Residual Solvents Determination In Pharmaceutical Products

Getting the books **residual solvents determination in pharmaceutical products** now is not type of challenging means. You could not unaided going taking into account ebook amassing or library or borrowing from your links to right of entry them. This is an categorically simple means to specifically acquire lead by on-line. This online revelation residual solvents determination in pharmaceutical products can be one of the options to accompany you with having supplementary time.

It will not waste your time. take on me, the e-book will extremely circulate you new situation to read. Just invest tiny epoch to admittance this on-line publication **residual solvents determination in pharmaceutical products** as skillfully as review them wherever you are now.

Solvent Microextraction John M Kokosa 2009-10-05
This book offers both a practical as well a theoretical approach to Solvent Microextraction (SME) and will help analytical chemists to evaluate SME for a given sample preparation. Introductory chapters overview a comparison of SME with other sample preparation methods, a summary of the technical aspects, and a detailed theoretical treatment of SME. The book then describes the practical aspects of the technique, with detailed "how to" chapters devoted to the preparation and analysis of

atmospheric, solid and liquid environmental, clinical and industrial samples. This text will serve as both a handy laboratory desk-reference and an indispensible instructional tool.

ICH Quality Guidelines - Andrew Teasdale 2017-09-29 Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. • Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies • Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines • Uses case studies to help readers understand and apply ICH guidelines • Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines • Includes coverage of stability testing, analytical method validation, impurities, biotechnology drugs and products, and good manufacturing practice (GMP)

Global New Drug Development - Jan A. Rosier 2014-07-03 The development of new drugs is very complex, costly and risky. Its success is highly dependent on an intense collaboration and interaction between many departments within the drug development organization, external investigators and service providers, in constant dialogue with regulatory authorities, payers, academic experts, clinicians and patient organizations. Within the different phases of the drug life cycle, drug development is by far the most crucial part for the initial and continued success of a drug on the market. This book offers an introduction to the field of drug development with a clear overview of the different processes that lead to a successful new medicine and of the regulatory pathways that

are used to launch a new drug that are both safe and efficacious. "This is the most comprehensive and detailed book on drug development I have ever read and I feel that it is likely to become a staple of drug development courses, such as those taught at Masters Level in my own University.... I think in the light of increasing integration of company and academic approaches to drug development both sides can read this book... (and, therefore)... this book could not be more timely." —Professor Mike Coleman, University of Aston, UK (from his review of the final manuscript)

Chromatographic Analysis of Pharmaceuticals - John A. Adamovics 2017-09-29

Updated and revised throughout. Second Edition explores the chromatographic methods used for the measurement of drugs, impurities, and excipients in pharmaceutical preparations--such as tablets, ointments, and injectables. Contains a 148-page table listing the chromatographic data of over 1300 drugs and related substances--including sample matrix analyzed, sample handling procedures, column packings, mobile phase, mode of detection, and more.

Solid Phase Microextraction - Sue Ann Wercinski 1999-07-09

An explanation of proven methods of chemical analysis, focusing on the myriad applications of solid phase microextraction (SPME) to laboratories performing high-sample throughput, quick sample turnaround time, low detection levels, and dirty sample matrices. It supplies commentary on developments in SPME technology from its inventor, Janusz Pawliszyn.

Handbook of Solvents, Volume 2 - George Wypych 2019-02-21

Handbook of Solvents, Volume Two: Use, Health, and Environment, Third Edition, contains the most comprehensive information ever published on solvents and an extensive analysis of the principles of solvent selection

and use. The book is intended to help formulators select ideal solvents, safety coordinators protect workers, and legislators and inspectors define and implement public safeguards on solvent usage, handling and disposal. The book begins with a discussion of solvent use in over 30 industries, which are the main consumers of solvents. The analysis is conducted based on available data and contains information on the types of solvents used and potential problems and solutions. In addition, the possibilities for solvent substitution are also discussed, with an emphasis on supercritical solvents, ionic liquids, ionic melts, and agriculture-based products. Assists in solvent selection by providing key information and insight on environmental and safety issues Provides essential best practice guidance for human health considerations Discusses the latest advances and trends in solvent technology, including modern methods of cleaning contaminated soils, selection of gloves, suits and respirators

