Extractables And Leachables Services Intertek

Practical Gas Chromatography
Respiratory Drug Delivery (1989)
Controlled Pulmonary Drug Delivery
New TSCA
Leachables and Extractables Handbook
Volume 3: Expectations and Realities of Multifunctional Drug Delivery Systems
Additives for Polyolefins
WHO Expert Committee on Specifications for Pharmaceutical Preparations
Materials Design and Applications
Essential Chemistry for Formulators of Semisolid and Liquid Dosages
An Implementation Guide
Biotechnology
Fifty-second Report
Pharmaceutical Dissolution Testing
Health Care Litigation Reform
1985 Annual Book of ASTM Standards
Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products
Who Expert Committee on Specifications for Pharmaceutical Preparations
Drug Delivery Trends
Lu's Basic Toxicology
From Bench to Bedside
Plant Health Management
Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals
Disposable Bioprocessing Systems
Optimizing Development through Integration of In Silico, In Vitro and In Vivo Approaches
A Guide to Best Practice
Method Validation in Pharmaceutical Analysis
Fundamentals of Modern Bioprocessing
Inhaled Medicines
Strategies for Identification and Control
Getting the Most out of Polypropylene, Polyethylene and TPO
Shelf-life Determination
Genotoxic Impurities
Integrated Safety and Risk Assessment for Medical Devices and Combination Products
Forty-seventh Report
Handbook of Green Chemistry, Green Processes, Designing Safer Chemicals
Wastewater Microbiology
Technologies and Applications

A Handbook for Operators

BROWN SADIE

Practical Gas Chromatography MDPI
An expertly written source on the devices, systems, and technologies used in the dissolution testing of oral pharmaceutical dosage forms, this reference provides reader-friendly chapters on currently utilized equipment, equipment qualification, consideration of the gastrointestinal physiology in test design, the analysis and interpretation of data and procedure automation -laying the foundation for the creation of appropriate and useful dissolution tests according to the anticipated location and duration of drug release from the dosage form within the gastrointestinal tract.
Respiratory Drug Delivery (1989) Springer Nature
"With the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016, the main body of chemical management law in the United States changed dramatically. This guide summarizes the new law, highlights the changes that will have the greatest impact, and offers pertinent analysis on the implementation of the new law."--
Controlled Pulmonary Drug Delivery William Andrew
Focusing on the practical applications, this user-oriented guide presents current technologies and strategies for systems-level lipid analysis, going beyond basic research to concentrate on commercial uses of lipidomics in biomarker and diagnostic development, as well as within pharmaceutical drug discovery and development. The editor and authors have experience of the most recent analytical instruments and techniques, allowing them to provide here first-hand practical experience for newcomers to the field. The first half of the book covers current methodologies, ranging from global to targeted lipidomics and shotgun approaches, while the second part discusses the role of lipidomics in biomedical and pharmaceutical research, covering such diverse fields as inflammation, metabolic syndrome, cardiovascular and neurological disease. Both small and large-scale, high-throughput approaches are discussed, resulting in an invaluable source for academic and industrial research and development.
New TSCA CRC Press
"Because leachables are non-drug-related impurities, there are increased concerns regarding the risks of inhaling them on a daily basis. This book describes the development and application of safety thresholds for Orally Inhaled and Nasal Drug Products (OINDP). It discusses best practices for evaluation and management of leachables and extractables throughout the pharma product lifecycle by providing practical knowledge about how and why safety thresholds were developed. This book also illustrates how to apply these concepts and principles to products beyond OINDP, and includes an appendix of experimental protocols for laboratory analysis"--Provided by publisher.
Leachables and Extractables Handbook CRC Press
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.
Volume 3: Expectations and Realities of Multifunctional Drug Delivery Systems John Wiley & Sons
The shift towards being as environmentally-friendly as possible has resulted in the need for this important reference on the topic of designing safer chemicals. Edited by the leading international experts in the field, Robert Boethling and Adelina Votchkova, this volume covers such topics as toxicity, reducing hazards and biochemical pesticides. An essential resource for anyone wishing to gain an understanding of the world of green chemistry, as well as for chemists, environmental agencies and chemical engineers. The Handbook of Green Chemistry comprises of 9 volumes in total, split into 3 subject-specific sets. The three sets are available individually. All 9 volumes are available individually, too. Set I: Green Catalysis - Volume 1: Homogeneous Catalysis - Volume 2: Heterogeneous Catalysis - Volume 3: Biocatalysis Set II: Green Solvents - Volume 4: Supercritical Solvents - Volume 5: Reactions in Water - Volume 6: Ionic Liquids Set III: Green Processes - Volume 7: Green Synthesis - Volume 8: Green Nanoscience - Volume 9: Designing Safer Chemicals The Handbook of Green Chemistry is also available as Online Edition. Podcasts Listen to two podcasts in which Professor Paul Anastas and Journals Editor Paul Trevorrow discuss the origin and expansion of Green Chemistry and give an overview of The Handbook of Green Chemistry.
Additives for Polyolefins American Water Works Association
"A comprehensive overview of clinical laboratory toxicology services and analytes"--
WHO Expert Committee on Specifications for Pharmaceutical Preparations Academic Press
Written by a researcher with experience designing, establishing, and validating biological manufacturing facilities worldwide, this is the first comprehensive introduction to disposable systems for biological drug manufacturing. It reviews the current state of the industry; tackles questions about safety, costs, regulations, and waste disposal; and guides readers to choose disposable components that meet their needs. This practical manual covers disposable containers, mixing systems, bioreactors, connectors and transfers, controls and sensors, downstream processing systems, filling and finishing systems, and filters. The author also shares his predictions for the future, calling disposable bioprocessing technology a "game changer."
Materials Design and Applications American Bar Association
The pace of new research and level of innovation repeatedly introduced into the field of drug delivery to the lung is surprising given its state of maturity since the introduction of the pressurized metered dose inhaler over a half a century ago. It is clear that our understanding of pulmonary drug delivery has now evolved to the point that inhalation aerosols can be controlled both spatially and temporally to optimize their biological effects. These abilities include controlling lung deposition, by

