Name	**Introduction in Good Pharmaceutical Practice**			
Type	Optional		Credits	2
Year of studied	II		semester	III
Number of hours	course	15	Practical/laboratory	
	SEMINARS	30	Individual work	15
Compound	Specialized			
Holder course	Valica Vladimir, PhD in pharmaceutical sciences, Professor			
Location	Malina mica, 66			
Requirements	Program: knowledge of chemistry general, inorganic, organic, chemistry biological, physiology, biology molecular, microbiology.			
	Competencies: It is a multidisciplinary field that lays the foundation for understanding the need for further specialized courses such as pharmaceutical chemistry, control of drugs, technology of drugs, pharmacology.			
Mission	Introduction to Good Pharmaceutical Practices is a necessary discipline for pharmacy students, as it will allow deeper integration of previously acquired knowledge and offers students the opportunity to integrate knowledge from pharmaceutical disciplines and to substantiate the practical skills required in specialized disciplines. Introduction to Good Pharmaceutical Practices is intended to help future pharmacists become familiar with contemporary requirements in GMP (Good Manufacturing Practices) and GLP (Good Laboratory Practices) used in drug technology, in the standardization and control of drugs, as well as to develop the practical skills necessary to ensure the quality of medicines.			
Topics	Good pharmaceutical practices. General considerations. The importance of good pharmaceutical practices in obtaining safe and harmless quality medicines. Basic GMP criteria. Basic GMP criteria. Guide to a Good Manufacturing Practice for Medicines. Structure, definition of the most important terms in RBPFM. Notions of Quality Management. Requirements for personnel, premises and equipment. Production requirements and quality control described in the RBFM guide. Possibilities of contract manufacturing and control. Importance of complaints and self-inspection. Documentation in RBFM. Standard Operating Procedures. Laboratory Practice Guide. Introduction and terminology. Definitions and deciphering the most important terms used in preclinical studies. Moldovan and international legislation in the field of preclinical studies and animal protection. Peculiarities of preclinical studies on laboratory animals. Notions of experimental pharmacotoxicology. Modeling pathologies in preclinical studies . Organization and conduct preclinical studies. Essential documents for conducting a preclinical study. Requirements for personnel, premises, equipment, test systems, animals. Quality management in preclinical studies. Standard Operating Procedures in GLP: introduction, general data, principles of elaboration. Reporting of results studied preclinical. Inspections and auditor in the study preclinical. Principles for preparing the preclinical study completion report. Reference documents. Types audit and Inspection report.			

Learning Outcomes	• To understand the characteristics of good pharmaceutical practices; • To be able to identify the main types of errors in the implementation process of good pharmaceutical practices; • To formulate conclusions regarding the implementation of good pharmaceutical practices; • To apply the acquired knowledge in studying good pharmaceutical practices to ensure the quality of medicines.
Practical maneuvers acquired	• Application of the basic principles of good pharmaceutical practices in the pharmaceutical activity process; • Ensuring efficient execution and effective involvement in group-organized activities. Identifying professional training needs according to the evolution of science in the field of good pharmaceutical practices; • Identifying opportunities for continuous education and effectively utilizing resources and learning techniques for personal development.
Form of ASSESSMENT	Exam