DESCRIPTION

Provides practical guidance on pharmaceutical analysis, written by leading experts with extensive industry experience

Analytical Testing for the Pharmaceutical GMP Laboratory presents a thorough overview of the pharmaceutical regulations, working processes, and drug development best practices used to maintain the quality and integrity of medicines. With a focus on smaller molecular weight drug substances and products, the book provides the knowledge necessary for establishing the pharmaceutical laboratory to support Quality Systems while maintaining compliance with Good Manufacturing Practices (GMP) regulations.

Concise yet comprehensive chapters contain up-to-date coverage of drug regulations, pharmaceutical analysis methodologies, control strategies, testing development and validation, method transfer, electronic data documentation, and more. Each chapter includes a table of contents, definitions of acronyms, a reference list, and ample tables and figures. Addressing the principal activities and regulatory challenges of analytical testing in the development and manufacturing of pharmaceutical drug products, this authoritative resource:

• Describes the structure, roles, core guidelines, and GMP regulations of the FDA and ICH.

• Covers the common analytical technologies used in pharmaceutical laboratories, including examples of analytical techniques used for the release and stability testing of drugs.

• Examines control strategies established from quality systems supported by real-world case studies.
• Explains the use of dissolution testing for products such as extended-release capsules, aerosols, and inhalers.

• Discusses good documentation and data reporting practices, stability programs, and the Laboratory Information Management System (LIMS) to maintain compliance.

• Includes calculations, application examples, and illustrations to assist readers in day-to-day laboratory operations.

• Contains practical information and templates to structure internal processes or common Standard Operating Procedures (SOPs).

*Analytical Testing for the Pharmaceutical GMP Laboratory* is a must-have reference for both early-career and experienced pharmaceutical scientists, analytical chemists, pharmacists, and quality control professionals. It is also both a resource for GMP laboratory training programs and an excellent textbook for undergraduate and graduate courses of analytical chemistry in pharmaceutical sciences or regulatory compliance programs.

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**ABOUT THE AUTHOR**

Kim Huynh-Ba, M.Sc., PMP, FAAPS, is the Chief Executive Officer and Managing Director of Pharmalytik LLC, where she provides consulting and training services to leading pharmaceutical companies and global organizations. She has decades of experience in strategic analytical development, risk management, strategic drug development, and stability sciences. She is an Adjunct Professor at Temple University School of Pharmacy and Illinois Institute of Technology (IIT) teaching GMPs and various regulatory compliance subjects.

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