



VALIDATING CHROMATOGRAPHIC METHODS

A PRACTICAL GUIDE

CD-ROM INCLUDED



DAVID M. BLIESNER

Validating Chromatographic Methods A Practical Guide

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Validating Chromatographic Methods David M. Bliesner, 2006-09-30 All the information and tools needed to set up a successful method validation system *Validating Chromatographic Methods* brings order and Current Good Manufacturing Practices to the often chaotic process of chromatographic method validation. It provides readers with both the practical information and the tools necessary to successfully set up a new validation system or upgrade a current system to fully comply with government safety and quality regulations. The net results are validated and transferable analytical methods that will serve for extended periods of time with minimal or no complications. This guide focuses on high performance liquid chromatographic methods validation; however, the concepts are generally applicable to the validation of other analytical techniques as well. Following an overview of analytical method validation and a discussion of its various components, the author dedicates a complete chapter to each step of validation: Method evaluation and further method development, Final method development and trial method validation, Formal method validation and report generation, Formal data review and report issuance. Templates and examples for Methods Validation, Standard Operating Procedures, Standard Test Methods, Methods Validation Protocols and Methods Validation Reports are all provided. Moreover, the guide features detailed flowcharts and checklists that lead readers through every stage of method validation to ensure success. All of the templates are also included on a supplementary support site enabling readers to easily work with and customize them. For scientists and technicians new to method validation, this guide provides all the information and tools needed to develop a top quality system. For those experienced with method validation, the guide helps to upgrade and improve existing systems.

Validation of Analytical Methods for Pharmaceutical Analysis Oona McPolin, 2009-05-01 This book provides a comprehensive guide on validating analytical methods. Key features: Full review of the available regulatory guidelines on validation and in particular ICH Sections of the guideline Q2 R1 have been reproduced in this book with the kind permission of the ICH Secretariat. Thorough discussion of each of the validation characteristics: Specificity, Linearity, Range, Accuracy, Precision, Detection Limit, Quantitation Limit, Robustness, System Suitability plus practical tips on how they may be studied. What to include in a validation protocol with advice on the experimental procedure to follow and selection of appropriate acceptance criteria. How to interpret and calculate the results of a validation study including the use of suitable statistical calculations. A fully explained case study demonstrating how to plan a validation study, what to include in the protocol, experiments to perform, setting acceptance criteria, interpretation of the results and reporting the study.

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Structured like a textbook the second edition of this reference covers all aspects of biopharmaceutical manufacturing including legal and regulatory issues production facility design and quality assurance with a focus on supply chain management and regulations in emerging markets and cost control The author has longstanding industrial expertise in biopharmaceutical production and years of experience teaching at universities As such this practical book is ideal for use in academia as well as for internal training within companies **Biosensors** Jagriti Narang,C.S. Pundir,2017-09-19

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