Analytical Chemistry In A Gmp Environment A Practical Guide

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Introduction to Pharmaceutical Analytical Chemistry - Stig Pedersen-Bjergaard 2019-02-11
The definitive textbook on the chemical analysis of pharmaceutical drugs – fully revised and updated Introduction to Pharmaceutical Analytical Chemistry enables students to gain fundamental knowledge of the vital concepts, techniques and applications of the chemical analysis of pharmaceutical ingredients, final pharmaceutical products and drug substances in biological fluids. A unique emphasis on pharmaceutical laboratory practices, such as sample preparation and separation techniques, provides an efficient and practical educational framework for undergraduate studies in areas

such as pharmaceutical sciences, analytical chemistry and forensic analysis. Suitable for foundational courses, this essential undergraduate text introduces the common analytical methods used in quantitative and qualitative chemical analysis of pharmaceuticals. This extensively revised second edition includes a new chapter on chemical analysis of biopharmaceuticals, which includes discussions on identification, purity testing and assay of peptide and protein-based formulations. Also new to this edition are improved colour illustrations and tables, a streamlined chapter structure and text revised for increased clarity and comprehension. Introduces the fundamental concepts of pharmaceutical analytical chemistry and statistics Presents a systematic investigation of pharmaceutical applications absent from other textbooks on the subject Examines various analytical techniques commonly used in pharmaceutical laboratories Provides practice problems, up-to-date practical examples and detailed illustrations Includes updated content aligned with the current European and United States Pharmacopeia regulations and guidelines Covering the analytical techniques and concepts necessary for pharmaceutical analytical chemistry, Introduction to Pharmaceutical Analytical Chemistry is ideally suited for students of chemical and pharmaceutical sciences as well as analytical chemists transitioning into the field of pharmaceutical analytical chemistry.

Laboratory Control System Operations in a GMP Environment - David M. Bliesner 2020-04-21

Develop an understanding of FDA and global regulatory agency requirements for Laboratory Control System (LCS) operations In Laboratory Control System Operations in a GMP Environment, readers are given the guidance they need to implement a CGMP compliant Laboratory Control System (LCS) that fits within

Global Regulatory guidelines. Using the Quality Systems Approach, regulatory agencies like the FDA and the European Medicine Agency have developed a scheme of systems for auditing pharmaceutical manufacturing facilities which includes evaluating the LCS. In this guide, readers learn the fundamental rules for operating a CGMP compliant Laboratory Control System. Designed to help leaders meet regulatory standards and operate more efficiently, the text includes chapters that cover Laboratory Equipment Qualification and Calibration, Laboratory Facilities, Method Validation and Method Transfer, Laboratory Computer Systems, Laboratory Investigations as well as Data Governance and Data Integrity. The text also includes chapters related to Laboratory Managerial and Administrative Systems, Laboratory Documentation Practices and Standard Operating Procedures and General Laboratory Compliance Practices. Additionally, a chapter outlining Stability Program operations is included in the text. In addition to these topics, it includes LCS information and tools such as: ● End of chapter templates, checklists, and LCS guidance to help you follow the required standards ● Electronic versions of each tool so users can use them outside of the text ● An In-depth understanding of what is required by the FDA and other globally significant regulatory authorities for GMP compliant systems For quality assurance professionals working within the pharmaceutical or biopharma industries, this text provides the insight and tools necessary to implement government-defined regulations.

Traceability in Chemical Measurement - Paul De Bièvre 2005-12-06

Metrological traceability of chemical measurement results means the establishment of a relation to metrological stated references through an unbroken chain of comparisons. This volume

collects 56 outstanding papers on the topic, mostly published in the period 2000-2003 in the journal "Accreditation and Quality Assurance". They provide the latest understanding, and possibly the rationale why it is important to integrate the concept of metrological traceability including suitable measurement standards such as certified reference materials, into the standard measurement procedures of every analytical laboratory. In addition, this anthology considers the benefits to both the analytical laboratory and the user of the measurement results.