adopting formulation strategies or device technologies, and controlling drug uptake and release through sophisticated particle technologies. The large number of contributions to the scientific literature and variety of excellent texts published in recent years is evidence for the continued interest in pulmonary drug delivery research. This reference text endeavors to bring together the fundamental theory and practice of controlled drug delivery to the airways that is unavailable elsewhere. Collating and synthesizing the material in this rapidly evolving field presented a challenge and ultimately a sense of achievement that is hopefully reflected in the content of the volume.

Essential Chemistry for Formulators of Semisolid and Liquid Dosages Humana Press

Shelf-Life Determination

An Implementation Guide WHO Technical Report

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use: - WHO guidelines on good herbal processing practices for herbal medicines; - Guidelines on good manufacturing practices for the manufacture of herbal medicines; - Considerations for requesting analysis of medicine samples; - WHO model certificate of analysis; - WHO guidance on testing of "suspect" falsified medicines; - Good pharmacopoeial practices - Chapter on monographs for compounded preparations; - Good pharmacopoeial practices - Chapter on monographs on herbal medicines; - Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products; - Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions; - Stability testing of active pharmaceutical ingredients and finished pharmaceutical products; and - Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities.

Biotechnology IBDC Publishers

Essential Chemistry for Formulators of Semisolid and Liquid DosagesAcademic Press

Fifty-second Report John Wiley & Sons

A real-world guide to the production and manufacturing of biopharmaceuticals While much has been written about the science of biopharmaceuticals, there is a need for practical, up-to-date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products. This book helps fill the gap in the field, examining all areas of biopharmaceuticals manufacturing, from development and formulation to production and packaging. Written by a group of experts from industry and academia, the book focuses on real-world methods for maintaining product integrity throughout the commercialization process, clearly explaining the fundamentals and essential pathways for all development stages. Coverage includes: Research and early development phase–appropriate approaches for ensuring product stability Development of commercially viable formulations for liquid and lyophilized dosage forms Optimal storage, packaging, and shipping methods Case studies relating to therapeutic monoclonal antibodies, recombinant proteins, and plasma fractions Useful analysis of successful and failed products Formulation and Process Development Strategies for Manufacturing Biopharma-ceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries, for government and regulatory agencies, and for anyone with an interest in the latest developments in the field.

Pharmaceutical Dissolution Testing Trans Tech Publications Ltd

International Conference on Materials Design and Applications (ICMDA 2018) Selected, peer reviewed papers from the 2018 International Conference on Materials Design and Applications (ICMDA 2018), April 04-06, 2018, Colombo, Sri Lanka

Health Care Litigation Reform Elsevier

This book provides a serious introduction to the subject of mass spectrometry, providing the reader with the tools and information to be well prepared to perform such demanding work in a real-life laboratory. This essential tool bridges several subjects and many disciplines including pharmaceutical, environmental and biomedical analysis that are utilizing mass spectrometry: Covers all aspects of the use of mass spectrometry for quantitation purposes Written in textbook style to facilitate understanding of this topic Presents fundamentals and real-world examples in a ‘learning-though-doing’ style

