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Ranked Set Sampling
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BENJAMIN WHITEHEAD

Particles and Nanoparticles in Pharmaceutical Products
Cambridge Scholars Publishing
This edited volume brings together the expertise of numerous specialists on the topic of particles – their physical, chemical, pharmacological and toxicological characteristics – when they are a component of pharmaceutical products and formulations. The book discusses in detail properties such as the composition, size, shape, surface properties and porosity of particles with respect to how they impact the formulations and products in which they are used and the effective delivery of pharmaceutical active ingredients. It considers all dosage forms of pharmaceuticals involving particles, from powders to tablets, creams to ointments, and solutions to dry-powder inhalers, also including the latest nanomedicine products. Further, it discusses examples of particle toxicity, as well as the important subject of pharmaceutical industry regulations, guidelines and legislation. The book is of interest to researchers and practitioners who work on testing and developing pharmaceutical dosage and delivery systems.
Issues in Pharmacology, Pharmacy, Drug Research, and Drug Innovation: 2011 Edition ScholarlyEditions
Rapid, inexpensive, and easy-to-deploy, near-infrared (NIR) spectroscopy can be used to analyze samples of virtually any composition, origin, and condition. The Handbook of Near Infrared Analysis, Fourth Edition, explores the factors necessary to

perform accurate and time- and cost-effective analyses across a growing spectrum of disciplines. This updated and expanded edition incorporates the latest advances in instrumentation, computerization, chemometrics applied to NIR spectroscopy, and method development in NIR spectroscopy, and underscores current trends in sample preparation, calibration transfer, process control, data analysis, instrument performance testing, and commercial NIR instrumentation. This work offers readers an unparalleled combination of theoretical foundations, cutting-edge applications, and practical experience. Additional features include the following: Explains how to perform accurate as well as time- and cost-effective analyses. Reviews software-enabled chemometric methods and other trends in data analysis. Highlights novel applications in pharmaceuticals, polymers, plastics, petrochemicals, textiles, foods and beverages, baked products, agricultural products, biomedicine, nutraceuticals, and counterfeit detection. Underscores current trends in sample preparation, calibration transfer, process control, data analysis, and multiple aspects of commercial NIR instrumentation. Offering the most complete single-source guide of its kind, the Handbook of Near Infrared Analysis, Fourth Edition, continues to offer practicing chemists and spectroscopists an unparalleled combination of theoretical foundations, cutting-edge applications, and detailed practical experience provided firsthand by more than 50 experts in the field.

The Use of Drugs in Food Animals CRC Press

Since the publication of the first edition in 2000, there has been an explosive growth of literature in biopharmaceutical research and development of new medicines. This encyclopedia (1) provides a comprehensive and unified presentation of designs and analyses used at different stages of the drug development process, (2) gives a well-balanced summary of current regulatory requirements, and (3) describes recently developed statistical methods in the pharmaceutical sciences. Features of the Fourth Edition: 1. 78 new and revised entries have been added for a total of 308 chapters and a fourth volume has been added to encompass the increased number of chapters. 2. Revised and updated entries reflect changes and recent developments in regulatory requirements for the drug review/approval process and statistical designs and methodologies. 3. Additional topics include multiple-stage adaptive trial design in clinical research, translational medicine, design and analysis of biosimilar drug development, big data analytics, and real world evidence for clinical research and development. 4. A table of contents organized by stages of biopharmaceutical development provides easy access to relevant topics. About the Editor: Shein-Chung Chow, Ph.D. is currently an Associate Director, Office of Biostatistics, U.S. Food and Drug Administration (FDA). Dr. Chow is an Adjunct Professor at Duke University School of Medicine, as well as Adjunct Professor at Duke-NUS, Singapore and North Carolina State University. Dr. Chow is the Editor-in-Chief of the Journal of Biopharmaceutical Statistics and the Chapman & Hall/CRC Biostatistics Book Series and the author of 28 books and over 300 methodology papers. He was elected Fellow of the American Statistical Association in 1995.

