

Programme: M. Sc. Part-II (Analytical Chemistry)

Course Code: ACO-502

Title of the Course: Calibration and Validation in Analytical Chemistry

Number of Credits: 3

Effective from AY: 2019-2020

Prerequisites for the course:	Students should have studied the theory/ instrumentation and application of some of the basic analytical techniques and statistical calculations related to topic. Knowledge of M.Sc.-Part I analytical courses is essential for better understanding of the course content	
Course Objectives:	1. Introduction of various aspect of calibration and validation 2. Study validation parameters and qualification of instrument	
Course Outcomes:	Students should be able to understand about calibration/validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about basics of calibration & validation, types, methodology and application, the qualification of various equipment's and instruments.	
Content:	<p>1. Calibration Significance of calibration in analytical chemistry. Standardizing methods; standards used, certified reference material. Blanks and controls; types and significance Statistical evaluation of analytical results; relative error, standard deviation, knowledge of q test, test of significance, linear Least Squares estimation and coefficient of regression Errors in calibration, Modes and protocols of calibration; External standard method, Standard addition method, Spiking, Internal standard method and standard bracket method. Introduction to common apparatus used in analytical laboratory and their calibration; volumetric glassware, Analytical Balances, pH meter, Oven and lab Refrigerator Excel-charts for calibration plot.</p> <p>2. Validation and qualification Introduction to validation, Validation and calibration of various instruments used for drug analysis such as UV-Visible Spectrophotometer, IR Spectrophotometer, Spectrofluorimeter, HPLC, HPTLC and GC. Validation and qualification, Overview of qualification of some instruments. Overview of installation, operation, and performance qualification (IQ, OQ, PQ) of analytical equipment. Regulatory requirements for analytical method validation International conference on harmonization (ICH) guideline Q2A Introduction to QA / QC, Safety Practices in a Chemical Laboratory</p> <p>3. Validation of analytical procedures Linearity and range criteria and their role in instrumental method validation Detailed discussion on accuracy and precision role in the method validation Role of quantification limit and specificity -Limit of Detection (LOD) and Limit of Quantification (LOQ) Robustness & method validation</p>	<p>13 hrs</p> <p>11 hrs</p> <p>12 hrs</p>

	Ruggedness of chromatographic method Ruggedness of sample preparation procedure Complete method validation package, analytical data, protocol, plan, revisions, and change controls.	
Pedagogy:	lectures/ tutorials/ seminars/ term papers/assignments/ presentations/ self-study or a combination of some of these. Sessions shall be interactive in nature to enable peer group learning.	
Text Books/ References / Readings	<ol style="list-style-type: none"> 1. M. E. Swartz, I. S. Krull, <i>Analytical method development & validation</i>, CRC Press book, 1997. 2. A. I. Vogel, <i>Text Book of Quantitative Inorganic Analysis</i>, Longman Scientific & Technical, 1989. 3. A. H. Wachter, R. A. Nash, <i>Pharmaceutical Process Validation</i>, Marcel Dekker Inc, 2003. 4. L. Huber, <i>Validation and Qualification in Analytical Laboratories</i>, Informa Healthcare USA Inc; 2007. 5. M. Valcarcel, <i>Principles of analytical chemistry: A text book</i>, Springer Publications, 2000. 6. D. Harvey, <i>Modern Analytical Chemistry</i>, MC Graw Hill, 2000. 7. B.W. Wenclawiak, M. Koch and E. Hadjicostas (Eds.), <i>Quality Assurance in Analytical Chemistry</i>, Springer, 2004. 	