Analytical Chemistry - Ira S. Krull 2012-11-07

The current text deals with several, very important topics of modern, Analytical Chemistry, such as analytical method validation in biotechnology today, principal component analysis, kinetic methods of analysis using potentiometric and spectrophotometric detectors, the current status of Analytical Chemistry and where it may move in the future, peptide and amino acid separations and identification, and several other, related topics in this growing and increasingly important area of Chemistry, in general. Analytical Chemistry has come to assume an incredibly important role in most, if not all, areas of scientific research today, from the current, Mars lander/rover, to underwater explorations to forensic science to DNA characterization for dedicated medicine treatments, to climate change, and others, just as important areas of modern, scientific research and development. Its usage in modern -omics R

Pharmaceutical Manufacturing Handbook - Shayne Cox Gad 2008-04-04

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that

govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

Pharmaceutical Analysis for Small Molecules - Behnam Davani 2017-08-14

A comprehensive introduction for scientists engaged in new drug development, analysis, and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates—especially chemistry, analytical chemistry, pharmacy, and pharmaceutical majors—into its ranks. However, because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult. Designed to assist both recent graduates, as well as experienced chemists or scientists with limited regulatory, compendial or pharmaceutical analysis background, make that transition, Pharmaceutical Analysis for Small Molecules is a concise, yet comprehensive introduction to the drug development process and analysis of chemically synthesized, small molecule drugs. It features contributions by distinguished experts in the field, including editor and author, Dr. Behnam Davani, an analytical chemist with decades of technical management and teaching experience in compendial, regulatory, and industry. This book provides an introduction to pharmaceutical analysis for small molecules (non-biologics) using commonly used techniques for drug characterization and performance tests. The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to

regulatory bodies for drug approval in order to market their products. In addition, related required supporting studies including good laboratory/documentation practices including analytical instrument qualification are highlighted in this book. Topics covered include: Drug Approval Process and Regulatory Requirements (private standards) Pharmacopeias and Compendial Approval Process (public standards) Common methods in pharmaceutical analysis (typically compendial) Common Calculations for assays and impurities and other specific tests Analytical Method Validation, Verification, Transfer Specifications including how to handle out of specification (OOS) and out of trend (OOT) Impurities including organic, inorganic, residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical Laboratories Analytical Instrument Qualifications including IQ, OQ, PQ and VQ Due to global nature of pharmaceutical industry, other topics on both regulatory (ICH) and Compendial harmonization are also highlighted. Pharmaceutical Analysis for Small Molecules is a valuable working resource for scientists directly or indirectly involved with the drug development process, including analytical chemists, pharmaceutical scientists, pharmacists, and quality control/quality assurance professionals. It also is an excellent text/reference for graduate students in analytical chemistry, pharmacy, pharmaceutical and regulatory sciences.

Proceedings of IAC-ETeL 2014 - Collective of authors 2014-02-24

Forensic Applications of High Performance Liquid Chromatography - Shirley Bayne 2017-07-27

Chromatography has many roles in forensic science, ranging from toxicology to environmental analysis. In particular, high-performance liquid chromatography (HPLC)

is a primary method of analysis in many types of laboratories. Maintaining a balance between practical solutions and the theoretical considerations involved in HPLC analysis, Forensic App

Analytical Chemistry - Gary D. Christian 2013-10-07

The 7th Edition of Gary Christian's Analytical Chemistry focuses on more in-depth coverage and information about Quantitative Analysis (aka Analytical Chemistry) and related fields. The content builds upon previous editions with more enhanced content that deals with principles and techniques of quantitative analysis with more examples of analytical techniques drawn from areas such as clinical chemistry, life sciences, air and water pollution, and industrial analyses.

Handbook of Pharmaceutical Analysis by HPLC - Satinder Ahuja 2005-02-09

High pressure liquid chromatography–frequently called high performance liquid chromatography (HPLC or, LC) is the premier analytical technique in pharmaceutical analysis and is predominantly used in the pharmaceutical industry. Written by selected experts in their respective fields, the Handbook of Pharmaceutical Analysis by HPLC Volume 6, provides a complete yet concise reference guide for utilizing the versatility of HPLC in drug development and quality control. Highlighting novel approaches in HPLC and the latest developments in hyphenated techniques, the book captures the essence of major pharmaceutical applications (assays, stability testing, impurity testing, dissolution testing, cleaning validation, high-throughput screening). A complete reference guide to HPLC Describes best practices in HPLC and offers 'tricks of the trade' in HPLC operation and method development Reviews key HPLC pharmaceutical applications and highlights currents trends in HPLC ancillary techniques, sample preparations, and data