Green Techniques for Organic Synthesis and Medicinal Chemistry - Wei Zhang 2012-05-10

An updated overview of the rapidly developing field of green engineering techniques for organic synthesis and medicinal chemistry Green chemistry remains a high priority in modern organic synthesis and pharmaceutical R&D, with important environmental and economic implications. This book presents comprehensive coverage of green chemistry techniques for organic and medicinal chemistry applications, summarizing the available new technologies, analyzing each technique's features and green chemistry characteristics, and providing examples to demonstrate applications for green organic synthesis and medicinal chemistry. The extensively revised edition of Green Techniques for Organic Synthesis and Medicinal Chemistry includes 7 entirely new chapters on topics

including green chemistry and innovation, green chemistry metrics, green chemistry and biological drugs, and the business case for green chemistry in the generic pharmaceutical industry. It is divided into 4 parts. The first part introduces readers to the concepts of green chemistry and green engineering, global environmental regulations, green analytical chemistry, green solvents, and green chemistry metrics. The other three sections cover green catalysis, green synthetic techniques, and green techniques and strategies in the pharmaceutical industry. Includes more than 30% new and updated material—plus seven brand new chapters Edited by highly regarded experts in the field (Berkeley Cue is one of the fathers of Green Chemistry in Pharma) with backgrounds in academia and industry Brings together a team of international authors from academia, industry, government agencies, and consultancies (including John Warner, one of the founders of the field of Green Chemistry) Green Techniques for Organic Synthesis and Medicinal Chemistry, Second Edition is an essential resource on green chemistry technologies for academic researchers, R&D professionals, and students working in organic chemistry and medicinal chemistry.

Specification of Drug Substances and Products - Christopher M. Riley 2013-08-21

Specification of Drug Substances and Products: Development and Validation of Analytical Methods is a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development and validation of analytical methods. This book is intended as more than a review of new regional guidelines, existing regulatory guidance, and industry practices. It provides a hands-on guide to understanding and applying these in practice. The authors

discuss critical issues, novel approaches, and future directions while also providing insight into how International Guidelines were developed and the rationale behind them. Guide to industry best practices of analytical methodologies used in the specification of new drug substances and products (e.g. DOE, QbD) Critical assessment of the application of ICH guidelines on method validation and specification setting, written by experts involved in the development and application of the guidelines to aid understanding of requirements and what is expected by regulatory authorities Direct applicability to the day-to-day activities in drug development and the potential to increase productivity

HPLC for Pharmaceutical Scientists - Yuri V. Kazakevich 2007-02-16

HPLC for Pharmaceutical Scientists is an excellent book for both novice and experienced pharmaceutical chemists who regularly use HPLC as an analytical tool to solve challenging problems in the pharmaceutical industry. It provides a unified approach to HPLC with an equal and balanced treatment of the theory and practice of HPLC in the pharmaceutical industry. In-depth discussion of retention processes, modern HPLC separation theory, properties of stationary phases and columns are well blended with the practical aspects of fast and effective method development and method validation. Practical and pragmatic approaches and actual examples of effective development of selective and rugged HPLC methods from a physico-chemical point of view are provided. This book elucidates the role of HPLC throughout the entire drug development process from drug candidate inception to marketed drug product and gives detailed specifics of HPLC application in each stage of drug development. The latest advancements and trends in hyphenated and specialized HPLC techniques

(LC-MS, LC-NMR, Preparative HPLC, High temperature HPLC, high pressure liquid chromatography) are also discussed.

