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Pharmaceutical Process Scale Up

Jan Harmsen



Pharmaceutical Process Scale Up:

Pharmaceutical Process Scale-Up, Third Edition Michael Levin, 2011-02-02 The third edition of *Pharmaceutical Process Scale Up* deals with the theory and practice of scale up in the pharmaceutical industry This thoroughly revised edition reflects the rapid changes in the field and includes New material on tableting scale up and compaction Regulatory appendices that cover FDA and EU Guidelines New chapters on risk evaluation and validation as related to scale up Practical advice on scale up solutions from world renowned experts in the field *Pharmaceutical Process Scale Up Third Edition* will provide an excellent insight in to the practical aspects of the process scale up and will be an invaluable source of information on batch enlargement techniques for formulators process engineers validation specialists and quality assurance personnel as well as production managers It will also provide interesting reading material for anyone involved in Process Analytical Technology PAT technology transfer and product globalization *Pharmaceutical Process Scale-Up, Second Edition* Michael Levin, 2005-10-18 Keeping pace with the increased influence of PAT in the pharmaceutical industry this completely updated reference spans the latest research and regulations technologies and expert solutions for every significant aspect of pharmaceutical process scale up clearly introducing readers to the theoretical concept of dimensional analysis to quantify similar processes on varying scales **Pharmaceutical Process Scale-Up** Michael Levin, 2001-12-12 Focusing on scientific and practical aspects of process scale up this resource details the theory and practice of transferring pharmaceutical processes from laboratory scale to the pilot plant and production scale It covers parenteral and nonparenteral liquids and semi solids products derived from biotechnology dry blending and powder handling *Pharmaceutical Process Engineering and Scale-up Principles* Anil B. Jindal, 2023-07-03 The book offers a comprehensive overview of the unit operations involved in the manufacturing process of 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

Industrial Process Scale-up Jan Harmsen, 2019-05-16 *Industrial Process Scale up A Practical Innovation Guide from Idea to Commercial Implementation Second Edition* helps industrial process innovators in research development and commercial start ups assess the risks of commercial scale implementation also providing them with practical guidelines and methods to reduce the risks to acceptable levels In addition the book can be used in cooperation with industrial R D people and academic researchers to shape open innovation programs and in education as a reference book This updated edition has the latest literature and has been expanded with a scale up of pharmaceutical processes and their history in both academia and the process industries Offers easily accessible step by step and concise guidelines for industrial process scale up Explains each stage of the innovation funnel from research development demonstration and commercial implementation for any process type and branch Based on industrial experiences and practices that reduce the risks of commercial scale implementation of new processes to acceptable levels and reduce cost and time of process innovation

Pharmaceutical Experimental Design Gareth A. Lewis, Didier Mathieu, Roger Phan-Tan-Luu, 1998-09-10 This useful reference describes the statistical planning and design of pharmaceutical experiments covering all stages in the development process including preformulation formulation process study and optimization scale up and robust process and formulation development Shows how to overcome pharmaceutical technological and economic constraint

Handbook of Pharmaceutical Granulation Technology Dilip M. Parikh, 2021-05-11 This fully revised edition of *Handbook of Pharmaceutical Granulation Technology* covers the rapid advances in the science of agglomeration process control process modelling scale up emerging particle engineering technologies along with current regulatory changes presented by some of the prominent scientist and subject matter experts around the globe Learn from more than 50 global subject matter experts who share their years of experience in areas ranging from drug delivery and pharmaceutical technology to advances in nanotechnology Every pharmaceutical scientist should own a copy of this fourth edition resource Key Features Theoretical discussions covering granulation and engineering perspectives Covers new advances in expert systems process modelling and bioavailability Chapters on emerging technologies in particle engineering Updated Current research and developments in granulation technologies

Validation of Pharmaceutical Processes James P. Agalloco, Frederick J. Carleton, 2007-09-25 Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations this third edition of *Validation of Pharmaceutical Processes* examines and blueprints every step of the validation process needed to remain

compliant and competitive The many chapters added to the prior compilation examine va **Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms, Third Edition** Linda A. Felton,James W. McGinity,2008-01-09 Thoroughly updated and expanded this new Third Edition provides the latest information on dosage forms film defects and polymer characterization Written by renowned leaders in the field Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms is easily the most comprehensive book available on the market today New to the Third Edition the interaction of drugs with functional polymers the influence of processing parameters on coating quality the stabilization of polymeric film coats plasticizers and their applications in pharmaceutical coatings adhesion of polymeric films to solid substrates basic properties of latex and pseudolatex colloidal dispersions Key topics included polymer interactions with drugs and excipients physical aging of polymeric films a complete overview and in depth analysis of recent advances in the field which includes information on the latest equipment used to apply polymers to a pharmaceutical system illustrated examples explaining the appropriate steps to be taken in order to solve formulation processing and stability problems to achieve an optimized dosage form