handling

Analytical Chemistry in a GMP Environment - James M. Miller 2000-05

How to hone your analytical skills and obtain high-quality data in the era of GMP requirements With increased regulatory pressures on the pharmaceutical industry, there is a growing need for capable analysts who can ensure appropriate scientific practices in laboratories and manufacturing sites worldwide. Based on Johnson & Johnson's acclaimed in-house training program, this practical guide provides guidance for laboratory analysts who must juggle the Food and Drug Administration's good manufacturing practices (GMP) rules with rapidly changing analytical technologies. Highly qualified industry experts walk readers step-by-step through the concepts, techniques, and tools necessary to perform analyses in an FDA-regulated environment, including clear instructions on all major analytical chemical methods-from spectroscopy to chromatography to dissolution. An ideal manual for formal training as well as an excellent self-study guide, Analytical Chemistry in a GMP Environment features: * The drug development process in the pharmaceutical industry * Uniform and consistent interpretation of GMP compliance issues * A review of the role of statistics and basic topics in analytical chemistry * An emphasis on high-performance liquid chromatographic (HPLC) methods * Chapters on detectors and quantitative analysis as well as data systems * Methods for ensuring that instruments meet standard operating procedures (SOP) requirements * Extensive appendixes for unifying terms, symbols, and procedural information

Pharmaceutical and Medical Applications of Near-Infrared Spectroscopy - Emil W. Ciurczak 2014-12-15

Since the completion of the first edition of this book, major developments have occurred in the pharmaceutical industry

that have shaped the field of near-infrared (NIR) spectroscopy. A new initiative from the U.S. Food and Drug Administration (FDA) to modernize regulations of pharmaceutical manufacturing and drug quality has helped position NIR sp

Preconcentration Techniques for Natural and Treated Waters - T.R. Crompton 2002-10-31

Equipment used for the analysis of water is frequently insufficiently sensitive to be able to detect the low concentrations of organic and inorganic substances present in samples. Applying preconcentration to the sample prior to analysis means the results gained are more accurate and can be used to report trends more effectively. Each chapter of Pr

Essential Elements for a GMP Analytical Chemistry Department - Thomas Catalano 2013-07-03

Essential Elements for a GMP Analytical Chemistry Department is a systematic approach to understanding the essential elements required for a successful GMP Analytical Department to function as an efficient and effective organization. It describes in detail a department structure which allows for the necessary processes to become available to all its personnel in a way where there is a free flow of information and interaction. The environment and culture created by this approach encourages and rewards the sharing of ideas, skills, and abilities among department personnel. The essential elements such as , SOP's, regulatory guidance's/guidelines, project teams, technical and department processes, personnel motivation, outsourcing, and hiring the best is among the many topics that are discussed in detail and how they can be implemented to build an efficient and effective Analytical Department. This book will serve as a valuable asset to the many companies required to perform GMP analytical method development, validation, analyses etc

including start-up, virtual, and generic pharmaceutical companies.

Manufacturing of Pharmaceutical Proteins - Stefan Behme 2022-04-18

An expert, single-volume overview of the core processes and disciplines of biopharmaceutical production In the newly revised Third Edition of Manufacturing of Pharmaceutical Proteins: From Technology to Economy, renowned chemical engineer Dr. Stefan Behme delivers a comprehensive text covering all aspects of biopharmaceutical manufacturing, including legal and regulatory considerations, production facility design, quality assurance, supply chain management, emerging market regulations, and cost control. Suitable as both a reference book and a training resource, this book extensively explores the impact of digital transformation on pharmaceutical protein manufacturers and includes a brand-new chapter dedicated to digitalization. The distinguished author provides readers with practical understanding of the terminology and principles driving the various fields involved with biotechnological production, including operations, legal, finance, and IT. He also offers: A thorough introduction to biopharmaceutical production, including value creation, product types, and biological basics Comprehensive explorations of the technology of the manufacturing process and analytics Practical discussions of pharmacology and drug safety, quality assurance, and pharmaceutical law In-depth examinations of pharmaceutical protein production facilities, including facility design and the planning, construction, and commissioning of a manufacturing plant Perfect for biotechnologists working in the pharmaceutical industry, Manufacturing of Pharmaceutical Proteins: From Technology to Economy will also earn a place in the libraries of pharmaceutical

engineers seeking a one-stop reference for all aspects of biopharmaceutical production.

