

DRUGS AND THE PHARMACEUTICAL SCIENCES

**Volume 212**

# GENERIC DRUG PRODUCT DEVELOPMENT

**Solid Oral Dosage Forms**

**Second Edition**

Edited by

**Leon Shargel**  
**Isadore Kanfer**



**CRC Press**  
Taylor & Francis Group

# Development Of Generic Drug Products Solid Oral Dosage Forms

**Kamal K. Midha, Henning Blume**



## **Development Of Generic Drug Products Solid Oral Dosage Forms:**

*Generic Drug Product Development* Leon Shargel, Isadore Kanfer, 2013-10-24 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** *Generic Drug Product Development* Leon Shargel, 2004-12-28 Keeping pace with the latest technologies in the field this guide describes the development of solid oral generic drug products from project initiation to market approval Focusing on immediate release and modified release dosage forms the book collects in depth discussions from more than 30 noted specialists on topics such as quality control experimental formulation pharmaceutical ingredients and bioequivalence and considers key elements in the formulation of generic drug products including the availability of raw materials chemical purity It also highlights constraints in generic drug development that differ from the formulation design of a brand name pharmaceutical product **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 is 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 *Design of Experiments for Pharmaceutical Product Development* Sarwar Beg, 2021-01-22 This book volume provides complete and updated information on the applications of Design of Experiments DoE and related multivariate techniques at various stages of pharmaceutical product development It discusses the applications of experimental designs that shall include oral topical transdermal injectables preparations and beyond for nanopharmaceutical

product development leading to dedicated case studies on various pharmaceutical experiments through illustrations art works tables and figures This book is a valuable guide for all academic and industrial researchers pharmaceutical and biomedical scientists undergraduate and postgraduate research scholars pharmacists biostatisticians biotechnologists formulations and process engineers regulatory affairs and quality assurance personnel *Handbook of Bioequivalence Testing* Sarfaraz K. Niazi, 2014-10-29 As the generic pharmaceutical industry continues to grow and thrive so does the need to conduct adequate efficient bioequivalence studies In recent years there have been significant changes to the statistical models for evaluating bioequivalence In addition advances in the analytical technology used to detect drug and metabolite levels have m

**Handbook of Pharmaceutical Manufacturing Formulations** Sarfaraz K. Niazi, 2016-04-19 The fourth volume in the series covers the techniques and technologies involved in the preparation of semisolid products such as ointments creams gels suppositories and special topical dosage forms Drug manufacturers need a thorough understanding of the specific requirements that regulatory agencies impose on the formulation and efficacy deter

**The Impact of Stereochemistry on Drug Development and Use** Hassan Y. Aboul-Enein, Irving W. Wainer, 1997-04-11 The past fifteen years have seen a revolution in the field of stereochemistry with breakthrough analytical techniques in enantiomeric separation profoundly affecting drug development and use This practical reference written by leading researchers focuses on the important roles chirality and stereoisomerism play in drug development efforts presenting for the first time a comprehensive overview of this rapidly evolving area of pharmacological research The book explores analytical pharmacological and regulatory topics in dealing with the theory and practice of stereochemistry in the pharmaceutical industry today This exciting broad appeal treatment extends from the analytical viewpoint in enantiomeric separation to the regulatory issues involved in the racemate versus enantiomer debate The authors include numerous examples and case studies and integrate material from a wide range of studies publications and workshops The introductory chapters outline the pharmacological effects of stereochemistry cover stereochemistry in drug metabolism and discuss problems inherent in the duality of enantiomers chemically identical yet spatially different molecules Contributions on the specific aspects of chirality and drug activity explore the toxicological effects of stereoselectivity illustrate how an understanding of the stereochemical composition of certain drugs can help avoid problems and offer tips on new clinical applications for existing drugs A full chapter is devoted to research opportunities in the development of new chirally pure drugs Other practical research topics range from the preparation of chirally pure compounds to the analytical determination of stereochemical composition to applications of circular dichroism CD spectroscopy Regulatory issues concerning the development and approval of stereoisomeric drugs are discussed in the final chapters This section offers an international perspective as well as a historical review of the ongoing debate surrounding regulatory guidelines Impact of Stereochemistry on Drug Development and Use is an essential reference for medicinal and analytical chemists pharmacologists drug metabolism and pharmacokinetic

scientists and personnel of regulatory agencies It is also a useful text for graduate students in stereochemistry and for anyone who wants to keep up with the swift pace of change in this dynamic field Impact of Stereochemistry on Drug Development and Use is an essential reference for medicinal and analytical chemists pharmacologists drug metabolism and pharmacokinetic scientists and personnel of regulatory agencies It is also a useful text for graduate students in stereochemistry and for anyone who wants to keep up with the swift pace of change in this dynamic field IMPACT OF STEREOCHEMISTRY ON DRUG DEVELOPMENT AND USE Twenty three expert contributions on the stereochemical revolution of the last fifteen years covering analytical pharmacological and regulatory topics show that drug development can no longer occur without consideration of drug stereochemistry We have come full circle and stand alongside Pasteur in amazement of nature's duality symmetry and dissymmetry and its chemical and pharmacological consequences from the Preface