Good Manufacturing Practices for Pharmaceuticals Academic Press

Continuous manufacturing of pharmaceuticals, including aspects

of modern process development is highlighted in this book with both the ‘why’ and the ‘how’, emphasizing process modeling and process analytical technologies. Presenting specific case studies and drawing upon extensive experience from industry and academic opinion leaders, this book focuses on the practical aspects of continuous manufacturing. It gives the readers the strategic perspective and technical depth needed to adopt and implement these technologies, where appropriate, in order to gain the competitive edge in speed, agility, and reliability. Features: Discusses scientific solutions and process analytical technology to enable continuous manufacturing in the development of new drugs Includes short stories about how some companies have adopted CM and what their drivers were and what benefits were realized Addresses economic and practical considerations, unlike many other technical books Emphasizes the practical aspects to give the reader the strategic imperative and technological depth to adopt and implement these technologies Highlights the "why" and the "how", focusing on the need analysis and process modeling and process analytical technologies

Chemical Engineering CRC Press

Due in part to an absence of universally accepted standardization methods, nutraceuticals and functional foods face regulatory ignorance, marketing incompetence and ethical impunity. Even though many researchers believe that there is a connection between nutraceuticals and functional foods and reduced health care expenses as well as disease prevent

Integrated Pharmaceutics Springer

The textbook addresses the lifecycle concepts (Stage 1, 2, 3) of Process Validation. Regulatory bodies such as US FDA, EMEA, WHO, PIC/S have adopted the ICH lifecycle approach. Organizations have an opportunity to harmonize and align PV activities for all regulated markets. The concepts discussed provides a direction on how to approach solid dose manufacturing process validation for regulatory compliance. Solid Oral Dose Process Validation, Lifecycle Approach: Application, Volume Two and the companion Volume One, Solid Dose Process Validation, The Basics, also available as a set, provide directions and solutions for the pharmaceutical industry. The topics and chapters give a systematic understanding for the application of lifecycle concepts in solid dose pharmaceutical manufacturing. Since solid dose formulations encompass majority of the pharmaceutical preparations, it is essential information for pharmaceutical professionals who use the process validation lifecycle approach. This set is published as a comprehensive solution for solid dose process validation.

Handbook of Pharmaceutical Granulation Technology Springer Nature

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 spectroscopy as an effective tool for pharmaceutical testing. Pharmaceutical and Medical Applications of Near-Infrared Spectroscopy: Second Edition reflects these developments and brings readers an up-to-date summary of how this technique is being applied to

pharmaceutical manufacturing. Topics include: The origins and principles of NIR spectroscopy, including early instrumentation, spectroscopic theory, and light-particle interaction The physics of each instrument type, the strengths and weaknesses of each, and the manufacturers that produce them The possible advantages of using NIR methods for monitoring or controlling blending, as well as practical concerns for mixing processes NIR spectroscopy as applied to traditional granulation, drug layering, and film coating of beads or granules Pharmaceutical assays, including qualitative analysis, quantitative analysis, determination of actives in tablets and capsules, and considerations for intact dosage form analysis Steps involved in the validation and acceptance of an NIR spectroscopy method, including quality assurance, qualification and verification of instruments, and the International Conference on Harmonization (ICH) guidelines Medical applications, including those related to blood glucose measurements, tissue and major organ analysis, fetal analysis, and cancer research Providing comprehensive coverage of NIR spectroscopy, from theory, mathematics, application, and mechanics of NIR analysis, the book supplies ample references to facilitate further research into this burgeoning field.

Handbook of Nutraceuticals Volume II John Wiley & Sons

The aim of this book is to present a range of analytical methods that can be used in formulation design and development and focus on how these systems can be applied to understand formulation components and the dosage form these build. To effectively design and exploit drug delivery systems, the underlying characteristic of a dosage form must be understood--from the characteristics of the individual formulation components, to how they act and interact within the formulation, and finally, to how this formulation responds in different biological environments. To achieve this, there is a wide range of analytical techniques that can be adopted to understand and elucidate the mechanics of drug delivery and drug formulation. Such methods include e.g. spectroscopic analysis, diffractometric analysis, thermal investigations, surface analytical techniques, particle size analysis, rheological techniques, methods to characterize drug stability and release, and biological analysis in appropriate cell and animal models. Whilst each of these methods can encompass a full research area in their own right, formulation scientists must be able to effectively apply these methods to the delivery system they are considering. The information in this book is designed to support researchers in their ability to fully characterize and analyze a range of delivery systems, using an appropriate selection of analytical techniques. Due to its consideration of regulatory approval, this book will also be suitable for industrial researchers both at early stage up to pre-clinical research.