Poorly Soluble Drugs - Gregory K. Webster 2017-01-06

This book is the first text to provide a comprehensive assessment of the application of fundamental principles of dissolution and drug release testing to poorly soluble compounds and formulations. Such drug products are, vis-à-vis their physical and chemical properties, inherently incompatible with aqueous dissolution. However, dissolution methods are required for product development and selection, as well as for the fulfillment of regulatory obligations with respect to biopharmaceutical assessment and product quality understanding. The percentage of poorly soluble drugs, defined in classes 2 and 4 of the Biopharmaceutics Classification System (BCS), has significantly increased in the modern pharmaceutical development pipeline. This book provides a thorough exposition of general method development strategies for such drugs, including instrumentation and media selection, the use of compendial and non-compendial techniques in product development, and phase-appropriate approaches to dissolution development. Emerging topics in the field of dissolution are also discussed, including biorelevant and biphasic dissolution, the use on enzymes in dissolution testing, dissolution of suspensions, and drug release of non-oral products. Of particular interest to the industrial pharmaceutical professional, a brief overview of the formulation and solubilization techniques employed in the development of BCS class 2 and 4 drugs to overcome solubility challenges is provided and is complemented by a collection of chapters that survey the approaches and considerations in developing dissolution methodologies for enabling drug delivery technologies, including nanosuspensions, lipid-based formulations, and stabilized

amorphous drug formulations.

Kirk-Othmer Concise Encyclopedia of Chemical Technology, 2 Volume Set - Kirk-Othmer 2007-07-16

This is an easily-accessible two-volume encyclopedia summarizing all the articles in the main volumes Kirk-Othmer Encyclopedia of Chemical Technology, Fifth Edition organized alphabetically. Written by prominent scholars from industry, academia, and research institutions, the Encyclopedia presents a wide scope of articles on chemical substances, properties, manufacturing, and uses; on industrial processes, unit operations in chemical engineering; and on fundamentals and scientific subjects related to the field.

Handbook of Stability Testing in Pharmaceutical Development - Kim Huynh-Ba 2008-11-16

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

High Performance Liquid Chromatography - Omar Al Sayed Omar 2022-02-21

The book provides an indispensable guide on how to use HPLC in pharmaceutical analysis and drug control. Following a hands-on approach, the authors give practical advices how to prepare stationary and mobile phases, choose a suitable detector and set up an HPLC analysis. The publication gives insight into the key pharmaceutical applications of HPLC and the latest requirements of the major regulatory agencies.

Modern HPLC for Practicing Scientists - Michael W. Dong 2016-04-06

A comprehesive yet concise guide to Modern HPLC Written for practitioners by a practitioner, Modern HPLC for Practicing Scientists is a concise text which presents the most important High-Performance Liquid Chromatography (HPLC)

fundamentals, applications, and developments. It describes basic theory and terminology for the novice, and reviews relevant concepts, best practices, and modern trends for the experienced practitioner. Moreover, the book serves well as an updated reference guide for busy laboratory analysts and researchers. Topics covered include: HPLC operation Method development Maintenance and troubleshooting Modern trends in HPLC such as quick-turnaround and "greener" methods Regulatory aspects While broad in scope, this book focuses particularly on reversed-phase HPLC, the most common separation mode, and on applications for the pharmaceutical industry, the largest user segment. Accessible to both novice and intermedate HPLC users, information is delivered in a straightforward manner illustrated with an abundance of diagrams, chromatograms, tables, and case studies, and supported with selected key references and Web resources. With intuitive explanations and clear figures, Modern HPLC for Practicing Scientists is an essential resource for practitioners of all levels who need to understand and utilize this versatile analytical technology.