**Dose Optimization in Drug Development** Rajesh Krishna, 2006-05 This reference provides a concise overview of the key principles in dose selection and optimization and demonstrates applicability to recent successful new drug applications Compiling key issues and current research on safety efficacy and clinical pharmacology and PK PD this volume critically highlights the multidisciplinary nature of drug development and spans the fields of pharmacokinetics clinical pharmacology biostatistics and experimental medicine

FDA Quality Standards for Generic Drug Products Susan M. Rosencrance, Lawrence Yu, 2018-03-01 FDA Quality Standards for Generic Drug Products features the history and evolution of the FDA's generic drug program along with an overview of the quality assessment process performed by the FDA and an in depth look at quality standards for a variety of dosage forms Chapters cover important topics such as quality by design the ANDA structure CMC process analytical technology and other emerging technologies design of experiments and statistics and the similarities and differences between the FDA and international regulatory agencies Edited and written by experienced leaders in the field this book contains case studies throughout and provides insider perspectives on what the future may hold for generic drugs An essential resource for pharmaceutical regulatory and academic scientists this book can be used to establish the necessary procedures and specifications in order to seek approval to develop quality products more quickly and easily Highlights recent developments regarding quality by design and quality standards associated with particular dosage forms including complex generic drug products Offers an overview of the FDA's current assessment process for ANDAs from filing to approval and discusses important considerations regarding post approval changes and lifecycle management Written by FDA scientists who actively review ANDAs and develop regulatory policies associated with generic drugs

*Modern Pharmaceutics* Alexander Taylor Florence, Jürgen Siepmann, 2009 Modern Pharmaceutics examines the impact of pharmaceutical biotechnology cell therapy pharmacogenomics biotherapeutics and nanotechnology on current practice and the potential for personalized medicines and implications for pediatric and geriatric formulations Reflecting the shift away from physical pharmacy Modern Pharmaceutics is the must have current reference text for

pharmaceutics and drug delivery     *Bio-International* Kamal K. Midha, Henning Blume, 1993     **Endotoxins** Kevin L. Williams, 2007-02-23 This source expertly examines the discovery biological structure control and continued clarification of endotoxin from a parenteral manufacturing perspective with in depth discussion of state of the art technologies involving Limulus amebocyte lysate LAL such as assay development automation depyrogenation Completely revised and expanded this Third Edition contains the knowledge necessary to apply endotoxin testing in the increasingly complex pharmaceutical environment featuring sections detailing the latest information regarding clinical advances regulation standards and validation procedures for computerized kinetic tests     Standard & Poor's Stock Reports ,2007-04     **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     *Moody's Handbook of NASDAQ Stocks* ,1994     *American Journal of Hospital Pharmacy* ,1993     **Shargel and Yu's Applied Biopharmaceutics & Pharmacokinetics, 8th Edition** Murray P. Ducharme, Leon Shargel, Andrew B. C. Yu, 2022-01-24 The authoritative textbook on the principles and practical applications of biopharmaceutics and pharmacokinetics Shargel Yu s Applied Biopharmaceutics Pharmacokinetics has been the standard textbook in its field for over 40 years This eighth edition includes recent scientific developments in the field and embodies the collective contribution of experts with deep knowledge and experience in the selected subject areas Shargel Yu s Applied Biopharmaceutics Pharmacokinetics Eighth Edition provides the reader with a fundamental understanding of biopharmaceutics and pharmacokinetics principles that can be applied to patient drug therapy and rational drug product development Shargel Yu s Applied Biopharmaceutics Pharmacokinetics Eighth Edition has been expanded and revised to include advancements in biopharmaceutics and pharmacokinetics The chapter sequence has been reorganized into four main

sections providing a more logical sequence for students The textbook starts with fundamental concepts followed by application of these principles to optimize drug therapy and to the rational development of drug products Each chapter includes theoretical concepts with practical examples and clinical applications Frequently asked questions provide a discussion of overall concepts Features Expanded and revised chapters to include scientific advances in biopharmaceutics and pharmacokinetics Four main sections providing a natural buildup of knowledge introduction to biopharmaceutics and pharmacokinetics fundamentals of biopharmaceutics pharmacokinetic calculations clinical pharmacokinetics and pharmacodynamics and biopharmaceutics and pharmacokinetics in drug product development Additional chapters for this edition include o Physiological factors related to drug absorption o Approaches to pharmacokinetics and pharmacodynamics calculations o Novel and complex dosage Forms o Clinical Development and Therapeutic Equivalence of Generic Drug and Biosimilar Products o Pharmacokinetics and Pharmacodynamics in Clinical Drug Product Development Additional information on drug therapy drug product performance and other related topics Frequently asked questions practice problems clinical examples and learning questions      **American Book Publishing Record** ,2003      *S & P Midcap 400 ... Directory* ,1997

**Generic Drug Substitution** Keith H. Fukumoto,1990

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