Cell and Gene Therapies Springer Science & Business Media

Issues in Pharmacology, Pharmacy, Drug Research, and Drug Innovation: 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Pharmacology, Pharmacy, Drug Research, and Drug Innovation. The editors have built Issues in Pharmacology, Pharmacy, Drug Research, and Drug Innovation: 2011 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Pharmacology, Pharmacy, Drug Research, and Drug Innovation 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 Pharmacology, Pharmacy, Drug Research, and Drug Innovation: 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/.

Water-Insoluble Drug Formulation Springer Nature

Basic Physical Pharmacy provides a thorough yet accessible overview of the principles of physical pharmacy and their application in drug formulation and administration. This definitive guide to physical pharmacy covers all types of pharmaceuticals, from traditional forms and dosages to nanotechnology-based novel dosage design.

Bayesian Methods in Pharmaceutical Research CRC Press

The use of drugs in food animal production has resulted in benefits throughout the food industry; however, their use has also raised public health safety concerns. The Use of Drugs in Food Animals provides an overview of why and how drugs are used in the major food-producing animal industriesâ€"poultry, dairy, beef, swine, and aquaculture. The volume discusses the prevalence of human pathogens in foods of animal origin. It also addresses the transfer of resistance in animal microbes to human pathogens and the resulting risk of human disease. The committee offers analysis and insight into these areas: Monitoring of drug residues. The book provides a brief overview of how the FDA and USDA monitor drug residues in foods of animal origin and describes quality assurance programs initiated by the poultry, dairy, beef, and swine industries. Antibiotic resistance. The committee reports what is known about this controversial problem and its potential effect on human health. The volume also looks at how drug use may be minimized with new approaches in genetics, nutrition, and animal management.

Continuous Pharmaceutical Processing and Process Analytical Technology CRC Press

Discover the latest ICH news from international experts in the pharmaceutical industry, academia, and regulatory bodies.The recent International Conference on Harmonisation (ICH) revisions of regulatory requirements for quality, nonclinical, and clinical pharmaceutical product registration are the focus of this timely update.This cutting-edge resou

Pharmaceutical Dosage Forms - Tablets Springer

Scientists have attributed more than 40 percent of the failures in new drug development to poor biopharmaceutical properties, particularly water insolubility. Issues surrounding water insolubility can postpone, or completely derail, important new drug development. Even much-needed reformulation of currently marketed products can be significantly affected by these challenges. Water Insolubility is the Primary Culprit in over 40% of New Drug Development Failures The most comprehensive resource on the topic, this second edition of Water Insoluble Drug Formulation brings together a distinguished team of experts to provide the scientific background and step-by-step guidance needed to deal with solubility issues in drug development.

Twenty-three chapters systematically describe solubility properties and their impact on formulation, from theory to industrial practice. With detailed discussion on how these properties contribute to solubilization and dissolution, the text also features six brand new chapters on water-insoluble drugs, exploring regulatory aspects, pharmacokinetic behavior, early phase formulation strategies, lipid based systems for oral delivery, modified release of insoluble drugs, and scalable manufacturing aspects. The book includes more than 15 water-insoluble drug delivery systems or technologies, illustrated with case studies featuring oral and parenteral applications. Highlighting the most current information and data available, this seminal volume reflects the significant progress that has been made in nearly all aspects of this field.

Case Studies in Bayesian Methods for Biopharmaceutical CMC Academic Press

Focusing on the application of physical pharmacy, drug design, and drug regulations as they relate to produce effective dosage forms for drug delivery, Integrated Pharmaceutics provides a comprehensive picture of pharmaceutical product design, describing the science and art behind the concepts of dosage form development. Combining physical pharmacy, product design, and regulatory affairs issues in a single book, the authors address topics governing drug regulations of United States, European, and Japanese agencies and detail new regulatory guidelines, including quality by design, design space analysis, and blend sample uniformity.