Pharmaceutical Analysis for Small Molecules - Behnam Davani 2017-08-01

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pharmaceutical analysis background, make that transition, Pharmaceutical Analysis for Small Molecules is a concise, yet comprehensive introduction to the drug development process and analysis of chemically synthesized, small molecule drugs. It features contributions by distinguished experts in the field, including editor and author, Dr. Behnam Davani, an analytical chemist with decades of technical management and teaching experience in compendial, regulatory, and industry. This book provides an introduction to pharmaceutical analysis for small molecules (non-biologics) using commonly used techniques for drug characterization and performance tests. The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their products. In addition, related required supporting studies including good laboratory/documentation practices including analytical instrument qualification are highlighted in this book. Topics covered include: Drug Approval Process and Regulatory Requirements (private standards) Pharmacopeias and Compendial Approval Process (public standards) Common methods in pharmaceutical analysis (typically compendial) Common Calculations for assays and impurities and other specific tests Analytical Method Validation, Verification, Transfer Specifications including how to handle out of specification (OOS) and out of trend (OOT) Impurities including organic, inorganic, residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical Laboratories Analytical Instrument Qualifications including IQ, OQ, PQ and VQ Due to global nature of pharmaceutical industry, other topics on both regulatory (ICH) and Compendial harmonization are also highlighted.

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Validation of Chromatography Data Systems - R. D. McDowall 2005

Validation of Chromatography Data Systems: Meeting Business and Regulatory Requirements introduces the basics of computer validation. It looks in detail at the requirements throughout the life cycle of a CDS for any regulated laboratory, from its concept, through writing the user requirements specification to selecting the system, testing and operational release, including using electronic signatures. This logical and uniquely organised book provides the background to the regulatory requirements, interpretation of the regulations and documented evidence needed to support a claim that a system is validated. Development of the system, risk management, operation and finally system retirement and data migration are discussed. Case studies and practical examples are provided where appropriate.

Good Clinical, Laboratory and Manufacturing Practices - Phillip A. Carson 2007

Spanning chemical, cosmetic and manufacturing industries, this book is aimed at: chemists, clinicians, ecotoxicologists, operation managers, pharmaceutical process managers, quality assurance officers, technicians and toxicologists.

Capillary Electrophoresis Methods for Pharmaceutical Analysis - Satinder Ahuja 2011-08-09

Capillary electrophoresis (CE) is a powerful analytical technique that is widely used in research and development and in quality control of

pharmaceuticals. Many reports of highly efficient separations and methods have been published over the past 15 years. CE offers several advantages over high-pressure or high-performance liquid chromatography (HPLC). These include simplicity, rapid analysis, automation, ruggedness, different mechanisms for selectivity, and low cost. Moreover, EC requires smaller sample size and yet offers higher efficiency and thus greater resolution power over HPLC. These characteristics are very attractive in research and development, even more so in pharmaceutical quality control (QC) and stability monitoring (SM) studies. This book will provide busy pharmaceutical scientists a complete yet concise reference guide for utilizing the versatility of CE in new drug development and quality control. - Provides current status and future developments in CE analysis of pharmaceuticals. - Explains how to develop and validate methods. - Includes major pharmaceutical applications including assays and impurity testing.

Chromatography - James M. Miller 2005-12-16

The first edition of Chromatography: Concepts and Contrasts,published in 1988, was one of the first books to discuss all thedifferent types of chromatography under one cover. The secondedition continues with these principles but has been updated toinclude new chapters on sampling and sample preparation, capillaryelectrophoresis and capillary electrochromatography (CEC),chromatography with mass spec detection, and industrial andgovernmental practices in regulated industries. Covers extraction, solid phase extraction (SPE), and solidphase microextraction (SPME), and introduces mass spectrometry Updated with the latest techniques in chromatography Discusses both liquid chromatography (LC)and gaschromatography(GC)

Handbook of Modern

Pharmaceutical Analysis - Satinder Ahuja 2001-08-02
This book describes the role modern pharmaceutical analysis plays in the development of new drugs. Detailed information is provided as to how the quality of drug products is assured from the point of discovery until the patient uses the drug. Coverage includes state-of-the-art topics such as analytics for combinatorial chemistry and high-throughput screening, formulation development, stability studies, international regulatory aspects and documentation, and future technologies that are likely to impact the field. Emphasis is placed on current, easy-to-follow methods that readers can apply in their laboratories. No book has effectively replaced the very popular text, Pharmaceutical Analysis, that was edited in the 1960s by Tak Higuchi. This book will fill that gap with an up-to-date treatment that is both handy and authoritative.
Practical Instrumental Analysis - Sergio Petrozzi 2012-09-24
This practical book in instrumental analytics conveys an overview of important methods of analysis and enables the reader to realistically learn the (principally technology-independent) working techniques the analytical chemist uses to develop methods and conduct validation. What is to be conveyed to the student is the fact that analysts in their capacity as problem-solvers perform services for certain groups of customers, i.e., the solution to the problem should in any case be processed in such a way as to be "fit for purpose". The book presents sixteen experiments in analytical chemistry laboratory courses. They consist of the classical curriculum used at universities and universities of applied sciences with chromatographic procedures, atom spectrometric methods, sensors and special methods (e.g. field flow fractionation, flow injection analysis and N-determination according to Kjeldahl). The carefully chosen