Identification and Determination of Impurities in Drugs - S. Görög 2000-05-19

Impurity profiling is the common name of a group of analytical activities, the aim of which is the detection, identification/structure elucidation and quantitative determination of organic and inorganic impurities, as well as residual solvents in bulk drugs and pharmaceutical formulations. Since this is the best way to characterise the quality and stability of bulk drugs and pharmaceutical formulations, this is the core activity in modern drug analysis. Due to the very rapid development of the analytical methodologies available for this purpose and the similarly rapid increase of the demands as regards the purity of drugs it is an important task to give a summary of the problems and the various possibilities offered by modern analytical chemistry for their solution. That is the aim of this book. The book is methodology-oriented. In the first chapter some important aspects of the background of impurity-related analytical studies (toxicological, pharmacopoeial aspects, the characterisation of the sources of impurities and the role of impurity profiling in various fields of drug research, production and therapeutic use) are summarised. Chapter two deals with related organic impurities, the strategies for impurity profiling, the use of chromatographic and related separation methods, spectroscopic, and hyphenated techniques. The subject of the third chapter is the identification and determination of residual solvents. The determination of inorganic impurities is discussed in chapter four. The special problems of degradation products as impurities are dealt with in chapter five. A separate chapter has been compiled to deal with one of the most up-to-

date problems in contemporary pharmaceutical analysis, the estimation of enantiomeric purity of chiral drugs. Chapter seven is devoted to various approaches to solve the problem of polymorphic modifications as impurities. Since in the broader sense of the word the microbiological purity of drugs and drug products also belongs to this circle, the most important information from this field is summarised in chapter eight. After the mainly methodology-oriented chapters, the final one concentrates on four groups of drugs (peptides, biotechnological products, antibiotics and steroids) in order to demonstrate the use of the methods described earlier.

Handbook of Analysis of Oligonucleotides and Related Products - Jose V. Bonilla 2011-02-23

Oligonucleotides represent one of the most significant pharmaceutical breakthroughs in recent years, showing great promise as diagnostic and therapeutic agents for malignant tumors, cardiovascular disease, diabetes, viral infections, and many other degenerative disorders. The Handbook of Analysis of Oligonucleotides and Related Products is an essential reference manual on the practical application of modern and emerging analytical techniques for the analysis of this unique class of compounds. A strong collaboration among thirty leading analytical scientists from around the world, the book provides readers with a comprehensive overview of the most commonly used analytical techniques and their advantages and limitations in assuring the identity, purity, quality, and strength of an oligonucleotide intended for therapeutic use. Topics discussed include: Strategies for enzymatic or chemical degradation of chemically modified oligonucleotides toward mass spectrometric sequencing Purity analysis by chromatographic or electrophoretic methods, including RP-HPLC, AX-HPLC, HILIC, SEC, and CGE

Characterization of sequence-related impurities in oligonucleotides by mass spectrometry and chromatography Structure elucidation by spectroscopic methods (IR, NMR, MS) as well as base composition and thermal melt analysis (Tm) Approaches for the accurate determination of molar extinction coefficient of oligonucleotides Accurate determination of assay values Assessment of the overall quality of oligonucleotides, including microbial analysis and determination of residual solvents and heavy metals Strategies for determining the chemical stability of oligonucleotides The use of hybridization techniques for supporting pharmacokinetics and drug metabolism studies in preclinical and clinical development Guidance for the presentation of relevant analytical information towards meeting current regulatory expectations for oligonucleotide therapeutics This resource provides a practical guide for applying state-of-the-art analytical techniques in research, development, and manufacturing settings.