Guideline on General Principles of Process Validation Jones & Bartlett Publishers

The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form, an

Dosage Form Design Considerations Springer

Encapsulated and Powdered Foods is a practical guide to the characterization and applications of the powdered form of foods. It details the uses of food powder as well as the physical, chemical, and functional properties of particular food powders, such as milk, cocoa, salts, and sugars. The author describes the powder manufacturing processe

Pharmaceutical Blending and Mixing CRC Press

There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.

Statistical Applications for Chemistry, Manufacturing and Controls (CMC) in the Pharmaceutical Industry Springer

Continuous pharmaceutical manufacturing is currently receiving much interest from industry and regulatory authorities, with the

joint aim of allowing rapid access of novel therapeutics and existing medications to the public, without compromising high quality. Research groups from different academic institutions have significantly contributed to this field with an immense amount of published research addressing a variety of topics related to continuous processing. The book is structured to have individual chapters on the different continuous unit operations involved in drug substance and drug product manufacturing. A wide spectrum of topics are covered, including basic principles of continuous manufacturing, applications of continuous flow chemistry in drug synthesis, continuous crystallization, continuous drying, feeders and blenders, roll compaction and continuous wet granulation.The underlying theme for each of these chapters is to present to the reader the recent advances in modeling, experimental investigations and equipment design as they pertain to each individual unit operation. The book also includes chapters on quality by design (QbD) and process analytical technology (PAT) for continuous processing, process control strategies including new concepts of quality-by-control (QbC), real-time process management and plant optimization, business and supply chain considerations related to continuous manufacturing as well as safety guidelines related to continuous chemistry. A separate chapter is dedicated to discussing regulatory aspects of continuous manufacturing, with description of current regulatory environment quality/GMP aspects, as well as regulatory gaps and challenges. Our aim from publishing this book is to make it a valuable reference for readers interested in this topic, with a desire to gain a fundamental understanding of engineering principles and mechanistic studies utilized in understanding and developing continuous processes. In addition, our advanced readers and practitioners in this field will find that the technical content of Continuous Pharmaceutical Processing is at the forefront of recent technological advances, with coverage of future prospects and challenges for this technology.

Encyclopedia of Biopharmaceutical Statistics - Four Volume Set John Wiley & Sons

Ranked Set Sampling is one of the new areas of study in this region of the world and is a growing subject of research. Recently, researchers have paid attention to the development of the types of sampling; though it was not welcome in the beginning, it has numerous advantages over the classical sampling techniques. Ranked Set Sampling is doubly random and can be used in any survey designs. The Pakistan Journal of Statistics had attracted statisticians and samplers around the world to write up aspects of Ranked Set Sampling. All of the essays in this book have been reviewed by many critics. This volume can be used as a reference book for postgraduate students in economics, social sciences, medical and biological sciences, and statistics. The subject is still a hot topic for MPhil and PhD students for their dissertations.

Continuous Pharmaceutical Processing ASQ Quality Press

This book examines statistical techniques that are critically important to Chemistry, Manufacturing, and Control (CMC) activities. Statistical methods are presented with a focus on applications unique to the CMC in the pharmaceutical industry. The target audience consists of statisticians and other scientists who are responsible for performing statistical analyses within a CMC environment. Basic statistical concepts are addressed in

Chapter 2 followed by applications to specific topics related to development and manufacturing. The mathematical level assumes an elementary understanding of statistical methods. The ability to use Excel or statistical packages such as Minitab, JMP, SAS, or R will provide more value to the reader. The motivation for this book came from an American Association of Pharmaceutical Scientists (AAPS) short course on statistical methods applied to CMC applications presented by four of the authors. One of the course participants asked us for a good reference book, and the only book recommended was written over 20 years ago by Chow and Liu (1995). We agreed that a more recent book would serve a need in our industry. Since we began this project, an edited book has been published on the same topic by Zhang (2016). The chapters in Zhang discuss statistical methods for CMC as well as drug discovery and nonclinical development. We believe our book complements Zhang by providing more detailed statistical analyses and examples.

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