



STAGES OF SCALE UP PROCESS



Department of Pharmaceutical Sciences

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Pharmaceutical Process Scale Up Gmpru

Mary T. am Ende, David J. am Ende

Pharmaceutical Process Scale Up Gmpru:

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 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 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

Pharmaceutical Process Chemistry for Synthesis Peter J. Harrington, 2011-02-23 There is a need to explain that generic versions of a drug may not be manufactured by the same process as brand name drugs and that the different processes may have dramatically different environmental impacts Two global forces are at odds today the push for greener processes and the push for lower drug prices This book brings this conflict into sharp focus by discussing in detail the published process chemistry for top selling small molecule drugs Providing insights about process route selection choice of reagents and reaction conditions *Pharmaceutical Process Chemistry for Synthesis* guides process chemists in identifying best processes for manufacturing these blockbuster drugs as they lose patent protection Further it highlights the strategies and methodology that might be useful for expediting the process research and development of the blockbusters of the future Written from a refreshingly objective perspective this book is essential for process chemists who need to devise practical syntheses for increasingly complex drugs in a constantly decreasing time frame *Pharmaceutical Process Development* John Blacker, Michael T Williams, 2011-08-17 Pharmaceutical process research and development is an exacting multidisciplinary effort but a somewhat neglected discipline in the chemical curriculum This book presents an overview of the many facets of process development and how recent advances in synthetic organic chemistry process technology and chemical engineering have impacted on the manufacture of pharmaceuticals In 15 concise chapters the book covers such diverse subjects as route selection and economics the interface with medicinal chemistry the impact of green chemistry safety the crucial role of physical organic measurements in gaining a deeper understanding of chemical behaviour the role of the analyst new tools and innovations in reactor design purification and separation solid state chemistry and its role in formulation The book ends with an assessment of future trends and challenges The book provides a valuable overview of both early and late stage chemical development how safe and scaleable synthetic routes are designed selected and developed the importance of the chemical engineering analytical and manufacturing interfaces the key enabling technologies including catalysis and biocatalysis the importance of the green chemical perspective and solid form issues The book written and edited by experts in the field is a contemporary holistic treatise with a logical sequence for process development and mini case histories within the chapters to bring alive different aspects of the process It is completely pharmaceutical themed encompassing all essential aspects from route and reagent selection to manufacture of the active compound The book is aimed at both graduates and postgraduates interested in a career in the pharmaceutical industry It informs them about the

breadth of the work carried out in chemical research and development departments and gives them a feel for the challenges involved in the job The book is also of value to academics who often understand the drug discovery arena but have far less appreciation of the drug development area and are thus unable to advise their students about the relative merits of careers in chemical development versus discovery

How to Validate a Pharmaceutical Process Steven Ostrove, 2016-06-07 How to Validate a Pharmaceutical Process provides a how to approach to developing and implementing a sustainable pharmaceutical process validation program The latest volume in the Expertise in Pharmaceutical Process Technology Series this book illustrates the methods and reasoning behind processes and protocols It also addresses practical problems and offers solutions to qualify and validate a pharmaceutical process Understanding the why is critical to a successful and defensible process validation making this book an essential research companion for all practitioners engaged in pharmaceutical process validation Thoroughly referenced and based on the latest research and literature Illustrates the most common issues related to developing and implementing a sustainable process validation program and provides examples on how to be successful Covers important topics such as the lifecycle approach quality by design risk assessment critical process parameters US and international regulatory guidelines and more

[Chemical Engineering in the Pharmaceutical Industry](#) Mary T. am Ende, David J. am Ende, 2019-04-01 A guide to the important chemical engineering concepts for the development of new drugs revised second edition The revised and updated second edition of Chemical 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 API s 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

Process Chemistry in the Pharmaceutical Industry, Volume 2 Kumar Gadamasetti, Tamim Braish, 2007-12-10 As pharmaceutical companies strive to develop safer medicines at a lower cost they must keep pace with the rapid growth of technology and research methodologies Defying the misconception of process chemistry as mere scale up work Process Chemistry in the Pharmaceutical Industry Vol 2 Challenges in an Ever Changing Climate explores novel applications of synthetic physical and analytical chemistry in drug discovery and development It offers an accurate depiction of the most up to date process research and development methods applied to synthesis clinical trials and commercializing drug candidates The second installment in this progressive series this volume reviews the latest breakthroughs to advance process chemistry including asymmetric synthesis crystallization morphology enzymatic intervention green chemistry macromolecules monoclonal antibodies biological molecules polymers enantioselectivity organometallic chemistry process analytical tools chemical engineering controls regulatory compliance and outsourcing globalization It explores new approaches to synthetic processes examines the latest safety methods and experiment design and suggests realistic solutions to problems encountered in manufacturing and process development Significant topics include atom economy ease of synthesis instrumentation automation quality control cost considerations green practices and future trends Jointly edited by the founder president of Delphian Pharmaceuticals and the director of Chemical R D at Pfizer this book brings together contributions by reputed scientists technologists engineers and professors from leading academic institutions such as the Imperial College UK the University of Tokyo ETH Switzerland the International University at Bremen Germany and the University of Connecticut USA and from principal pharmaceutical companies that include Merck Bristol Myers Squibb Pfizer Novartis Eli Lilly AstraZeneca and DSM

