Supercritical Fluid Technology For Drug Product Development

Pharmaceutical Product DevelopmentGeneric Drug Product DevelopmentGeneric Drug Product DevelopmentPharmaceutical Drug Product Development and Process OptimizationGeneric Drug Product DevelopmentDrug and Biological DevelopmentQuality by Design for Biopharmaceutical Drug Product DevelopmentComprehensive Quality by Design for Pharmaceutical Product Development and ManufactureBiological Drug ProductsThe Development and Control of New Drug ProductsCombination ProductsDevelopment of Biopharmaceutical Drug-Device ProductsChemical Engineering in the Pharmaceutical IndustryGeneric Drug Product DevelopmentConsiderations in the Development of Drug Product FormulariesPharmaceutical Drug Product Development and Process OptimizationComprehensive Pharmacy ReviewAnsel's Pharmaceutical Dosage Forms and Drug Delivery SystemsPharmaco-complexityGlobal Marketing Management Vandana B. Patravale Isadore Kanfer Leon Shargel Sarwar Beg Isadore Kanfer Ronald P. Evens Feroz Jameel Gintaras V. Reklaitis Wei Wang M. Pernarowski Smita Gopalaswamy Feroz Jameel Mary T. am Ende Leon Shargel Academy of Pharmaceutical Sciences. Committee on Drug Product Equivalence Taylor & Francis Group Leon Shargel Loyd V. Allen Anthony J. Hickey Masaaki (Mike) Kotabe

Pharmaceutical Product Development Generic Drug Product Development Generic Drug Product Development Pharmaceutical Drug Product Development and Process Optimization Generic Drug Product Development Drug and Biological Development Quality by Design for Biopharmaceutical Drug Product Development Comprehensive Quality by Design for Pharmaceutical Product Development and Manufacture Biological Drug Products The Development and Control of New Drug Products Combination Products Development of Biopharmaceutical Drug-Device Products Chemical Engineering in the Pharmaceutical Industry Generic Drug Product Development Considerations in the Development of Drug Product Formularies Pharmaceutical Drug Product Development and Process Optimization Comprehensive Pharmacy Review Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems Pharmaco-complexity Global Marketing Management *Vandana B. Patravale Isadore Kanfer Leon Shargel Sarwar Beg Isadore Kanfer Ronald P. Evens Feroz Jameel Gintaras V. Reklaitis Wei Wang M. Pernarowski Smita Gopalaswamy Feroz Jameel Mary T. am Ende Leon Shargel Academy of Pharmaceutical Sciences. Committee on Drug Product Equivalence Taylor & Francis Group Leon Shargel Loyd V. Allen Anthony J. Hickey Masaaki (Mike) Kotabe*

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

due to a worldwide need for lower cost drug therapy use of generic and multi source drug products have 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 therapeutica

in this era of increased pharmaceutical industry competition success for generic drug companies is dependent on their ability to manufacture therapeutic equivalent drug products in an economical and timely manner while also being cognizant of patent infringement and other legal and regulatory concerns generic drug product development solid oral dosage forms second edition presents in depth discussions from more than 30 noted specialists describing the development of generic drug products from the raw materials to the development of a therapeutic equivalent drug product to regulatory approval major topics discussed include active pharmaceutical ingredients experimental formulation development including a new section on quality by design qbd scale up commercial product formulation quality control and bioequivalence drug product performance anda regulatory process post approval changes post marketing surveillance legislative and patent challenges this second edition also contains a new chapter on the relationship between the fda and the united states pharmacopeia and in chapter 4 using specific examples the application of quality by design qbd during formulation development is examined the book is a thorough guide to the development of solid oral generic dosage formulations this textbook is ideal for the pharmaceutical industry graduate programs in pharmaceutical sciences and health professionals working in the area of generic drug development

pharmaceutical manufacturers are constantly facing quality crises of drug products leading to an escalating number of product recalls and rejects due to the involvement of multiple factors the goal of achieving consistent product quality is always a great challenge for pharmaceutical scientists this volume addresses this challenge by using the quality by design qbd concept which was instituted to focus on the systematic development of drug products with predefined objectives to provide enhanced product and process understanding this volume presents and discusses the vital precepts underlying the efficient effective and cost effective development of pharmaceutical drug products it focuses on the adoption of systematic quality principles of pharmaceutical development which is imperative in achieving continuous improvement in end product quality and also leads to reducing cost time and effort while meeting regulatory requirements the volume covers the important new advances in the development of solid oral dosage forms modified release oral dosage forms parenteral dosage forms semisolid dosage forms transdermal drug delivery systems inhalational dosage forms ocular drug delivery systems nanopharmaceutical products and