Handbook of Modern Pharmaceutical Analysis Satinder Ahuja 2010-11-11

Handbook of Modern Pharmaceutical Analysis, Second Edition, synthesizes the complex research and recent changes in the field, while covering the techniques and technology required for today's laboratories. The work integrates strategy, case studies, methodologies, and implications of new regulatory structures, providing complete coverage of quality assurance from the point of discovery to the point of use. Treats pharmaceutical analysis (PA) as an integral partner to the drug development process rather than as a service to it Covers method development, validation, selection, testing, modeling, and simulation studies combined with advanced exploration of assays, impurity testing, biomolecules, and chiral separations Features detailed coverage of QA, ethics,

and regulatory guidance (quality by design, good manufacturing practice), as well as high-tech methodologies and technologies from "lab-on-a-chip" to LC-MS, LC-NMR, and LC-NMR-MS

Specification of Drug Substances and Products - Christopher M. Riley 2020-07-23

Specification of Drug Substances and Products: Development and Validation of Analytical Methods, Second Edition, presents a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development, validation of analytical methods, and their application in practice. This thoroughly revised second edition covers topics not covered or not substantially covered in the first edition, including method development and validation in the clinical phase, method transfer, process analytical technology, analytical life cycle management, special challenges with generic drugs, genotoxic impurities, topical products, nasal sprays and inhalation products, and biotechnology products. The book's authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines, and/or subject-matter experts in the industry, academia and in government laboratories. Presents a critical assessment of the application of ICH guidelines on method validation and specification setting Written by subject-matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis, control and specification of new drug substances and products Covers the latest statistical approaches (including analytical quality by design) in the development of specifications, method validation and shelf-life

prediction

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.

Handbook of Analytical Quality by Design - Sarwar Beg 2021-01-09

Handbook of Analytical Quality by Design addresses the steps involved in analytical method development and validation in an effort to avoid quality crises in later stages. The AQbD approach significantly enhances method performance and robustness which are crucial during inter-laboratory studies and also affect the analytical lifecycle of the developed method. Sections cover sample preparation problems and the usefulness of the QbD concept involving Quality Risk Management (QRM), Design of Experiments (DoE) and Multivariate (MVT) Statistical Approaches to solve by optimizing the developed method, along with validation for different techniques like HPLC, UPLC, UFLC, LC-MS and electrophoresis. This will be an ideal resource for graduate students and professionals working in the pharmaceutical industry, analytical chemistry, regulatory agencies, and those in related academic fields. Concise language for easy understanding of the novel and holistic concept Covers key aspects of analytical development and validation Provides a robust, flexible, operable range for an analytical method with greater excellence and regulatory compliance

Green Chemistry Strategies for Drug Discovery - Emily A. Peterson 2015-06-11

The incorporation of Green Chemistry is a relatively new phenomenon in the drug discovery discipline, since the scale that chemists operate on in drug discovery is smaller than those of process and manufacturing chemistry. The

necessary metrics are more difficult to obtain in drug discovery due to the diversity of reactions conducted. However, pharmaceutical companies are realizing that incorporation of green chemistry techniques at earlier stages of drug development can speed the development of a drug candidate. Written by experts who have pioneered green chemistry efforts within their own institutions, this book provides a practical guide for both academic and industrial labs wanting to know where to start with introducing greener approaches for greatest return on investment. The Editors have taken a comprehensive approach to the topic, covering the entire drug discovery process from molecule conception, through synthesis, formulation and toxicology with specific examples and case studies where green chemistry strategies have been implemented. Emerging techniques for performing greener drug discovery chemistry are addressed as well as cutting-edge topics like biologics discovery and continuous processing. Moreover, important surrounding issues such as intellectual property are included. This book serves as a practical guide for both academic and industrial chemists who work across the breadth of the drug discovery discipline. Ultimately, readers will learn how to incorporate green chemistry strategies into their everyday workflow without slowing down their science.

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.

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.

Statistical Design and Analysis in Pharmaceutical Science - Shein-Chung Chow 2018-10-03 "Offers a comprehensive, unified presentation of statistical designs and methods of analysis for all stages of pharmaceutical development--emphasizing biopharmaceutical applications and demonstrating statistical techniques with real-world examples."