Continuous Pharmaceutical Processing Zoltan K Nagy, Arwa El Hagrasy, Jim Litster, 2020-06-10 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

The Management of Chemical Process Development in the Pharmaceutical Industry Derek Walker, 2008-03-03 Here is a practical guide that not only presents insights into the organization and management of the disciplines involved in chemical process development but also provides basic knowledge of these disciplines enabling process development practitioners to recognize and assimilate them in their work This book illustrates practical considerations through many examples of the successful direction and integration of the activities of chemists analysts chemical engineers and biologists as well as safety regulatory and environmental professionals in productive teams Moreover this reference provides guidance on Directing and carrying out specific tasks and courses of action Making and communicating clear and achievable decisions Solving problems on the spot Managing the administrative aspects of chemical process development The author Dr Derek Walker has directed chemical process development work for four decades combining firsthand chemical synthesis experience with many other disciplines needed to create chemical processes You will benefit from his advice and unique insights into Understanding the workings of matrix organizations Defining missions and creating action plans Developing interdisciplinary approaches to problem solving Holding review meetings revising goals and motivating staff Prioritizing programs and responses to emergencies In addition you ll learn how successful chemists in collaboration with other disciplines define the best green chemistry for process scale up including accommodating FDA requirements in the last process steps and addressing safety and environmental matters early in their work Case studies provide incisive perspective on these issues A chapter on recognizing and patenting intellectual property emphasizes the importance of comprehensive literature surveys and understanding invention A chapter on the future challenges you to think beyond narrow constraints and explore new horizons

Handbook of Pharmaceutical Wet Granulation Ajit S. Narang, Sherif I.F. Badawy, 2025-12-01 Handbook of Pharmaceutical Wet Granulation Theory and Practice in a Quality by Design Paradigm Second Edition offers a single and comprehensive reference dedicated to all aspects of pharmaceutical wet granulation taking a holistic approach by combining introductory principles with practical solutions Chapters are written by international experts across industry academic and regulatory settings and cover a wide spectrum of relevant and contemporary wet

granulation topics techniques and processes This completely revised and updated edition features five new chapters covering new AI tools applied to scaling up granulation processes model driven design machine learning models for granule property prediction design and scale up of fluid bed granulation and process analytical methods This book is the perfect reference for pharmaceutical manufacturing professionals Academic researchers will benefit from the practical advice provided by the editors and chapter authors Discusses fundamentals of theory and current industrial practice in the field of wet granulation including product and process design and role of material properties in wet granulation Examines the modern evolution of wet granulation through current topics such as established and novel process analytical technologies PATs and product development and scale up paradigms Written for scientists working within the pharmaceutical industry as well as academics regulatory officials and equipment vendors who provide PAT tools and granulation equipment

Pharmaceutical Process Chemistry Dr S Hemalatha, N Indira Rani, S Muni Sireesha, 2025-02-25 Key Topics Covered Fundamentals of Process Chemistry and its evolution in the pharmaceutical industry Synthetic Strategies Unit Processes including nitration oxidation halogenation reduction and biotransformation Scale Up Techniques Industrial Operations such as extraction crystallization filtration and distillation Process Optimization Lean Manufacturing integrating Six Sigma AI and continuous manufacturing Regulatory Safety Considerations aligned with ICH FDA EMA and WHO guidelines *Pharmaceutical Product Development* Vandana B. Patravale, John I. Disouza, Maharukh Rustomjee, 2016-05-25 Pharmaceutical product development is a multidisciplinary activity involving extensive efforts in systematic product development and optimization in compliance with regulatory authorities to ensure the quality efficacy and safety of resulting products Pharmaceutical Product Development equips the pharmaceutical formulation scientist with extensive and up to date knowledge of drug product development and covers all steps from the beginning of product conception to the final packaged form that enters the market and lifecycle management thereof Applications of core scientific principles for product development are also thoroughly discussed in conjunction with the latest approaches involving design of experiment and quality by design with comprehensive illustrations based on practical case studies of several dosage forms The book presents pharmaceutical product development information in an easy to read mode with simplified theories case studies and guidelines for students academicians and professionals in the pharmaceutical industry It is an invaluable resource and hands on guide covering managerial regulatory and practical aspects of pharmaceutical product lifecycle management *Comprehensive Guide to Pharmaceutical Process Chemistry* Prof V Girija Sastry, Dr N Siva Kumar, Y Achyutha Valli Devi, 2025-03-21 Written By Prof V Girija Sastry who is a distinguished Professor at A U College of College of Pharmaceutical Sciences with over three decades of academic and research experience This book offers an in depth exploration of the essential principles and practices that define pharmaceutical process chemistry bridging the gap between research and commercial production Aimed at both students and professionals it provides a comprehensive guide to the complexities involved in scaling up pharmaceutical production while ensuring that the

