

Pharmaceutical Process Validation

Second Edition, Revised and Expanded

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Pharmaceutical Process Engineering Second Edition Drugs And The Pharmaceutical Sciences

David J. am Ende, Mary T. am Ende



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solid and liquid dosage forms along with the scale up of each operation This book is a valuable resource for professionals working in the pharmaceutical industry and researchers seeking to develop a comprehensive understanding of the various aspects of the manufacturing process The book is divided into four sections covering a range of topics Section I provide readers with a comprehensive understanding of the basic principles behind the manufacturing process of solid and liquid dosage forms Section II covers the different unit operations involved in the production of solid dosage forms including mixing granulation drying compression coating and size reduction This section includes case studies to provide readers with practical insights into the scale up principles involved in the manufacturing process Section III focuses on the manufacturing and scale up of liquid formulations covering topics such as mixing filtration and scale up of liquid mixing process This section offers a comprehensive understanding of the various aspects of the manufacturing process including the challenges and opportunities associated with the scale up of liquid formulations Finally Section IV includes two chapters that describe the manufacturing and scale up of advanced drug delivery systems including the manufacturing and scale up of nanoparticles and biotechnology derived products This section provides readers with insights into the development of innovative drug delivery systems and the challenges involved in their scale up Overall the book is an essential guide for professionals and researchers seeking a deeper understanding of the manufacturing process The case studies and practical examples offer valuable insights into the challenges and opportunities involved in the scale up process making it an indispensable resource for those involved in the pharmaceutical industry Only book that is dedicated to pharmaceutical process engineering and scale up Contain numerous case studies for easy reference Covers solid liquid and advanced dosage forms

Pharmaceutical Preformulation and Formulation Mark Gibson,2016-04-19 Pharmaceutical Preformulation and Formulation A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process as well as the shift from developing small molecules to the growth of biopharmaceuticals The book meets the ne *Handbook of Drug Screening* Ramakrishna Seethala,Litao Zhang,2016-04-19 Building upon the foundation of basics discussed in the previous edition the Second Edition provides a more in depth look at the latest methods and technologies of advanced drug screening an essential function of drug discovery With extensively updated content and 21 new chapters this text examines quality and efficiency of drug target validation **The Pharmaceutical Regulatory Process** Ira R. Berry,Robert P. Martin,2008-12-02 This Second Edition examines the mechanisms and means to establish regulatory compliance for pharmaceutical products and company practices It focuses on major legislative revisions that impact requirements for drug safety reviews product regulatory approvals and marketing practices Written by top industry professionals practicing attorneys an **Pharmaceutical Extrusion Technology** Isaac Ghebre-Selassie,Charles Martin,2003-05-14 Pharmaceutical Extrusion Technology is the only resource to provide in depth descriptions and analyses of the key parameters of extruders and extrusion processes The book highlights

the applicability of melt extrusion in pharmaceutical drug development and product manufacturing including controlled release dissolution rate and bioavailability enhancement and granulation technology It brings together the technical information necessary to develop and market pharmaceutical dosage forms that meet current quality and regulatory requirements and details extruder hardware and controls process definition and troubleshooting of single and twin screw extrusion processes and more

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Generic Drug Product Development Leon Shargel, Isadore Kanfer, 2016-04-19 Generic Drug Product Development Specialty Dosage Forms explores the issues related to providing evidence of pharmaceutical equivalence and bioequivalence for specialty drug products It describes various scientific approaches and regulatory requirements for manufacturers who need to demonstrate the therapeutic equivalence of generic specialty dru

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Engineering in the Pharmaceutical Industry offers a guide to the experimental and computational methods related to drug product design and development. The second edition has been greatly expanded and covers a range of topics related to formulation design and process development of drug products. The authors review basic analytics for quantitation of drug product quality attributes such as potency, purity, content, uniformity, and dissolution that are addressed with consideration of the applied statistics, process analytical technology, and process control. The 2nd Edition is divided into two separate books: 1 Active Pharmaceutical Ingredients (APIs) and 2 Drug Product Design, Development, and Modeling. The contributors explore technology transfer and scale up of batch processes that are exemplified experimentally and computationally. Written for engineers working in the field, the book examines *in silico* process modeling tools that streamline experimental screening approaches. In addition, the authors discuss the emerging field of continuous drug product manufacturing. This revised second edition contains 21 new or revised chapters, including chapters on quality by design, computational approaches for drug product modeling, process design with PAT, and process control engineering challenges and solutions. Covers chemistry and engineering activities related to dosage form design and process development and scale up. Offers analytical methods and applied statistics that highlight drug product quality attributes as design features. Presents updated and new example calculations and associated solutions. Includes contributions from leading experts in the field. Written for pharmaceutical engineers, chemical engineers, undergraduate and graduation students, and professionals in the field of pharmaceutical sciences and manufacturing. **Chemical Engineering in the Pharmaceutical Industry, Second Edition** contains information designed to be of use from the engineer's perspective and spans information from solid to semi-solid to lyophilized drug products.

Generic Drug Product Development Isadore Kanfer, Leon Shargel, 2016-04-19. Due to a worldwide need for lower cost drug therapy, use of generic and multi-source drug products has been increasing. To meet international patent and trade agreements, the development and sale of these products must conform to national and international laws, and generic products must prove that they are of the same quality and are therapeutically equivalent.

Molecular Recognition in Pharmacology Mikhail Darkhovskiy, 2023-12-11. This unique volume traces the behavior of the drug substance starting from the initial pre-contact stage and ending with the formation of the complex. Molecular recognition lies in the foundation of every life form and includes many mysteries. Currently, studies on this topic in pharmacology are limited to determining the properties of complexes of medicinal substances (drugs) with specific complementary biomolecules: receptors, enzymes, ion channels, etc. The results present the mechanisms preventing drugs from such non-specific binding. This direction is very fruitful, although the phenomenon of molecular recognition is far wider. Features: Presents the basics of thermodynamics and kinetics of complex formation between ligands and receptors. Selected novel therapeutic concepts are tested and validated. Provides a review of the pharmacophore approach and drug design methods. By its nature, pharmacology is a multidisciplinary science; hence, disciplinary areas include chemistry, biology, and neuroscience. Discusses hot topics, including 3D

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and with the necessary rigor required by federal regulatory agencies in the pharmaceutical industry The material will enable teachers lecturers and professors in biotechnology to prepare courses on basic concepts and applications for the purification of biotechnological products of industrial interest These can be applied in practice for example with projects on purification development on an industrial scale or useful unit operations for the development of bioproducts of commercial interest Features Purification and development of new bioproducts and improvement of those being produced Provides a background and concepts on the purification of biomolecules and with an industrial perspective It allows professionals to understand the entire process of developing a biopharmaceutical or bio food from bench to industry in biotechnology one of the fastest growing sectors of the economy It promotes the dissemination of information in a didactic way which is of paramount importance for interdisciplinary fields It enables the reader to follow step by step stages of the development of a new biopharmaceutical and allows the optimization of existing processes Transdermal Drug Delivery Systems Jonathan Hadgraft, 2002-10-29 Presents authoritative state of the art discussions of the key issues pertinent to transdermal drug delivery examining those topics necessary to enable a critical evaluation of a drug candidate s potential to be delivered across the skin from physical chemistry and assessment of drug permeability to available enhancement technologies to regulator

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