

Subject card

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|--|---|--|-------------------------------------|------------|--|---------|-----|
| Subject name and code | Validation methods, PG_00054413 | | | | | | |
| Field of study | Chemistry | | | | | | |
| Date of commencement of studies | October 2024 | Academic year of realisation of subject | | | 2024/2025 | | |
| Education level | postgraduate studies | Subject group | | | Obligatory subject group 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 | | | | | |
| Conducting unit | Pracownia Analizy Związków Naturalnych -> Katedra Analizy Środowiska -> Faculty of Chemistry | | | | | | |
| Name and surname of lecturer (lecturers) | Subject supervisor | | dr hab. Marek Gołębiowski | | | | |
| | Teachers | | dr hab. Marek Gołębiowski | | | | |
| 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 | | | | | | |
| | Additional information: multimedia-based lecture | | | | | | |
| 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 | <ol style="list-style-type: none"> 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 | | | | | | |

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| Learning outcomes | Course outcome | Subject outcome | Method of verification |
| | [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 |
| | [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_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 |
| 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, ruggedness, 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 ruggedness), 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 | Adresy na platformie eNauczanie: | |
| Example issues/ example questions/ tasks being completed | | | |

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| Work placement | Not applicable |
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