processes are safe efficient and compliant with global standards Key Features In Depth Coverage of pharmaceutical process chemistry including reaction kinetics extraction techniques distillation crystallization and process optimization Detailed Exploration of green chemistry principles highlighting the importance of sustainable practices in pharmaceutical manufacturing Comprehensive Overview of global regulatory frameworks such as FDA EMA ICH and WHO ensuring that pharmaceutical products meet safety efficacy and quality standards Practical Insights from case studies showcasing successful process optimization and scale up strategies in the pharmaceutical industry This book is an indispensable resource for understanding the full spectrum of pharmaceutical process chemistry from the development of active pharmaceutical ingredients APIs to the commercialization of pharmaceutical products

Pharmaceutical Process Design and Management D. Wylie McVay Jr, Dr Kate McCormick, 2012-08-01 A quality product or service is the successful and profitable outcome of organising resources as judged by the final customer Every business unit needs processes in order to do this effectively and all processes must be documented so that achievements can be measured and future improvements planned and implemented Pharmaceutical Process Design and Management takes a step wise approach to process management It presents the various elements comprising a process man machine materials method and environment it looks at quality control and quality assurance tools for quality improvements and ways of structuring a process into discrete fully accountable elements it proposes that for processes to run successfully all operators must be the initial problem solvers finally it illustrates how with the right tools every problem can be broken down into solvable elements Learn how to deploy a science and risk based approach to pharmaceutical manufacturing by taking a fundamental approach to process design and management and as a consequence keep your customers satisfied and your profits healthy

Active Pharmaceutical Ingredient Manufacturing Girish K. Malhotra, 2022-04-19 The book reviews the history of current brand and generic business in pharmaceuticals manufacturing practices Based on examples the reader can interpolate extrapolate and exploit mutual behavior physical and chemical properties of chemicals to design and commercialize processes that fulfill the demands also manipulate chemical unit processes and unit operations to reduce minimize effluents and lower environmental impact i.e. reduce global warming Readers will be able to simplify process development design and commercialize economic manufacturing processes

From Bench to Pilot Plant Mehdi Nafissi, John A. Ragan, Keith M. DeVries, 2002 This volume explains the process development for chemists working in the pharmaceutical industry from the design of the molecule and its synthesis to scale up chemical modification which meets operational and cost effective needs to organic revision of the synthetic pathway for safety and extended manufacturing

Process Chemistry in the Pharmaceutical Industry Kumar Gadamasetti, 1999-05-06 Providing guidance for chemists and other scientists entering pharmaceutical discovery and development this up to the minute reference presents contributions from an international group of nearly 50 renowned researchers offering a solid grounding in synthetic and physical organic chemistry and clarifying the roles of various

specialties in the development of new drugs Featuring over 1000 references tables and illustrations Process Chemistry in the Pharmaceutical Industry is sure to find its way to the bookshelves of organic physical analytical process and medicinal chemists and biochemists pharmacists and upper level undergraduate and graduate students in these disciplines

Pharmaceutical Engineering: A Primer for Advanced Process Development René Holm, Noor Al-Rifai, Ashish Kumar, 2024-10-01 Pharmaceutical Engineering A Primer for Advanced Process Development Volume One Liquid Dosage form Process Design provides a comprehensive engineering focused description of pharmaceutical dosage form process development and manufacturing The set is split into two volumes where Volume One focuses on liquids and Volume Two on solids Each volume introduces the most commonly used manufacturing processes for pharmaceutical dosage forms and addresses critical formulation and process parameters that influence drug product process performance and product quality This is supplemented with detailed descriptions of engineering models as well as tools that can be used to support their development and verification such as process analytical technology PAT as well as the appropriate utilization of process and equipment knowledge Typical scale up challenges inspired by real industrial examples will be presented as well as a review of the latest correlations theories and models that can form the basis for science based scale ups and transfers

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