Static Headspace-Gas

Chromatography - Bruno Kolb 2006-05-05
STATIC HEADSPACE-GAS CHROMATOGRAPHY THE ONLY REFERENCE TO PROVIDE BOTH CURRENT AND THOROUGH COVERAGE OF THIS IMPORTANT ANALYTICAL TECHNIQUE Static headspace-gas chromatography (HS-GC) is an indispensable technique for analyzing volatile organic compounds, enabling the analyst to assay a variety of sample matrices while avoiding the costly and time-consuming preparation involved with traditional GC. Static Headspace-Gas Chromatography: Theory and Practice has long been the only reference to provide in-depth coverage of this method of analysis. The Second Edition has been thoroughly updated to reflect the most recent developments and practices, and also includes coverage of solid-phase microextraction (SPME) and the purge-and-trap technique. Chapters cover: Principles of static and dynamic headspace analysis, including the evolution of HS-GC methods and regulatory methods using static HS-GC Basic theory of headspace analysis—physicochemical relationships, sensitivity, and the principles of multiple headspace extraction HS-GC techniques—vials, cleaning, caps, sample volume, enrichment, and cryogenic techniques Sample handling Cryogenic HS-GC Method development in HS-GC Nonequilibrium static headspace analysis Determination of physicochemical functions such as vapor pressures, activity coefficients, and more Comprehensive and focused, Static Headspace-Gas Chromatography, Second Edition provides an excellent resource to help the reader achieve optimal chromatographic results. Practical examples with original data help readers to master determinations in a wide variety of areas, such as forensic, environmental, pharmaceutical, and industrial applications.

Analytical Method Development and Validation - Michael E. Swartz 2018-10-03 Describes analytical methods development, optimization and validation, and provides examples of successful methods development and validation in high-performance liquid chromatography (HPLC) areas. The text presents an overview of Food and Drug Administration (FDA)/International Conference on Harmonization (ICH) regulatory guidelines, compliance with validation requirements for regulatory agencies, and methods validation criteria stipulated by the US Pharmacopia, FDA and ICH.

Pharmaceutical Product Development - Vandana B. Patravale 2016-05-25 Pharmaceutical product development is a multidisciplinary activity involving extensive efforts in systematic product development and optimization in compliance with regulatory authorities to ensure the quality, efficacy and safety of resulting products. Pharmaceutical Product Development equips the pharmaceutical formulation scientist with extensive and up-to-date knowledge of drug product development and covers all steps from the beginning of product conception to the final packaged form that enters the market and lifecycle management thereof. Applications of core scientific principles for product development are also thoroughly discussed in conjunction with the latest approaches involving design of experiment and quality by design with comprehensive illustrations based on practical case studies of several dosage forms. The book presents pharmaceutical product development information in an easy-to-read mode with simplified theories, case studies and guidelines for students, academicians and professionals in the pharmaceutical industry. It is an invaluable resource and hands-on guide covering

managerial, regulatory and practical aspects of pharmaceutical product lifecycle management.

Encyclopedia of Chromatography - Jack Cazes 2009-10-12

Thoroughly revised and expanded, the third edition of the Encyclopedia of Chromatography is an authoritative source of information for researchers in chemistry, biology, physics, engineering, and materials science. This quick reference and guide to specific chromatographic techniques and theory provides a basic introduction to the science and techn

Basic Science of PET Imaging - Magdy M. Khalil 2016-11-07

This book offers a wide-ranging and up-to-date overview of the basic science underlying PET and its preclinical and clinical applications in modern medicine. In addition, it provides the reader with a sound understanding of the scientific principles and use of PET in routine practice and biomedical imaging research. The opening sections address the fundamental physics, radiation safety, CT scanning dosimetry, and dosimetry of PET radiotracers, chemistry and regulation of PET radiopharmaceuticals, with information on labeling strategies, tracer quality control, and regulation of radiopharmaceutical production in Europe and the United States. PET physics and instrumentation are then discussed, covering the basic principles of PET and PET scanning systems, hybrid PET/CT and PET/MR imaging, system calibration, acceptance testing, and quality control. Subsequent sections focus on image reconstruction, processing, and quantitation in PET and hybrid PET and on imaging artifacts and correction techniques, with particular attention to partial volume correction and motion artifacts. The book closes by examining clinical applications of PET and hybrid PET and their physiological and/or molecular basis in conjunction with technical foundations in

the disciplines of oncology, cardiology and neurology, PET in pediatric malignancy and its role in radiotherapy treatment planning. Basic Science of PET Imaging will meet the needs of nuclear medicine practitioners, other radiology specialists, and trainees in these fields.