combination of theoretical description of the methods of analysis and the detailed instructions given are what characterizes this book. The instructions to the experiments are so detailed that the measurements can, for the most part, be taken without the help of additional literature. The book is complemented with tips for effective literature and database research on the topics of organization and the practical workflow of experiments in analytical laboratory, on the topic of the use of laboratory logs as well as on writing technical reports and grading them (Evaluation Guidelines for Laboratory Experiments). A small introduction to Quality Management, a brief glance at the history of analytical chemistry as well as a detailed appendix on the topic of safety in analytical laboratories and a short introduction to the new system of grading and marking chemicals using the "Globally Harmonized System of Classification and Labelling of Chemicals (GHS)", round off this book. This book is therefore an indispensable workbook for students, internship assistants and lecturers (in the area of chemistry, biotechnology, food technology and environmental technology) in the basic training program of analytics at universities and universities of applied sciences.

HPLC Method Development for Pharmaceuticals - Satinder Ahuja 2011-09-21

High pressure, or high performance, liquid chromatography (HPLC) is the method of choice for checking purity of new drug candidates, monitoring changes during scale up or revision of synthetic procedures, evaluating new formulations, and running control/assurance of the final drug product. HPLC Method Development for Pharmaceuticals provides an extensive overview of modern HPLC method development that addresses these unique concerns. Includes a review and update of the current state of the art and science of HPLC, including theory, modes of

HPLC, column chemistry, retention mechanisms, chiral separations, modern instrumentation (including ultrahigh-pressure systems), and sample preparation. Emphasis has been placed on implementation in a pharmaceutical setting and on providing a practical perspective. HPLC Method Development for Pharmaceuticals is intended to be particularly useful for both novice and experienced HPLC method development chemists in the pharmaceutical industry and for managers who are seeking to update their knowledge. Covers the requirements for HPLC in a pharmaceutical setting including strategies for software and hardware validation to allow for use in a regulated laboratory Provides an overview of the pharmaceutical development process (clinical phases, chemical and pharmaceutical development activities) Discusses how HPLC is used in each phase of pharmaceutical development and how methods are developed to support activities in each phase

Leachables and Extractables Handbook - Douglas J. Ball 2012-02-08

A practical and science-based approach for addressingtoxicological concerns related to leachables and extractablesassociated with inhalation drug products Packaging and device components of Orally Inhaled and Nasal DrugProducts (OINDP)—such as metered dose inhalers, dry powderinhalers, and nasal sprays—pose potential safety risks fromleachables and extractables, chemicals that can be released ormigrate from these components into the drug product. Addressing theconcepts, background, historical use, and development of safetythresholds and their utility for qualifying leachables andextractables in OINDP, the Leachables and Extractables Handbooktakes a practical approach to familiarize readers with the recentrecommendations for

safety and risk assessment established througha joint effort of scientists from the FDA, academia, and industry.Coverage includes best practices for the chemical evaluation andmanagement of leachables and extractables throughout thepharmaceutical product life cycle, as well as: Guidance for pharmaceutical professionals to qualify andrisk-assess container closure system leachables and extractables indrug products Principles for defining toxicological safety thresholds that areapplicable to OINDP and potentially applicable to other drugproducts Regulatory perspectives, along with an appendix of key terms anddefinitions, case studies, and sample protocols Analytical chemists, packaging and device engineers, formulationdevelopment scientists, component suppliers, regulatory affairsspecialists, and toxicologists will all benefit from the wealth ofinformation offered in this important text.

Determination of Metals in Natural and Treated Water - T R Crompton 2013-04-08

Determination of Metals in Natural and Treated Waters draws together all the available literature and presents in a systematic fashion the latest analytical techniques for detecting metals in non-saline and saline natural and treated water. Broad outlines of different methods and their applicability in certain situations are given allowing the chem

Essential Elements for a GMP Analytical Chemistry Department - Thomas Catalano 2013-06-20

Essential Elements for a GMP Analytical Chemistry Department is a systematic approach to understanding the essential elements required for a successful GMP Analytical Department to function as an efficient and effective organization. It describes in detail a department structure which allows for the necessary processes to become available to all its personnel in a way where there is a free flow of information and interaction.

