Name of the discipline	**Drug development and pharmaceutical research**			
Type	compulsory		Credits	4
Year of study	IV		semester	VIII
Number of hours	course	15	Practical/laboratory work	45
	SEMINARS		Individual work	60
compound	Specialized			
Course holder	PhD in Pharmaceutical Sciences, Associate Professor Uncu Livia PhD in Pharmaceutical Sciences, Assistant Professor Donici Elena			
location	Malina Mica, 66			
Prerequisites and requirements of:	Program: knowledge of biomedical mathematics and statistics, pharmaceutical chemistry, pharmaceutical technology, pharmacology, toxicology, pharmacognosy.			
	Skills: Knowledge of mathematical calculation methods; chemical structures; advanced digital skills (using the internet, developing and processing Word, Excel documents; using text editors, spreadsheets and presentation applications), communication and teamwork skills.			
The mission of the discipline	To develop skills for carrying out research activities by pharmacy students in compliance with contemporary requirements and standards of modern research in the field of medicine. The need for the course Drug Development and Pharmaceutical Research also arises from the fact that the results of pharmaceutical scientific research make a huge contribution to the development of society and technical and scientific progress. The discipline constitutes a tool for investigating, organizing and communicating experiments and their results and operates with specific notions that must be mastered and applied effectively in the field of research, including for the development and completion of the bachelor's thesis; it provides the necessary data to guide the pharmacy student facing a new experiment or a research project in the pharmaceutical field.			
The topic presented	Fundamental notions of research methodology and pharmaceutical scientific research instruments. Planning and design of a research study. M ethodologies for carrying out pharmaceutical research . Stages of developing a drug. Specialized bibliographic research. Organization, documentation via the Internet (search engines, international scientific databases), writing one's own bibliographic records (classical or electronic system). Critical bibliographic study. Reviewing a specialized scientific article. Processing experimental data. Notions of analyzing experimental results. Basic notions in statistics. Statistical significance tests. Regression and calibration. Validation principles. Validation of analysis methods. Quality control of experimental results and their validation. Drawing up the validation report. Dissemination of research results. Intellectual property. Stability studies in the drug research process. Notions of pharmaceutical dossier. Drawing up the plan of a bachelor's thesis; drawing up a research report.			
Study purposes	• to choose a research topic according to the importance of the topic, problem solving, previous results, information validation; • to correctly formulate a research problem; • to carry out a specialized bibliographic study; • to establish working hypotheses for research; • to choose the study variables correctly;			

	• to use ethical norms in scientific research; • determine the shelf life of a medicine using the classical method and the accelerated degradation method; • to know and apply in practice the principles of validation of a drug dosing method; • to create a review of a specialized scientific article; • to write and edit a specialized scientific article; • to complete a pharmaceutical file.
Purchased practical skills	• formulating the research problem and working hypothesis; • drawing up the research plan and the design of an experiment; • identifying dependent and independent variables in an experimental study; • statistical evaluation of the results of an experimental study; • applying statistical significance tests in data analysis, processing and interpretation; • data evaluation in the validation process of analysis methods and technological processes; • stability assessment and shelf life determination in the process of developing a new drug; • developing the scientific summary, writing the specialized article; • analysis and preparation of the pharmaceutical file for the drug.
Evaluation form	Exam at the end of the semester.