*), multi-drug-resistant *Mycobacterium tuberculosis*, multi-drug-resistant *Plasmodium Falciparum*] and therapeutic options available.

TOPICS ANTI-BACTERIAL AGENTS	Penicillins; cephalosporins; monobactam; carbapenems; β-lactamase inhibitors; glycopeptides; lipoglycopeptides; lipopeptides; cycloserine; fosfomycin; bacitracin; aminoglycosides; tetracyclines and glycylcyclines; macrolides and ketolides; lincosamides; streptogramins; chloramphenicol; oxazolidinones; sulfonamides and trimethoprim; fluoroquinolones; metronidazole, fidaxomicin, bezlotuxumab, polymixins, bacitracin.

TOPICS ANTI-MYCOBACTERIAL AGENTS	Isoniazid; rifamycins; pyrazinamide; ethambutol; ethionamide; bedaquiline; delamanid; pretomanid; clofazimine; dapsone; anti-mycobacteria agents for multi-drug-resistant (MDR) and extensively drug-resistant (XDR TB) tuberculosis.

TOPICS ANTIFUNGAL AGENTS	Amphotericin B; flucytosine; imidazoles and triazoles; echinocandins; griseofulvin; terbinafine; nystatin.

TOPICS ANTIVIRAL DRUGS ANTIRETROVIRAL DRUGS	Anti-herpes, anti-influenza, anti-hepatitis B, anti-hepatitis C, anti-hepatitis D, anti-RSV agents, anti-SARS-CoV-2 agents: remdesivir; molnupinavir; nirmatrelvir/ritonavir, agents used for non-hospitalized and hospitalized COVID-19 patients; Anti-HIV agents: nucleoside and nucleotide reverse transcriptase inhibitors; non-nucleoside reverse transcriptase inhibitors; protease inhibitors; entry inhibitors; integrase inhibitors; ibalizumab.

TOPICS ANTIPROTOZOAL DRUGS	Metronidazole; pentamidine; eflornithine; suramin; melalsoprol; miltefosine; nifurtimox and benznidazole; sodium stibogluconate; antimalarial agents: artemisinin and derivatives; atovaquone; pyrimethamine; proguanil; quinolines.

TOPICS ANTIHELMINTHIC DRUGS	Benzimidazoles; diethylcarbamazine; ivermectin; praziquantel; pyrantel pamoate.

TOPICS ANTI-CANCER THERAPY	General Principles of anti-cancer pharmacological treatment (classification, drug resistance, mechanisms of action; rational bases for drug selection and drug association).

TOPICS CYTOTOXIC AGENTS	- Alkylating and platinum agents; - Antimetabolites: folic acid analogues, purine and pyrimidine analogues; - Microtubule damaging agents: vinca alkaloyds, taxanes, epothilones, eribulin, estramustine; - Camptothecin analogues; - Antibiotics: dactinomycin, anthracyclines, mitoxantrone; - Bleomycin; - Mitomycin C; - Epipodophyllotoxins; - Trabectedin; - L-asparaginase; - Hydroxyurea.

TOPICS DIFFERENTIATING AGENTS	- Retinoids; - Arsenic trioxide; - Histone deacetylase inhibitors; histone methyltransferase inhibitors.

TOPICS TARGETED THERAPIES	- Kinase inhibitors, monoclonal antibodies; antibody fragments and antibody-drug conjugates; - Proteasome inhibitors; - mTOR inhibitors; - Immunomodulatory Drugs (IMiDs): thalidomide, lenalidomide and pomalidomide;