1985 Annual Book of ASTM Standards Stationery Office

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)

Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products CRC Press

This book focuses on the polyolefin additives that are currently important in the plastics industry, alongside new additives of increasing interest, such as nanofillers and environmentally sustainable materials. As much as possible, each chapter emphasizes the performance of the additives in the polymer, and the value each relevant additive brings to polypropylene or polyethylene. Where possible, similar additives are compared by capability and relative cost. With major sections for each additive function, this book provides a highly practical guide for engineers and scientists creating and using polyolefin compounds, who will find in this book a wealth of detail and practical guidance. This unique resource will enable them to make practical decisions about the use of the various additives, fillers, and reinforcements specific to this family of materials. ABOUT THE AUTHOR Michael Tolinski is a freelance writer and a lecturer at the University of Michigan's College of Engineering. He is a frequent contributor to Plastics Engineering and Manufacturing Engineering. Structured to make it easy for the reader to find solutions for specific property requirements Contains a number of short case studies about companies that have used or developed a particular additive to achieve a desired

result Covers environmental resistance, mechanical property enhancement, appearance enhancement, processing aids, and other modifications of form and function

Who Expert Committee on Specifications for Pharmaceutical Preparations John Wiley & Sons

A needed resource for pharmaceutical scientists and cosmetic chemists, Essential Chemistry for Formulators of Semisolid and Liquid Dosages provides insight into the basic chemistry of mixing different phases and test methods for the stability study of nonsolid formulations. The book covers foundational surface/colloid chemistry, which forms the necessary background for making emulsions, suspensions, solutions, and nano drug delivery systems, and the chemistry of mixing, which is critical for further formulation of drug delivery systems into semisolid (gels, creams, lotions, and ointments) or liquid final dosages. Expanding on these foundational principles, this useful guide explores stability testing methods, such as particle size, rheological/viscosity, microscopy, and chemical, and closes with a valuable discussion of regulatory issues. Essential Chemistry for Formulators of Semisolid and Liquid Dosages offers scientists and students the foundation and practical guidance to make and analyze semisolid and liquid formulations. Unique coverage of the underlying chemistry that makes possible stable dosages Quality content written by experienced experts from the drug development industry Valuable information for academic and industrial scientists developing topical and liquid dosage formulations for pharmaceutical as well as skin care and cosmetic products

Drug Delivery Trends John Wiley & Sons

WHO's international guidelines, written and physical standards developed under the aegis of this Expert Committee for more than 60 years are designed to serve all Member States, international organizations, United Nations agencies, regional and interregional harmonization efforts, and underpin important initiatives, including the prequalification of medicines, the Roll Back Malaria Programme, Stop TB, essential medicines and medicines for children. The Forty-seventh WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted 26 new monographs and general texts for inclusion in The International Pharmacopoeia,/I>. The specifications under development are internationally applicable test methodologies for anti-infective, antimalarial, antituberculosis, contraceptives and antiretroviral medicines, as well as medicines for children. In addition, the following four written standards were adopted in the area of quality assurance and are now available for implementation : * Release procedure for International Chemical Reference Substances (update); * WHO guideline on quality risk management (new) * WHO guideline on variations to a prequalified product (update) * Collaborative procedure between the WHO Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products (new).

Lu's Basic Toxicology John Wiley & Sons

Continuing a long tradition, Lu’s Basic Toxicology, Seventh Edition, combines relatively comprehensive coverage of toxic substances in food, air, and water with brevity, thereby continuing to serve as an updated introductory text for toxicology students and for those involved in allied sciences that require a background in toxicology. The new edition, which now becomes an edited work with contributions from experts around the globe, features four new chapters and a number of existing chapters that have been updated and expanded, notably those on mechanisms of toxic effects, conventional toxicity studies, the cardiovascular system, and risk assessment and regulatory toxicology. The book consists of four parts (Part I–Part IV) that provide guidance on principles of toxicology and testing procedures for toxicities as well as a concise, yet detailed, mechanism of both target organ and nontarget organ toxicities. The book is rounded off with a final section (Part IV) on the toxic effects of chemicals and risk assessment, giving toxicologists, both students and practicing professionals, the necessary tools to enhance their practice. This edition includes new chapters on Clinical Toxicology, Systems Toxicology, Chemicals and Children, and Toxicology of Reproductive Systems, providing the essentials of these topics in the same style as the other chapters in the book. With separate subject and chemical indexes, this is a useful, quick shelf reference for everyone working in toxicology today.