Karl Fischer Titration - Eugen Scholz 2012-12-06

The Karl Fischer titration is used in many different ways following its publication in 1935 and further applications are continually being explored. At the present time we are experiencing another phase of expansion, as shown by the development of new titration equipment and new reagents. KF equipment increasingly incorporates microprocessors which enable the course of a titration to be programmed thus sim plifying the titration. Coulometric titrators allow water determinations in the micro gram-range: the KF titration has become a micro-method. The new pyridine-free re agents make its application significantly more pleasant and open up further possibili ties on account of their accuracy. To make the approach to Karl Fischer titrations easier, we have summarized the present knowledge in this monograph and we have complemented it with our own studies and practical experience. As this book should remain "readable", we have tried to keep the fundamentals to a minimum. Historical developments are only mentioned if they seem to be necessary for understanding the KF reaction. The ap plications are described more fully. Specific details which may interest a particular reader can be found in the original publications cited. The referenced literature is in chronological order as the year of publication may also prove informative. Thus, [6902] for example denotes 69 for 1969 being the year of publication and 02 is a non-recurring progressive number. The referenced litera ture includes summaries which we hope will be of help to find the "right" publica tion easily.

Cumulated Index Medicus - 1999

Quality Control and Evaluation of Herbal Drugs - Pulok K. Mukherjee 2019-05-30 Quality Control and Evaluation of Herbal Drugs brings together current thinking and practices for evaluation of natural products and traditional medicines. The use of herbal medicine in therapeutics is on the rise in both developed and developing countries and this book facilitates the necessary development of quality standards for these medicines.This book elucidates on various challenges and opportunities for quality evaluation of herbal drugs with several integrated approaches including metabolomics, chemoprofiling, marker analysis, stability testing, good practices for manufacturing, clinical aspects, Ethnopharmacology and Ethnomedicine inspired drug development. Written by Prof. Pulok K Mukherjee, a leader in this field; the book highlights on various methods, techniques and approaches for evaluating the purity, quality, safety and efficacy of herbal drugs. Particular attention is paid to methods that assess these drugs' activity, the compounds responsible and their underlying mechanisms of action. The book describes the quality control parameters followed in India and other countries, including Japan, China, Bangladesh, and other Asian countries, as well as the regulatory profiles of the European Union and North America. This book will be useful in bio-prospecting of natural products and traditional medicine-inspired drug discovery and development. Provides new information on the research and development of natural remedies - essential reading on the study and use of natural resources for preventative or healing purposes Brings together current thinking and practices in quality control and standardization of herbal drugs highlighting several integrated approaches for metabolomics, chemo-profiling and marker analysis Aids in developing knowledge of various

techniques including macroscopy, microscopy, HPTLC, HPLC, LC-MS/MS, GC-MS etc. with the development of integrated methods for evaluation of botanicals used in traditional medicine Assessment of herbal drugs through bio-analytical techniques, bioassay guided isolation, enzyme inhibition, pharmacological, microbiological, antiviral assays and safety related quality issues References global organizations, such as the WHO, USFDA, CDSCO, AYUSH, TCM and others to serve as a comprehensive document for enforcement agencies, NGOs and regulatory authorities

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

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.