The environment and culture created by this approach encourages and rewards the sharing of ideas, skills, and abilities among department personnel. The essential elements such as , SOP's, regulatory guidance's/guidelines, project teams, technical and department processes, personnel motivation, outsourcing, and hiring the best is among the many topics that are discussed in detail and how they can be implemented to build an efficient and effective Analytical Department. This book will serve as a valuable asset to the many companies required to perform GMP analytical method development, validation, analyses etc including start-up, virtual, and generic pharmaceutical companies.

Method Validation in Pharmaceutical Analysis - Joachim Ermer 2006-03-06 Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmaceutists, QA officers, and public authorities.

Analytical Testing for the Pharmaceutical GMP Laboratory - Kim Huynh-Ba

2022-04-19

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.

HPLC and UHPLC for Practicing Scientists - Michael W. Dong 2019-07-10

A concise yet comprehensive reference guide on HPLC/UHPLC that focuses on its fundamentals, latest developments, and best practices in the pharmaceutical and biotechnology industries Written for practitioners by an expert practitioner, this new edition of HPLC and UHPLC for Practicing Scientists adds numerous updates to its coverage of high-performance liquid chromatography, including comprehensive information on UHPLC (ultra-high-pressure liquid chromatography) and the continuing migration of HPLC to UHPLC, the modern standard platform. In addition to introducing readers to HPLC's fundamentals, applications, and developments, the book describes basic theory and terminology for the novice, and reviews relevant concepts, best practices, and modern trends for the experienced practitioner. HPLC and UHPLC for Practicing Scientists, Second Edition offers three new chapters. One is a standalone chapter on UHPLC, covering concepts, benefits, practices, and potential issues. Another examines liquid chromatography/mass spectrometry (LC/MS). The third reviews at the analysis of

recombinant biologics, particularly monoclonal antibodies (mAbs), used as therapeutics. While all chapters are revised in the new edition, five chapters are essentially rewritten (HPLC columns, instrumentation, pharmaceutical analysis, method development, and regulatory aspects). The book also includes problem and answer sections at the end of each chapter. Overviews fundamentals of HPLC to UHPLC, including theories, columns, and instruments with an abundance of tables, figures, and key references Features brand new chapters on UHPLC, LC/MS, and analysis of recombinant biologics Presents updated information on the best practices in method development, validation, operation, troubleshooting, and maintaining regulatory compliance for both HPLC and UHPLC Contains major revisions to all chapters of the first edition and substantial rewrites of chapters on HPLC columns, instrumentation, pharmaceutical analysis, method development, and regulatory aspects Includes end-of-chapter quizzes as assessment and learning aids Offers a reference guide to graduate students and practicing scientists in pharmaceutical, biotechnology, and other industries Filled with intuitive explanations, case studies, and clear figures, HPLC and UHPLC for Practicing Scientists, Second Edition is an essential resource for practitioners of all levels who need to understand and utilize this versatile analytical technology. It will be a great benefit to every busy laboratory analyst and researcher.

CleanRooms - 2009-03

A central resource of technology and methods for environments where the control of contamination is critical.

Traditional Herbal Medicine Research Methods - Willow J.H. Liu 2011-03-29

This book introduces the methodology for collection and identification of herbal

materials, extraction and isolation of compounds from herbs, in vitro bioassay, in vivo animal test, toxicology, and clinical trials of herbal research. To fully understand and make the best use of herbal medicines requires the close combination of chemistry, biochemistry, biology, pharmacology, and clinical science. Although there are many books about traditional medicines research, they mostly focus on either chemical or pharmacological study results of certain plants. This book, however, covers the systematic study and analysis of herbal medicines in general – including chemical isolation and identification, bioassay and mechanism study, pharmacological experiment, and quality control of the raw plant material and end products.

Chromatographic Analysis of the Environment - Leo M.L. Nollet 2017-03-03

This detailed handbook covers different chromatographic analysis techniques and chromatographic data for compounds found in air, water, and soil, and sludge. The new edition outlines developments relevant to environmental analysis, especially when using chromatographic mass spectrometric techniques. It addresses new issues, new lines of discussion, and new findings, and develops in greater detail the aspects related to chromatographic analysis in the environment. It also includes different analytical methodologies, addresses instrumental aspects, and outlines conclusions and perspectives for the future.

