

Analytical Method Validation and Instrument Performance Verification

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Validation describes the procedures used to analyze pharmaceutical products so that the data generated will comply with the requirements of regulatory bodies of the US, Canada, Europe and Japan. Calibration of Instruments describes the process of fixing, checking or correcting the graduations of instruments so that they comply with those regulatory bodies. This book provides a thorough explanation of both the fundamental and practical aspects of biopharmaceutical and bioanalytical methods validation. It teaches the proper procedures for using the tools and analysis methods in a regulated lab setting. Readers will learn the appropriate procedures for calibration of laboratory instrumentation and validation of analytical methods of analysis. These procedures must be executed properly in all regulated laboratories, including pharmaceutical and biopharmaceutical laboratories, clinical testing laboratories (hospitals, medical offices) and in food and cosmetic testing laboratories.

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Analytical Method Validation and Instrument Performance Verification Summary Details

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editorial:

Review

"It is a treasure of helpful hints and techniques which can aid even experienced analysts through some of the ICH procedures." (*Metrohm Information*, 4th July 2005)

"While most useful for pharmaceutical laboratories, it may also be useful in certain university and government laboratories." (*E-STREAMS*, February 2005)

"...a treasure of helpful hints and techniques that can aid even experienced analysts through some of the ICH procedures." (*Inside Laboratory Management*, July/August 2004)

"Given the need for generating reliable analytical data, this book provides practical guidance for validating common and not-so-common analytical methods and for verifying the performance of instruments..." (*Journal of the American Chemical Society*, June 9, 2004)

"...a very useful reference text...warmly recommended" (*Organic Process Research & Development Journal*)

From the Back Cover

Teaches proper procedures for using tools and analytical methods in a regulated lab setting

All regulated laboratories, including pharmaceutical, clinical testing, and food and cosmetics testing laboratories, must properly execute the calibration of instruments and validation of analytical methods.

Following correct procedures ensures the generation of reliable data, which leads to the manufacture of safe and effective products.

Analytical Method Validation and Instrument Performance Verification provides a uniquely practical approach to method validation and instrument performance verification. Each chapter starts with general requirements, then moves to the strategies and steps taken to fulfill these conditions, and finishes with a discussion of practical problems and their solutions. Coverage includes:

- Method validation of potency, related substances, and dissolution testing
- Validation for pharmaceutical excipients, heavy metals, and bioanalysis
- Performance verification for common analytical instruments including HPLC, UV-Vis spectrophotometers, and pH meters
- The LCMS system calibration
- Proper environmental chamber qualification
- Entire qualification process for computer equipment, hardware, and software
- Validation of Excel spreadsheets
- Regulatory requirements of the FDA, ICH, Europe, and Japan

Full of practical tips on validation techniques and detailed discussions of instrument performance verification, this comprehensive guide represents a one-stop reference for remaining current in today's regulatory environment.

Analytical Method Validation and Instrument Performance Verification provides an invaluable working reference for laboratory managers, calibration scientists, and research and development scientists.

About the Author

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