Drug Discovery and Development, Volume 2 Mukund S. Chorghade,2007-09-24 From first principles to real world applications here is the first comprehensive guide to drug discovery and development Modern drug discovery and development require the collaborative efforts of specialists in a broadarray of scientific technical and business disciplines from biochemistry to molecular biology organic chemistry to medicinal chemistry pharmacology to marketing Yet surprisingly until now there were no authoritative references offering a complete fully integrated picture of the process The only comprehensive guide of its kind this groundbreaking two volume resource provides an overview of the entire sequence of operations involved in drug discovery and develop ment from initial conceptualization to commercialization to clinicians and medical practitioners Volume 1 Drug Discovery describes all the steps in the discovery process including conceptualizing a drug creating a library of candidates for testing screening candidates for in vitro and in vivo activity conducting and analyzing the results of clinical trials and modifying a drug as necessary Volume 2 Drug Development delves into the nitty gritty details of optimizing the synthetic route drug manufacturing outsourcing and marketing including drug coloring and delivery methods Featuring contributions from a world class team of experts Drug Discovery and Development Features fascinating case studies including the discovery and development of erythromycin analogs Tagamet and Ultiva remifentanyl Discusses the discovery of medications for bacterial infections Parkinson s disease psoriasis peptic ulcers atopic dermatitis asthma and cancer Includes chapters on combinatorial chemistry molecular biology based drug discovery genomics and chemogenomics Drug Discovery and Development is an indispensable working resource for industrial chemists biologists biochemists and executives who work in the pharmaceutical industry **How to Scale-Up a Wet Granulation End Point Scientifically** Michael Levin,2015-10-07 How to Scale Up a Wet Granulation End Point Scientifically provides a single source devoted to all relevant information on the scale up of a wet granulation end point Contents include a general description

problem identification and theoretical background with supporting literature case studies potential solutions and more By outlining issues related to scale up and end point determination and then using practical examples and advice to address these issues *How to Scale Up a Wet Granulation End Point Scientifically* is a valuable and essential resource for all those pharmaceutical scientists and technologists engaged in the granulation process Thoroughly referenced and based on the latest research and literature Part of the Expertise in Pharmaceutical Process Technology Series edited by internationally respected expert Michael Levin Illustrates the most common problems related to scale up of a wet granulation end point and provides valuable insights on how to solve these problems in a practical way *Handbook of Formulating Dermal Applications* Nava Dayan, 2016-12-07 The conceptualization and formulation of skin care products intended for topical use is a multifaceted and evolving area of science Formulators must account for myriad skin types emerging opportunities for product development as well as a very temperamental retail market Originally published as *Apply Topically* in 2013 now out of print this reissued detailed and comprehensive handbook offers a practical approach to the formulation chemist's day to day endeavors by Addressing the innumerable challenges facing the chemist both in design and at the bench such as formulating with for specific properties formulation processing and production techniques sensory and elegance stability and preservation color cosmetics sunscreens Offering valuable guidance to troubleshooting issues regarding ingredient selection and interaction regulatory concerns that must be addressed early in development and the extrapolation of preservative systems fragrances stability and texture aids Exploring the advantages and limitations of raw materials Addressing scale up and pilot production process and concerns Testing and Measurements Methods The 22 chapters written by industry experts such as Roger L McMullen Paul Thau Hemi Nae Ada Polla Howard Epstein Joseph Albanese Mark Chandler Steve Herman Gary Kelm Patricia Aikens and Sam Shefer along with many others give the reader and user the ultimate handbook on topical product development *Developing Solid Oral Dosage Forms* Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lawrence Yu, Rao V. Mantri, 2016-11-08 *Developing Solid Oral Dosage Forms* Pharmaceutical Theory and Practice Second Edition illustrates how to develop high quality safe and effective pharmaceutical products by discussing the latest techniques tools and scientific advances in preformulation investigation formulation process design characterization scale up and production operations This book covers the essential principles of physical pharmacy biopharmaceutics and industrial pharmacy and their application to the research and development process of oral dosage forms Chapters have been added combined deleted and completely revised as necessary to produce a comprehensive well organized valuable reference for industry professionals and academics engaged in all aspects of the development process New and important topics include spray drying amorphous solid dispersion using hot melt extrusion modeling and simulation bioequivalence of complex modified released dosage forms biowaivers and much more Written and edited by an international team of leading experts with experience and knowledge across industry academia and regulatory settings Includes new chapters covering the pharmaceutical applications of surface

phenomenon predictive biopharmaceutics and pharmacokinetics the development of formulations for drug discovery support and much more Presents new case studies throughout and a section completely devoted to regulatory aspects including global product regulation and international perspectives