Generic Drug Product Development - Leon Shargel 2013-10-24

In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns.Generic Drug Product

Development: Solid Oral

Chromatographic Methods Development - Gregory K. Webster 2019-10-28

This book is a comprehensive compilation of modern and cutting-edge chromatographic techniques written by pharmaceutical industry experts, academics, and vendors in the field. This book is an inclusive guide to developing all chromatographic methods (such as liquid chromatography and gas chromatography). It covers modern techniques for developing methods using chromatographic development software, requirements for validations, discussion on orthogonality, and how to transfer methods from HPLC to UHPLC. The text introduces some newer techniques that are heavily employed by chemists analyzing proteins and RNAi, as well as novel techniques such as counter current chromatography. This book is valuable for both the novice starting out in undergraduate labs and those who are new to the pharmaceutical industry and is a useful reference for seasoned analysts.

Statistical Methods in Analytical Chemistry - Peter C. Meier 2005-03-04

This new edition of a successful, bestselling book continues toprovide you with practical information on the use of statisticalmethods for solving real-world problems in complex industrialenvironments. Complete with examples from the chemical andpharmaceutical laboratory and manufacturing areas, this thoroughlyupdated book clearly demonstrates how to obtain reliable results bychoosing the most appropriate experimental design and dataevaluation methods. Unlike other books on the subject, Statistical Methods inAnalytical Chemistry, Second Edition presents and solves problemsin the context of a comprehensive decision-making process under GMPrules: Would you recommend the destruction of a $100,000 batch ofproduct if

one of four repeat determinations barely fails thespecification limit? How would you prevent this from happening inthe first place? Are you sure the calculator you are using istelling the truth? To help you control these situations, the newedition: * Covers univariate, bivariate, and multivariate data * Features case studies from the pharmaceutical and chemicalindustries demonstrating typical problems analysts encounter andthe techniques used to solve them * Offers information on ancillary techniques, including a shortintroduction to optimization, exploratory data analysis, smoothingand computer simulation, and recapitulation of errorpropagation * Boasts numerous Excel files and compiled Visual Basic programs-nostatistical table lookups required! * Uses Monte Carlo simulation to illustrate the variabilityinherent in statistically indistinguishable data sets Statistical Methods in Analytical Chemistry, Second Edition is anexcellent, one-of-a-kind resource for laboratory scientists andengineers and project managers who need to assess data reliability;QC staff, regulators, and customers who want to frame realisticrequirements and specifications; as well as educators looking forreal-life experiments and advanced students in chemistry andpharmaceutical science. From the reviews of Statistical Methods in Analytical Chemistry,First Edition: "This book is extremely valuable. The authors supply many veryuseful programs along with their source code. Thus, the user cancheck the authenticity of the result and gain a greaterunderstanding of the algorithm from the code. It should be on thebookshelf of every analytical chemist."-Applied Spectroscopy "The authors have compiled an interesting collection of data toillustrate the application of statistical methods . . . includingcalibrating, setting detection limits, analyzing

ANOVA data,analyzing stability data, and determining the influence of errorpropagation."-Clinical Chemistry "The examples are taken from a chemical/pharmaceutical environment,but serve as convenient vehicles for the discussion of when to usewhich test, and how to make sense out of the results. Whilepractical use of statistics is the major concern, it is put intoperspective, and the reader is urged to use plausibilitychecks."-Journal of Chemical Education "The discussion of univariate statistical tests is one of the morethorough I have seen in this type of book . . . The treatment oflinear regression is also thorough, and a complete set of equationsfor uncertainty in the results is presented . . . The bibliographyis extensive and will serve as a valuable resource for thoseseeking more information on virtually any topic covered in thebook."-Journal of American Chemical Society "This book treats the application of statistics to analyticalchemistry in a very practical manner. [It] integrates PC computingpower, testing programs, and analytical know-how in the context ofgood manufacturing practice/good laboratory practice (GMP/GLP) . ..The book is of value in many fields of analytical chemistry andshould be available in all relevant libraries."-Chemometrics andIntelligent Laboratory Systems