



FEDERAL UNIVERSITY OF CEARÁ
Provost Office of Research and Graduate Studies

COURSE PROGRAM

1. PROGRAM:	
Program	GRADUATE PROGRAM IN CHEMISTRY
2. COMPONENT TYPE:	
Activity ()	Course (X) Module ()
3. LEVEL:	
Master's Degree (X) Doctorate (X)	
4. COMPONENT IDENTIFICATION:	
Name:	VALIDATION OF ANALYSIS METHODS
Code:	CEP9499
Hours:	64
Credits:	04
Optional course:	Yes (X) No ()
Compulsory course:	Yes (X) No ()
Area:	ANALYTICAL CHEMISTRY
5. PROFESSOR:	
Profa. Dra. Helena Becker, Profa. Dra. Elisane Longhinotti, Profa. Dra. Wladiana Oliveira Matos, Dr. Guilherme Julião Zocolo	
6. ABSTRACT:	
Statistical treatment of data obtained in chemical analysis. Validation concepts. Current Legislation. Analytical parameters used in validation. Case of study.	
7. COURSE PROGRAM:	
Introduction to the course. Statistical elements. Validation concepts. Brazilian legislation and which regulate the validation of analytical methods. Method validation, validation protocols; analytical parameters used in validation: accuracy, precision, linearity, linear range, sensitivity, limit of detection and limit of quantification, selectivity, specificity and robustness. Case studies.	
8. EVALUATION PROCESS:	
Theoretical evaluation – 60% Seminars – 40%	
9. BIBLIOGRAPHY:	
1. AOAC INTERNATIONAL. Quality Assurance Principles for Analytical Labs. 3rd Ed, available for purchase from www.aoac.org 2. Eurachem: http://www.eurachem.ul.pt - Guide to Quality in Analytical Chemistry: An Aid to Accreditation (2002) - Traceability in Chemical Measurements. A guide to achieving comparable measurement results (2003)	

3. LEITE, Flávio. Validação em análise química. Editora Átomo, 4ª Ed, 2002
4. MILLER, J.C. & MILLER, J.N., Statistic for Analytical Chemistry, 202pp, John Wiley & Sons, 1984
5. SKOOG, D.A, WEST, D.M.; HOLLER, F.J., Fundamentals of Analytical Chemistry, 6th ed., USA, Saunders College, 1991
6. Guia para laboratórios químicos: um auxílio à organização e ao credenciamento de laboratórios, INMETRO, 1999.
7. Harmonized guidelines for single laboratory validation of methods of analysis - International Union of Pure and Applied Chemistry: (IUPAC), 2002.
8. Guia para a Qualidade em Química Analítica. Uma assistência à habilitação. Séries temáticas 1 – Laboratório- ANVISA: 2005
9. ILAC requirements for the accreditation of providers of proficiency testing schemes, 1997.
10. Projeto Internacional de norma ISO 17025, ABNT, 1998.
11. Projeto NBR ISO 9000:2000, ABNT, 2000.
12. Ensaio de proficiência por comparações Inter laboratoriais, ISO Guia 43-1, Parte 1.
13. Ensaio de proficiência por comparações Inter laboratoriais, ISO Guia 43-2, Parte 2:
14. Seleção e uso de programas de ensaios de proficiência por organismos de credenciamento de laboratórios, ABNT, 1999.
15. Desenvolvimento e operação de programas de ensaios de proficiência, ABNT, 1999.
16. Validation of test methods. General principles and concepts, European cooperation for accreditation of laboratories, EAL-P11, 1997.
17. Format and contents of test methods and procedures for validation and verification of chemical test methods, National Association of Testing Authorities (NATA), Australia, 1997.