

Subject card

Subject name and code	Validation methods, PG_00054413						
Field of study	Chemistry						
Date of commencement of studies	October 2025		Academic year of realisation of subject		2025/2026		
Education level	Master's studies		Subject group		Obligatory subject group in the field of study Optional subject group Subject group related to scientific research in the field of study		
Mode of study	full-time studies		Mode of delivery		at the university		
Year of study	1		Language of instruction		Polish		
Semester of study	1		ECTS credits		1.0		
Learning profile	academic		Assessment form		credit		
Conducting unit	Laboratory of Natural Products Analysis -> Department of Environmental Analysis -> Faculty of Chemistry -> Rector						
Name and surname of lecturer (lecturers)	Subject supervisor		dr hab. Marek Gołębiowski				
	Teachers						
Lesson types	Lesson type	Lecture	Tutorial	Laboratory	Project	Seminar	SUM
	Number of study hours	15.0	0.0	0.0	0.0	0.0	15
	E-learning hours included: 0.0						
Learning activity and number of study hours	Learning activity	Participation in didactic classes included in study plan		Participation in consultation hours		Self-study	SUM
	Number of study hours	15		2.0		8.0	25
Subject objectives	1. Familiarize the students with the parameters subjected to validation, 2. Acquiring the knowledge about calculations necessary for the validation of analytical methods, 3. Acquiring the knowledge for choosing the right analytical technique, 4. Acquiring the skill of designing of experiments regarding the validation of analytical methods for analysis of selected analytes 5. Acquiring the skill to prepare a validation report for an analytical method						

Learning outcomes	Course outcome	Subject outcome	Method of verification
	[CHEMMU2_W08] Demonstrates knowledge of theoretical computational and IT methods used to solve problems in chemistry.	1. knows and describes the parameters of the method subject to validation 2. can calculate validation parameters of analytical methods, 3. Evaluates the parameters used to validation of analytical methods 4. Consciously evaluates the values of calculated validation parameters	[SW4] test/exam - oral or written
	[CHEMMU2_W09] Classifies specialist IT tools used in statistical evaluation of experiment results.	1. knows and describes the stages of the analysis in the interlaboratory comparisons 2. can calculate validation parameters of analytical methods 3. draws conclusions from the calculated validation parameters 4. Consciously evaluates the values of calculated validation parameters	[SW4] test/exam - oral or written
	[CHEMMU2_W06] Applies mathematics to the extent necessary to understand, describe and model chemical processes of medium complexity.	1. Demonstrates the skills to assess the parameters used to validation of analytical methods 2. Demonstrates the skills to determine the parameters used to validation of analytical methods 3. Evaluates the parameters used to validation of analytical methods	[SW4] test/exam - oral or written
Subject contents	Stages of the validation procedure, validation parameters of the analytical methodology: (precision, accuracy, linearity, measuring range, sensitivity, detection limit, quantification limit, specificity, selectivity, robustness, ruggednes, precision vs. accuracy, precision measures, repeatability, intermediate precision and reproducibility, comparison of the precision of two methods, comparison of the precision of several analytical methods, accuracy vs. trueness, accuracy measures, statistical conclusions on the basis of selected statistical tests, determination of the linearity, range and sensitivity methods on the basis of linear regression, determination of the linearity on the basis of detector response to concentration of analyte ratio, methods of determining the detection and quantification limit, verification of the specificity, selectivity, robustness and ruggednes), Determination of characteristic parameters of the test methods, the characteristics of the analytical procedure, the order of determining the validation parameters, the choice of analytical methods: standardized methods, methods developed in the laboratory, non-standardized methods, alternative methods, the scope of validation, initial validation, re-validation, criteria for validation of microbiological methods, validation methods of analysis of selected analytes (description of the selected analytes, description of the analytical methods, choice of the analytical methods, comparison of the analytical techniques). Inter-laboratory tests, proficiency tests, standardization tests, certification of materials, inter-laboratory comparisons. Stages in the analysis of data from inter-laboratory comparisons. Reference materials in the validation process: types of reference materials (certified and noncertified materials, reference materials with or without matrices), properties of reference materials (representativeness, homogeneity, stability), examples of reference materials.		
Prerequisites and co-requisites	Basic knowledge and skills in statistics are required.		
Assessment methods and criteria	Subject passing criteria	Passing threshold	Percentage of the final grade
	written exam with test and open questions	51.0%	100.0%
Recommended reading	Basic literature	1. Konieczka P., J. Namieśnik i in.: Assessment and quality control of analytical results. Centrum Doskonałości Analityki i Monitoringu Środowiskowego, Gdańsk 2004. 2. Łomnicki A.: Introduction to statistics for naturalists. Wydawnictwo Naukowe PWN, Warszawa 2003 3. Czermiński J. B., A. Iwasiewicz i in.: Statistical methods for chemists. Wydawnictwo Naukowe PWN, Warszawa 1992.	
	Supplementary literature	1. Kabata-Pendias A., B. Szteke (red.): Problems of the quality of trace analysis in research on the natural environment. Wydawnictwo Zofii Dobkowskiej, Warszawa 1998. 2. Mazerski J.: Basics of chemometrics. Wydawnictwo Politechniki Gdańskiej, Gdańsk 2000. 3. Dobosz M.: Computer-aided statistical data analysis. Akademicka Oficyna Wydawnicza EXIT, Warszawa 2001.	
	eResources addresses		
	Example issues/ example questions/ tasks being completed		

Work placement	Not applicable
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