nanoparticles for oral delivery

the assessment of bioequivalence is an important process whereby the bioavailability of a generic drug product is compared with its brand name counterpart generic pharmaceutical products must be approved as therapeutic equivalents to the brand name alternative in order to be interchangeable the demonstration of bioequivalence is an important comp

this book offers a complete discussion of product development in the pharmaceutical and biotechnology industries from discovery to product launch through life cycle management the book is organized for optimal usefulness in the education and training of health care professionals md pharmd phd at universities the format is a set of figures tables and lists along with detailed narrative descriptions including real life examples illustrations controversies in industry and references the editors and authors of the book are industry and research experts in a variety of disciplines

this volume explores the application of quality by design qbd to biopharmaceutical drug product development twenty eight comprehensive chapters cover dosage forms liquid and lyophilized drug products the introductory chapters of this book define key elements of qbd and examine how these elements are integrated into drug product development these chapters also discuss lessons learned from the fda office of biotechnology products pilot program following chapters demonstrate how qbd is used for formulation development ranging from screening of formulations to developability assessment to development of lyophilized and liquid formats the next few chapters study the use of small scale and surrogate models as well as qbd application to drug product processes such as drug substance freezing and thawing mixing sterile filtration filling lyophilization inspection and shipping and handling later chapters describe more specialized applications of qbd in the drug product realm this includes the use of qbd in primary containers devices and combination product development the volume also explores qbd applied to vaccine development automation mathematical modeling and monitoring and controlling processes and defining control strategies it concludes with a discussion on the application of qbd to drug product technology transfer as well as overall regulatory considerations and lifecycle management quality by design for biopharmaceutical drug product development is an authoritative resource for scientists and researchers interested in expanding their knowledge on qbd principles and uses in creating better drugs

covers a widespread view of quality by design qbd encompassing the many stages involved in the development of a new drug product the book provides a broad view of quality by design qbd and shows how qbd concepts and analysis facilitate the development and manufacture of high quality products qbd is seen as a framework for building process understanding for implementing robust and effective manufacturing processes and provides the underpinnings for a

science based regulation of the pharmaceutical industry edited by the three renowned researchers in the field comprehensive quality by design for pharmaceutical product development and manufacture guides pharmaceutical engineers and scientists involved in product and process development as well as teachers on how to utilize qbd practices and applications effectively while complying with government regulations the material is divided into three main sections the first six chapters address the role of key technologies including process modeling process analytical technology automated process control and statistical methodology in supporting qbd and establishing the associated design space the second section consisting of seven chapters present a range of thoroughly developed case studies in which the tools and methodologies discussed in the first section are used to support specific drug substance and drug product qbd related developments the last section discussed the needs for integrated tools and reviews the status of information technology tools available for systematic data and knowledge management to support qbd and related activities highlights demonstrates quality by design qbd concepts through concrete detailed industrial case studies involving of the use of best practices and assessment of regulatory implications chapters are devoted to applications of qbd methodology in three main processing sectors drug substance process development oral drug product manufacture parenteral product processing and solid liquid processing reviews the spectrum of process model types and their relevance the range of state of the art real time monitoring tools and chemometrics and alternative automatic process control strategies and methods for both batch and continuous processes the role of the design space is demonstrated through specific examples and the importance of understanding the risk management aspects of design space definition is highlighted comprehensive quality by design for pharmaceutical product development and manufacture is an ideal book for practitioners researchers and graduate students involved in the development research or studying of a new drug and its associated manufacturing process