Quality Management and Quality Control - Paulo Pereira (mikrobiolog.) 2019-04-10

Quality management (QM) practices are the basis for the

successful implementation and maintenance of any QM system. Quality control (QC) is identified as a QM component. Therefore, QM effectiveness is dependent on the QC strategy. QC practice is more or less complex depending on the type of production. The book is focused on new trends and developments in QM and QC in several types of industries from a worldwide perspective. Its content has been organized into two sections and seven chapters written by well-recognized researchers worldwide. Several approaches are debated based on sample traceability, analytical method validation, required parameters, class of exponential regression-type estimators of the population means, determination of impurities, viewpoints, and case studies.

Mutagenic Impurities - Andrew Teasdale 2022-02-15 Learn to implement effective control measures for mutagenic impurities in pharmaceutical development In Mutagenic Impurities: Strategies for Identification and Control, distinguished chemist Andrew Teasdale delivers a thorough examination of mutagenic impurities and their impact on the pharmaceutical industry. The book incorporates the adoption of the ICH M7 guideline and focuses on mutagenic impurities from both a toxicological and analytical perspective. The editor has created a primary reference for any professional or student studying or working with mutagenic impurities and offers readers a definitive narrative of applicable guidelines and practical, tested solutions. It demonstrates the development of effective control measures, including chapters on the purge tool for risk assessment. The book incorporates a discussion of N-Nitrosamines which was arguably the largest mutagenic impurity issue ever faced by the pharmaceutical industry, resulting in the recall of Zantac and similar drugs resulting from N-Nitrosamine contamination. Readers will

also benefit from the inclusion of: A thorough introduction to the development of regulatory guidelines for mutagenic and genotoxic impurities, including a historical perspective on the development of the EMEA guidelines and the ICH M7 guideline An exploration of in silico assessment of mutagenicity, including use of structure activity relationship evaluation as a tool in the evaluation of the genotoxic potential of impurities A discussion of a toxicological perspective on mutagenic impurities, including the assessment of mutagenicity and examining the mutagenic and carcinogenic potential of common synthetic reagents Perfect for chemists, analysts, and regulatory professionals, Mutagenic Impurities: Strategies for Identification and Control will also earn a place in the libraries of toxicologists and clinical safety scientists seeking a one-stop reference on the subject of mutagenic impurity identification and control.

Chemical Analysis Steen Hansen 2011-12-12

This textbook is the first to present a systematic introduction to chemical analysis of pharmaceutical raw materials, finished pharmaceutical products, and of drugs in biological fluids, which are carried out in pharmaceutical laboratories worldwide. In addition, this textbook teaches the fundamentals of all the major analytical techniques used in the pharmaceutical laboratory, and teaches the international pharmacopoeias and guidelines of importance for the field. It is primarily intended for the pharmacy student, to teach the requirements in “analytical chemistry” for the 5 years pharmacy curriculum, but the textbook is also intended for analytical chemists moving into the field of pharmaceutical analysis. Addresses the basic concepts, then establishes the foundations for the common analytical methods that are currently used in the quantitative and qualitative

Introduction to Pharmaceutical chemical analysis of

pharmaceutical drugs Provides an understanding of common analytical techniques used in all areas of pharmaceutical development Suitable for a foundation course in chemical and pharmaceutical sciences Aimed at undergraduate students of degrees in Pharmaceutical Science/Chemistry Analytical Science/Chemistry, Forensic analysis Includes many illustrative examples

Taxol - Matthew Suffness 1995-05-25

This volume brings together all aspects of TAXOL® research, development, and clinical use. It provides comprehensive knowledge of the compound and a perspective of the complex interrelationships needed for its development and production. Each chapter is written by an authority in the field. Chapters are carefully coordinated to maximize information on key topics while avoiding overlap and duplication. Previously unpublished material is presented along with thorough reviews of each topic.

Development and Validation of Analytical Methods Christopher M. Riley 1996-05-29

The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising

two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always

remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

Handbook of Solvents - George Wypych 2001

A comprehensive, extensive textual analysis of the principles of solvent selection and use, the handbook is intended to help formulators select ideal solvents, safety coordinators to protect workers, and legislators and inspectors to define and implement technically correct public safeguards for use, handling, and disposal.

