



PROGRAMS AND BIBLIOGRAPHY

Subject	
Code	Name
QA851	Analytical methods validation

Vector
OF:S-5 T:002 P:000 L:000 O:000 D:000 HS:002 SL:002 C:002 AV:N EX:S FM:75%

Pre requirement
QA584

Summary
Validation of analytical methods

Program
Quality warranty: validation, internal quality control, proficiency testing, accreditation. ISO systems rules. Instrumental and operational qualification. Calibration. Analytical methods validation. Validation parameters: linear range, linearity, matrix effect, selectivity, precision (repeatability and reproducibility), accuracy, robustness, limit of detection and limit of quantification. Statistical data treatment and use of electronic spreadsheets. Variances homogeneity. Anomalous results identification, regression significance tests. Uncertainties. Validation protocols and legislations aspects.

Bibliography
<ol style="list-style-type: none">1. Instituto Nacional de Metrologia, Normalização e Qualidade Industrial (INMETRO). Orientações sobre Validação de Métodos de Ensaio Químicos, DOQ-CGCRE-008, 2nd revision, 2007.2. Instituto Nacional de Metrologia, Normalização e Qualidade Industrial (INMETRO); Orientações sobre Validação de Métodos de Ensaio Químicos, DOQ-CGCRE-008, 4th revision, 2011.3. International Conference on Harmonization (ICH); Validation of Analytical Procedures: Text and methodology Q2 (R1), 2005.4. Thompson, M.; Ellison, S. L. R.; Wood, R. Pure Appl. Chem. 2002, 74, 835-855.5. Eurachem; The Fitness for Purpose of Analytical Methods. A Laboratory Guide to Method Validation and Related Topics, 1998.6. Miller, J.C; Miller, J.N. Statistics for Analytical Chemistry. Ellis Horwood, 3rd edition 1993.7. ANVISA – Consulta Pública n° 129, de 12 de fevereiro de 2016.

Evaluation criteria
For grading policy, see: Regimento Geral de Graduação, Seção I – Normas Gerais, Capítulo V – Da Avaliação do Aluno na Disciplina. Students are required to attend 75 % of the lectures. For further details, see: Regimento Geral de Graduação, capítulo VI, seção X, artigo 72.