tested and proven solutions to the challenges of biological drug product development biological drug products play a central role in combating human diseases however developing new successful biological drugs presents many challenges including labor intensive production processes tighter regulatory controls and increased market competition this book reviews the current state of the science offering readers a single resource that sets forth the fundamentals as well as tested and proven development strategies for biological drugs moreover the book prepares readers for the challenges that typically arise during drug development offering straightforward solutions to improve their ability to pass through all the regulatory hurdles and deliver new drug products to the market biological drug products begins with general considerations for the development of any biological drug product and then explores the strategies and challenges involved in the development of specific types of biologics divided into five parts the book examines part 1 general aspects part 2 proteins and peptides part 3 vaccines part 4 novel biologics part 5 product administration delivery each chapter has been prepared by one or more leading experts in biological drug development contributions are based on a comprehensive review and analysis of the current literature as well as the authors first hand experience developing and testing new drugs references at the end of each chapter serve as a gateway to original research papers and reviews in the field by incorporating lessons

learned and future directions for research biological drug products enables pharmaceutical scientists and students to improve their success rate in developing new biologics to treat a broad range of human diseases

the field of combination product development products born of the integration of medical devices biologics and drugs is so new that while literature abounds on each part individually there are very few publications including fda documents available concerning the unique challenges posed by this nascent but fast growing area providing

the biotechnology biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as antibody drug conjugates adcs bispecific t cell engager bites dual variable domain dvd antibodies and fusion proteins that are currently being used as therapeutic agents for immunology oncology and other disease conditions regulatory agencies have raised the bar for the development and manufacture of antibody based products expecting to see the use of quality by design qbd elements demonstrating an in depth understanding of product and process based on sound science drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self administration are being marketed as combination products a survey of the market indicates that there is a strong need for a new book that will provide one stop shopping for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development the new book entitled development of biopharmaceutical drug device products is a reference text for scientists and engineers in the biopharmaceutical industry academia or regulatory agencies with insightful chapters from experts in the field this new book reviews first principles covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody based products it covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development formulation strategies for new modalities and the analytical techniques used to characterize them it also addresses important considerations for later stage development such as the development of robust formulations and processes including process engineering and modeling of manufacturing unit operations the design of analytical comparability studies and characterization of primary containers pre filled syringes and vials finally the latter half of the book reviews key considerations to ensure the development and approval of a patient centered delivery system design this involves the evolving regulatory framework with perspectives from both the us and eu industry experts the role of international standards design control risk management human factors and its importance in the product development and regulatory approval process as well as review of the risk based approach to bridging between devices used in clinical trials and the to be marketed device finally case studies are provided throughout the typical readership would have biology and or engineering degrees and would include researchers scientific leaders industry specialists and technology developers working in the biopharmaceutical field

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

in this era of increased pharmaceutical industry competition success for generic drug companies is dependent on their ability to manufacture therapeutic equivalent drug products in an economical and timely manner while also being cognizant of patent infringement and other legal and regulatory concerns generic drug product development solid oral

this volume presents and discusses the vital precepts underlying the efficient effective and cost effective development of pharmaceutical drug products it focuses on the adoption of systematic quality principles of pharmaceutical development

this thoroughly updated edition features contributions from more than 24 specialists and reflects the current progress in pharmacy education and practice written for pharmacy students who are preparing for the naplex test and for pharmacy undergraduates and professionals who need detailed summaries of pharmacy subjects this study guide covers chemistry pharmaceutics pharmacology pharmacy practice drug therapy and other topics a separate booklet of

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thanks to its comprehensive coverage clear explanations and logical organization ansel s pharmaceutical dosage forms and drug delivery systems has been a core pharmaceutics text in the pharmacy curriculum for more than 40 years as you progress through this thoroughly updated ninth edition you ll master all the principles practices and technologies essential for the preparation of pharmaceutical dosage forms and drug delivery systems the text s integrated approach will help you understand the interrelationships among pharmaceutical and biopharmaceutical principles product design formulation manufacturing compounding and the clinical application of dosage forms for effective patient care book jacket

non linear phenomena pervade the pharmaceutical sciences understanding the interface between each of these phenomena and the way in which they contribute to overarching processes such as pharmaceutical product development may ultimately result in more efficient less costly and rapid implementation the benefit to society is self evident in that affordable treatments would be rapidly forthcoming we have aggregated these phenomena into one topic pharmaco complexity non linear phenomena and drug product development

emphasising the multilateral global nature of marketing this book aims to provide the marketeer with a better understanding of how the various functional areas interface with marketing

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