

Study program: Integrating Academic Studies in Pharmacy			
Course title: Accreditation of Testing Laboratories			
Teacher: Ljilja D. Torović, Branislava U. Srđenović Čonić			
Course status: Elective			
ECTS Credits: 3			
Condition: /			
Course aim Introduction to the accreditation of testing laboratories in the field of quality control.			
Expected outcome of the course: Knowledge: Guidelines, recommendations, and tools used in the process of laboratory accreditation. Skills: Capacity for professional work in the field of accreditation of testing laboratories.			
Course description			
<i>Theoretical education</i> General requirements: impartiality and confidentiality. Structural requirements. Resource requirements: personnel; facilities and environmental conditions; equipment; metrological traceability; externally provided products and services. Process requirements: review of requests, tenders and contracts; selection, verification and validation of methods; sampling; handling of test items; technical records; evaluation of measurement uncertainty; ensuring the validity of the results; reporting of the results -common and specific requirements, reporting statement of conformity, reporting opinions and interpretations; complaints; nonconforming work; control of data and information management. Management system requirements: documentation, control of documentation and records; actions to address risks and opportunities; improvement; corrective actions; internal audits; management reviews.			
<i>Practical education</i> Method verification and validation – choice and determination of performance characteristics (limits of detection and quantification, linearity, precision, trueness). Assessment of measurement uncertainty – identification and quantification of contributions to measurement uncertainty. Internal quality control – plans and procedures (choice of procedures and control samples), collection and evaluation of data.			
Literature			
<i>Compulsory:</i>			
1. SRPS ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories. Belgrade: Institute of Standardisation of Serbia; 2017.			
<i>Additional:</i>			
1. Barwick VJ, Prichard E (Eds). Eurachem guide: Terminology in analytical measurements – Introduction to VIM 3. Eurachem; 2011. Available from: www.eurachem.org .			
2. Magnusson B, Ornemark U, editors. Eurachem Guide: The Fitness for Purpose of Analytical Methods – A Laboratory Guide to Method Validation and Related Topics. 2nd ed. Eurachem; 2014. Available from: www.eurachem.org .			
3. Nordtest TR567. Internal quality control handbook. Oslo, Norway: Nordic Innovation Centre; 2008. Available from: www.nordtest.info .			
4. Nordtest TR537. Handbook for calculation of measurement uncertainty. Oslo, Norway: Nordic Innovation Centre; 2008. Available from: www.nordtest.info .			
5. ILAC-G8:09/2019: Guidelines on Decision Rules and Statements of Conformity. Silverwater, Australia: ILAC; 2019. Available from: www.ilac.org .			
Number of active classes	Theoretical classes: 30		Practical classes: 15
Teaching methods Theoretical and practical, essay.			
Student activity assessment (maximally 100 points)			
Pre-exam activities	points	Final exam	points
Lectures	5	Written	-
Practices	35	Oral	60
Colloquium	-	
Essay	-		