Continuous Pharmaceutical Processing and Process Analytical Technology Ajit S. Narang, Atul Dubey, 2023-03-01 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

Pharmaceutical Manufacturing Handbook Shayne Cox Gad, 2008-03-17 This handbook features contributions from a team of expert authors representing the many disciplines within science engineering and technology that are involved in pharmaceutical manufacturing They provide the information and tools you need to design implement operate and troubleshoot a pharmaceutical manufacturing system The editor with more than thirty years experience working with pharmaceutical and biotechnology companies carefully reviewed all the chapters to ensure that each one is thorough accurate and clear

Continuous Manufacturing of Pharmaceuticals Peter Kleinebudde, Johannes Khinast, Jukka Rantanen, 2017-07-14 A comprehensive look at existing technologies and processes for continuous manufacturing of pharmaceuticals As rising costs outpace new drug development the pharmaceutical industry has come under intense pressure to improve the efficiency of its manufacturing processes Continuous process manufacturing provides a proven solution Among its many benefits are minimized waste energy consumption and raw material use the accelerated introduction of new drugs the use of smaller production facilities with lower building and capital costs the ability to monitor drug quality on a continuous basis and enhanced process reliability and flexibility Continuous Manufacturing of Pharmaceuticals prepares professionals to take advantage of that exciting new approach to improving drug manufacturing efficiency This book covers key aspects of the continuous manufacturing of pharmaceuticals The first part provides an overview of key chemical engineering principles and the current regulatory environment The second covers existing technologies for manufacturing both small molecule based products and protein peptide products The following section is devoted to process analytical tools for continuously operating manufacturing

environments The final two sections treat the integration of several individual parts of processing into fully operating continuous process systems and summarize state of art approaches for innovative new manufacturing principles Brings together the essential know how for anyone working in drug manufacturing as well as chemical food and pharmaceutical scientists working on continuous processing Covers chemical engineering principles regulatory aspects primary and secondary manufacturing process analytical technology and quality by design Contains contributions from researchers in leading pharmaceutical companies the FDA and academic institutions Offers an extremely well informed look at the most promising future approaches to continuous manufacturing of innovative pharmaceutical products Timely comprehensive and authoritative Continuous Manufacturing of Pharmaceuticals is an important professional resource for researchers in industry and academe working in the fields of pharmaceuticals development and manufacturing Pharmaceutical Process Validation Robert A. Nash, Alfred H. Wachter, 2003-03-27 The third edition of this text contains additional chapters which cover troubleshooting procedures validation in contract manufacturing and current harmonization trends **Parenteral Medications, Fourth Edition** Sandeep Nema, John D. Ludwig, 2019-07-19 Parenteral Medications is an authoritative comprehensive reference work on the formulation and manufacturing of parenteral dosage forms effectively balancing theoretical considerations with practical aspects of their development Previously published as a three volume set all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration Key Features Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation processing manufacturing parenteral technology including advanced delivery and cell therapies The book is divided into seven sections Section 1 Parenteral Drug Administration and Delivery Devices Section 2 Formulation Design and Development Section 3 Specialized Drug Delivery Systems Section 4 Primary Packaging and Container Closure Integrity Section 5 Facility Design and Environmental Control Section 6 Sterilization and Pharmaceutical Processing Section 7 Quality Testing and Regulatory Requirements **Pharmaceutical Process Engineering** Anthony J. Hickey, David Ganderton, 2016-03-09 With step by step methods of drug production and knowledge of major unit operations and key concepts of pharmaceutical engineering this guide will help to improve communication among the varied professionals working in the pharmaceutical industry Key features REVISION OF A BESTSELLER Updates include recent advances in the field to keep pharmac Chemical Engineering in the Pharmaceutical Industry David J. am Ende, 2011-03-10 This book deals with various unique elements in

the drug development process within chemical engineering science and pharmaceutical R D The book is intended to be used as a professional reference and potentially as a text book reference in pharmaceutical engineering and pharmaceutical sciences Many of the experimental methods related to pharmaceutical process development are learned on the job This book is intended to provide many of those important concepts that R D Engineers and manufacturing Engineers should know and be familiar if they are going to be successful in the Pharmaceutical Industry These include basic analytics for quantitation of reaction components often skipped in ChE Reaction Engineering and kinetics books In addition Chemical Engineering in the Pharmaceutical Industry introduces contemporary methods of data analysis for kinetic modeling and extends these concepts into Quality by Design strategies for regulatory filings For the current professionals in silico process modeling tools that streamline experimental screening approaches is also new and presented here Continuous flow processing although mainstream for ChE is unique in this context given the range of scales and the complex economics associated with transforming existing batch plant capacity The book will be split into four distinct yet related parts These parts will address the fundamentals of analytical techniques for engineers thermodynamic modeling and finally provides an appendix with common engineering tools and examples of their applications

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