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Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence Umesh V. Banakar, 2022-01-19 Explore the cutting edge of dissolution testing in an authoritative one stop resource In *Pharmaceutical Dissolution Testing Bioavailability and Bioequivalence Science Applications and Beyond* distinguished pharmaceutical advisor and consultant Dr Umesh Banakar delivers a comprehensive and up to date reference covering the established and emerging roles of dissolution testing in pharmaceutical drug development After discussing the fundamentals of the subject the included resources go on to explore common testing practices and methods along with their associated challenges and issues in the drug development life cycle Over 19 chapters and 1100 references allow practicing scientists to fully understand the role of dissolution apart from mere quality control Readers will discover a wide range of topics including automation generic and biosimilar drug development patents and clinical safety This volume offers a one stop resource for information otherwise scattered amongst several different regulatory regimes It also includes A thorough introduction to the fundamentals and essential applications of pharmaceutical dissolution testing Comprehensive explorations of the foundations and drug development applications of bioavailability and bioequivalence Practical discussions about solubility dissolution permeability and classification systems in drug development In depth examinations of the mechanics of dissolution including mathematical models and simulations An elaborate assessment of biophysiological relevant dissolution testing and IVIVCs and their unique applications A complete understanding of the methods requirements and global regulatory expectations pertaining to dissolution testing of generic drug products Ideal for drug product development and formulation scientists quality control and assurance professionals and regulators *Pharmaceutical Dissolution Testing Bioavailability and Bioequivalence* is also the perfect resource for intellectual property assessors

Drug Delivery Trends Ranjita Shegokar, 2020-03-01 *Drug Delivery Trends* examines a drift in the pharmaceutical field across the wide range of dosage forms drug delivery systems micro and nanoparticulate at the regulatory front and on new types of therapies in the market This volume additionally covers the challenges on drug delivery systems in terms of preclinical and current ways of determining quality and the options to solve the challenges associated with this Most small medium scale industries and academics struggle with initial regulatory challenges so a detailed discussion on regulatory trend covers the necessary basic understanding of regulatory procedures and provides the required guidance The series *Expectations and Realities of Multifunctional Drug Delivery Systems* examines the fabrication optimization biological aspects regulatory and clinical success of wide range of drug delivery carriers This series reviews multifunctionality and applications of drug delivery systems industrial trends regulatory challenges and in vivo success stories Throughout the volumes discussions on diverse aspects of drug delivery carriers such as clinical engineering and regulatory facilitate insight sharing across expertise area and form a link for collaborations between industry academic scientists and clinical researchers *Expectations and Realities of Multifunctional Drug Delivery Systems* connects formulation

scientists regulatory experts engineers clinical experts and regulatory stake holders The wide scope of the book ensures it as a valuable reference resource for researchers in both academia and the pharmaceutical industry who want to learn more about drug delivery systems Encompasses trends in drug delivery systems and selected dosage forms Illustrates regulatory preclinical and quality principles Contains in depth investigation of upcoming types of drug delivery systems

Developing Solid Oral Dosage Forms Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lirong Liu, William Porter, 2009-03-10 Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms It covers essential principles of physical pharmacy biopharmaceutics and industrial pharmacy as well as various aspects of state of the art techniques and approaches in pharmaceutical sciences and technologies along with examples and or case studies in product development The objective of this book is to offer updated or current knowledge and skills required for rational oral product design and development The specific goals are to provide readers with Basics of modern theories of physical pharmacy biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation formulation process design characterization and scale up in pharmaceutical sciences and technologies New developments challenges trends opportunities intellectual property issues and regulations in solid product development The first book ever that provides comprehensive and in depth coverage of what s required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market including the most updated science and technologies practice applications regulation intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well established authors co authors of diverse background knowledge skills and experience from industry academia and regulatory agencies

Statistics in Drug Research Shein-Chung Chow, Jun Shao, 2002-02-20 Emphasizing the role of good statistical practices GSP in drug research and formulation this book outlines important statistics applications for each stage of pharmaceutical development to ensure the valid design analysis and assessment of drug products under investigation and establish the safety and efficacy of pharmaceutical compounds Cove

Handbook of Dissolution Testing William A. Hanson, 1982

Transactions of the American Institute of Mining and Metallurgical Engineers, 1930
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Applied Biopharmaceutics & Pharmacokinetics, Fifth Edition Leon Shargel, Susanna Wu-Pong, Andrew Yu, 2004-09-09 The most comprehensive text on the practical applications of biopharmaceutics and pharmacokinetics 4 STAR DOODY S REVIEW The updated edition provides the reader with a solid foundation in the basic principles of pharmacokinetics and biopharmaceutics Students will be able to apply the information to their clinical practice and researchers will find this to be a valuable reference This

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