Wide Spectra of Quality Control - Isin Akyar 2011-11-09

Quality control is a standard which certainly has become a style of living. With the improvement of technology every day, we meet new and complicated devices and methods in different fields. Quality control explains the directed use of testing to measure the achievement of a specific standard. It is the process, procedures and authority used to accept or reject all components, drug product containers, closures, in-process materials, packaging material, labeling and drug products, and the authority to review production records to assure that no errors have occurred.The quality which is supposed to be achieved is not a concept which can be controlled by easy, numerical or other means, but it is the control over the intrinsic quality of a test facility and its studies. The aim of this book is to share useful and practical knowledge about quality control in several fields with the people who want to improve their knowledge.

Pharmaceutical Industry Practices on Genotoxic Impurities Heewon Lee 2014-08-29

A great deal of confusion and uncertainty over genotoxic

impurity (GTI) identification, assessment, and control exists in the pharmaceutical industry today. Pharmaceutical Industry Practices on Genotoxic Impurities strives to facilitate scientific and systematic consensus on GTI management by presenting rationales, strategies, methods, interpretations, practices, and case studies from the pharmaceutical industry. Featuring the contributions of industry leaders from nine major pharmaceutical companies, this authoritative text: Explores the safety, quality, and regulatory aspects of GTIs Provides an overview of the latest FDA and EMEA guidelines Explains the how and why of various GTI control tactics and practices Describes genotoxicity evaluation, acceptable exposure calculation, and analytical methods for testing Includes real-life examples of GTI control in drug substance and drug product development processes Containing case studies from large and small pharmaceutical firms in multiple geographical regions, Pharmaceutical Industry Practices on Genotoxic Impurities supplies an overview of—and a current framework for—GTI control in the pharmaceutical industry, demonstrating how proper management of GTIs can occur with the appropriate guidance, a firm grasp of the practical implications, and effective information sharing between disciplines.

YBB 00312004-2015: Translated English of Chinese Standard. YBB00312004-2015 - https://www.chinesestandard.net 2017-07-09

[After payment, write to & get a FREE-of-charge, unprotected true-PDF from: Sales@ChineseStandard.net] This Method applies to the determination of residual solvent of pharmaceutical packaging materials. Residual solvent of pharmaceutical packaging materials refers to organic volatile substances which are used in the raw and auxiliary materials and the production process, but are not

fully removed during the production process of pharmaceutical packaging materials. The residual quantity of organic solvent in pharmaceutical packaging materials shall be as specified for each product. The types of solvent to be tested shall be determined in accordance with the characteristics of formulas and technologies of products; they are not limited to the solvents described in this Standard.

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.

Formulating Poorly Water Soluble Drugs - Robert O. Williams III 2016-12-16

The objective of this volume is to consolidate within a single text the most current knowledge, practical methods, and regulatory considerations pertaining to formulations development with poorly water-soluble molecules. A pharmaceutical scientist’s approach toward solubility enhancement of a poorly water-soluble molecule typically

includes detailed characterization of the compound's physiochemical properties, solid-state modifications, advanced formulation design, non-conventional process technologies, advanced analytical characterization, and specialized product performance analysis techniques. The scientist must also be aware of the unique regulatory considerations pertaining to the non-conventional approaches often utilized for poorly water-soluble drugs. One faced with the challenge of developing a drug product from a poorly soluble compound must possess at minimum a working knowledge of each of the abovementioned facets and detailed knowledge of most. In light of the magnitude of the growing solubility problem to drug development, this is a significant burden especially when considering that knowledge in most of these areas is relatively new and continues to develop

Issues in Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology: 2011 Edition - 2012-01-09

Issues in Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology: 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology. The editors have built Issues in Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology: 2011 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Issues in Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology: 2011 Edition has

been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.