Name of the discipline	**Bioequivalence of drugs and biosimilar products**			
Type	Optional		Credits	2
Year of study	V		semester	IX
Number of hours	course	13	Practical/laboratory work	
	SEMINARS	26	Individual work	21
compound	Specialized			
Course holder	PhD in Pharmaceutical Sciences, Associate Professor Uncu Livia			
location	Malina Mica, 66			
Prerequisites and requirements of:	Program: Bioequivalence of drugs and biosimilar products requires multidisciplinary prerequisites, which combine previously acquired knowledge in inorganic chemistry, organic chemistry, physical chemistry, pharmaceutical and toxicological chemistry, pharmaceutical technology and correlate with other specialized disciplines such as medicinal chemistry, biopharmacy and pharmacology.			
	Skills: Knowledge of chemical structures; chemical and physicochemical analysis techniques; elements of pharmacokinetics and biotransformation of drugs; mathematical and statistical calculations; basic digital skills (use of the Internet, document processing, use of text editors, spreadsheets and presentation applications), communication and teamwork skills.			
The mission of the discipline	Bioequivalence of drugs and biosimilar products discipline is to develop the methodology and strategy for assessing the pharmaceutical and biological equivalence of original and generic medicines, in accordance with national and international requirements; elucidating the importance of studying medical and pharmaceutical aspects, such as: the physicochemical properties of the medicinal substance, the role of excipients, the pharmacokinetic parameters of the studied substances, other factors that influence bioavailability.			
The topic presented	Bioequivalence of drugs, objectives and problems. The purpose of the provisions on bioequivalence studies. National and European regulatory framework. Bioequivalence study - one of the types of clinical studies of drugs. Terminology. Normative basis of the Republic of Moldova. Regulations for studying bioequivalence. Bioavailability. General considerations. Biopharmaceutical classification system for medicinal products. Determination of bioavailability. Biological barriers to the transport of medicinal substances. The extent of absorption or bioavailability. The use of plasma and urinary levels of metabolites to determine bioavailability. Categories of products for which bioequivalence studies are required. Methodology of a bioequivalence study. Study planning and preliminary stages. Study protocol. In vitro dissolution test. Its importance in pharmaceutical bioavailability research. Norms for bioequivalence. Method of quantitative determination. Method validation. Pharmaceutical products involving a route of administration with a preabsorptive stage.			
Study purposes	• have the ability and willingness to analyze the bioequivalence study of medicines using the methods necessary for the proposed purpose ; • have the ability and capacity to evaluate and interpret the results of a drug bioequivalence study ;			

	• to have the ability and availability to determine the characteristics physicochemical properties of the forms pharmaceuticals, including tablets, capsules, ointments and others. • to know the pharmacokinetic parameters necessary for the bioequivalence study; • have the ability and willingness to provide advice to medical workers and consumers of medicines and other pharmaceutical products; • to be able to work with literature scientific, to can effect the search information scientific, to consider information obtained , to turn the information found into a problem - solving tool professional.
Purchased practical skills	• planning and execution of a pharmaceutical equivalence study; • application of instrumental methods in bioequivalence studies; • biopharmaceutical evaluation of drugs from various pharmacotherapeutic classes; • assessing the bioavailability of different types of pharmaceutical forms; • calculating bioavailability parameters and their comparative assessment for original and generic drugs; • informing and advising patients and healthcare professionals regarding bioequivalence.
Evaluation form	Exam.