AND OTHER ANTICANCER DRUGS	- Poly(ADP-ribose) polymerase (PARP) inhibitors; IDH inhibitors, Bcl2 inhibitors; SMO inhibitors
TOPICS HORMONAL AGENTS FOR CANCER TREATMENT	- Selective estrogen-receptor modulators (SERM) and down-regulators (SERD), aromatase inhibitors, gonadotropin-releasing hormone agonists and antagonists; - Anti-androgens.
TEXTBOOKS	Goodman and Gilman's The Pharmacological Basis of Therapeutics, 14th edition (2023), Laurence L Brunton, Björn C. Knollmann (eds), McGraw Hill. Katzung's Basic and Clinical Pharmacology. 16th edition, Todd W. Vanderah, McGraw Hill, 2024
EXAM METHOD	The exam will be oral. According to the student's preference, the exam can be taken in one single session or may be split in two parts (in two different days/sessions): a) general pharmacology (PK/PD), cardio/neuro-psycho/GI/endocrine pharmacology, etc. b) general pharmacology (PK/PD), antimicrobial and antiviral agents, and anti-cancer drugs **EVALUATION** **Failed exam:** Poor or lacking knowledge and understanding of the topics; limited ability to analyze and summarize data and information, frequent generalizations of the requested contents; inability to use technical language. **18-20:** Barely sufficient knowledge and understanding of the topics, with obvious imperfections; barely sufficient ability to analyze, summarize data and information, and limited autonomy of judgment; poor ability to use technical language. **21-23:** Sufficient knowledge and understanding of the topics; sufficient ability to analyze, summarize data 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; adequate ability to analyze and summarize data and information with ability to rigorously discuss the required contents; good ability to use technical language. **27-29:** Good knowledge and understanding of the required contents; good ability to analyze and summarize data and information together with ability to rigorously discuss and present 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 data and information with the ability to discuss and present the required contents in a rigorous, innovative and original way; excellent ability to use technical language.
EXAM COMMISSION	The Coordinator, full Professors of the disciplines, Professors of similar disciplines, Specialists of the subject, compose the exam Commission of the Integrated Course.

Graziani Grazia, President
Maria Luisa Barbaccia
Franzese Ornella
Ceci Claudia

CONTACTS

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PREREQUISITES: It is necessary to have previous knowledge and competence in the following subjects: Human anatomy1, Histology and Embryology, Biology and genetics, Chemistry and Biochemistry, Microbiology, General Pathology.

KNOWLEDGES AND ABILITIES TO ACQUIRE:

At the end of the course, the student should be able to:

1. Knowledge and Understanding

- Provide a comprehensive knowledge of the fundamentals of pharmacology and therapeutic uses of the major classes of clinically important drugs currently used in medical practice.
- Discuss basic scientific concepts and principles that will serve as the foundation for understanding the pharmacology of specific drugs, such as the pharmacokinetics, metabolism, dosing, toxicity.
- Understand the scientific basis underlying how two different drugs can interact within the body and reciprocally modify the respective plasma concentration and/or clinical effects.
- Understand the pharmacology and clinical use of the major class of clinically important drugs, focusing on indication, mechanism of action, pharmacokinetic, adverse effects, contraindications and drug interaction.
- Discuss interventions for effective treatment and mechanisms of health maintenance to prevent disease.

2. Applying Knowledge and Understanding

- Apply theoretical knowledge to the clinical and laboratory setting, being able to recognize the general diagnostic aspects of diseases and specific therapeutic possibilities.
- Become familiar with procedures for performing and reporting laboratory experiments.
- Demonstrate ability towards problem-solving (i.e., if a patient shows a lack of response to a drug or does not tolerate it, propose one among available alternatives).
- Provide a differential diagnosis based on given specific clinical data and hypothesize the most suitable among the available therapeutic approaches.

3. Making Judgements

- Recognize the importance of an in-depth knowledge of the topics consistent with proper medical education.
- Identify the benefits and adverse effects of any diagnostic and therapeutic interventions.
- Identify the fundamental role of a proper theoretical knowledge of the subject in clinical practice.

4. Communication Skills

- Give an oral presentation of topics in an organized and consistent manner.
- Utilize a proper scientific language coherent with the topic of discussion and adequate to the level of understanding of the interlocutor.

5. Learning Skills

- Be able to adapt thinking and behavior according to specific learning/work needs.
- Marshal the ever-growing amount of scientific evidence to optimize her/his medical education process.