

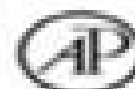


SECOND EDITION

Developing Solid Oral Dosage Forms

Pharmaceutical Theory & Practice

*Edited by Yibing Qiu, Yisheng Chen, Geoff G. Z. Zhang,
Lawrence Yu, and Rao V. Mantri*



Developing Solid Oral Dosage Forms Pharmaceutical Theory Practice

**Chung Chow Chan, Kwok Chow, Bill
McKay, Michelle Fung**



Developing Solid Oral Dosage Forms Pharmaceutical Theory Practice:

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. *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 **Developing Solid Oral Dosage Forms** Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lawrence Yu, Rao V. Mantri, 2026-01-01 Developing Solid Oral Dosage Forms Pharmaceutical Theory and Practice Third Edition is a comprehensive and up to date guide for professionals and academics engaged in all aspects of the development process of oral dosage forms This new edition reflects the significant impact of AI and ML on pharmaceutical science in recent years with six new chapters and extensive updates to existing content The book covers essential principles of physical pharmacy biopharmaceutics and industrial pharmacy as well as their application to the research and development process of oral dosage forms The Third Edition features new chapters on Evaluation of Drug Absorption from Oral Dosage Forms Dissolution Evaluation of Enabling Formulations Based on Supersaturation Patient Centric Drug Product Design and Design of Improved and Differentiated Products through 505 b 2 NDA Pathway Additionally existing chapters have been updated combined or completely rewritten to provide a well organized and valuable reference Topics such as spray drying amorphous solid dispersion using hot melt extrusion modeling and simulation bioequivalence of complex modified release dosage forms biowaivers and more are covered in this edition Developing Solid Oral Dosage Forms Pharmaceutical Theory and Practice Third Edition is an indispensable resource for industry professionals and academics looking to stay current with the latest advancements in solid formulation development This book not only provides a thorough understanding of the principles and techniques involved in the development process but also offers practical guidance on how to apply these concepts to real world situations With its extensive coverage of new topics and updates to existing chapters this edition is an essential tool for those working in the field of pharmaceutical science Updated with six new chapters through coverage of the AI and ML impact in oral formulation and the latest developments in 3D printing continuous manufacturing and Industry 4.0 in pharma Includes practical application showing how essential principles are applied to real world situations Covers both Industry and Academic content needs for professionals researchers and students alike Addresses preformulation formulation process design characterization scale up and production operations Introduces the patient centric drug product design process

Physico-Chemical Aspects of Dosage Forms and Biopharmaceutics Amit Kumar Nayak, Kalyan Kumar Sen, 2024-08-09 Physico Chemical Aspects of Dosage Forms and Biopharmaceutics Recent and Future Trends in Pharmaceutics Volume Two explores aspects of pharmaceutics with an original approach that focuses on technology novelties and future trends The field of pharmaceutics is highly dynamic and rapidly expanding day by day so it demands a variety of amplified efforts for designing and developing pharmaceutical processes and formulation strategies Readers will find practical information for conducting research in pharmaceutics that is ideal for researchers in academia and industry as well as advanced graduate students in pharmaceutics In addition the book discusses the most recent developments in biopharmaceutics including important and exciting areas such as solubility of drugs pharmaceutical granulation routes of drug administration drug absorption bioavailability and bioequivalence Provides extensive details on the most recent developments in

biopharmaceutics Contains contributions from leading experts from academia research industry and regulatory agencies Includes high quality illustrations flow charts and tables for easier understanding of the concepts Discusses practical examples and research case studies How to Develop Robust Solid Oral Dosage Forms Bhavishya Mittal,2016-10-05 How to Develop Robust Solid Oral Dosage Forms from Conception to Post Approval uses a practical and hands on approach to cover the development process of solid oral dosage forms in one single source The book details all of the necessary steps from formulation through the post approval phase and contains industry case studies real world advice and troubleshooting tips By merging the latest scientific information with practical instructions this book provides pharmaceutical scientists in formulation research and development with a concrete look at the key aspects in the development of solid oral dosage forms Focuses on important topics such as robustness bioavailability formulation design continuous processing stability tests modified release dosage forms international guidelines process scale up and much more Part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin Discusses common real world problems and offers both theoretical and practical solutions to these everyday issues *Oral Drug Delivery for Modified Release Formulations* Edmund S. Kostewicz,Maria Vertzoni,Heather A. E. Benson,Michael S. Roberts,2022-04-04 ORAL DRUG DELIVERY FOR MODIFIED RELEASE FORMULATIONS Provides pharmaceutical development scientists with a detailed reference guide for the development of MR formulations Oral Drug Delivery for Modified Release Formulations is an up to date review of the key aspects of oral absorption from modified release MR dosage forms This edited volume provides in depth coverage of the physiological factors that influence drug release and of the design and evaluation of MR formulations Divided into three sections the book begins by describing the gastrointestinal tract GIT and detailing the conditions and absorption processes occurring in the GIT that determine a formulation s oral bioavailability The second section explores the design of modified release formulations covering early drug substance testing the biopharmaceutics classification system an array of formulation technologies that can be used for MR dosage forms and more The final section focuses on in vitro in silico and in vivo evaluation and regulatory considerations for MR formulations Topics include biorelevant dissolution testing preclinical evaluation and physiologically based pharmacokinetic modelling PBPK of in vivo behaviour Featuring contributions from leading researchers with expertise in the different aspects of MR formulations this volume Provides authoritative coverage of physiology physicochemical determinants and in vitro in vivo correlation IVIVC Explains the different types of MR formulations and defines the key terms used in the field Discusses the present status of MR technologies and identifies current gaps in research Includes a summary of regulatory guidelines from both the US and the EU Shares industrial experiences and perspectives on the evaluation of MR dosage formulations Oral Drug Delivery for Modified Release Formulations is an invaluable reference and guide for researchers industrial scientists and graduate students in general areas of drug delivery including pharmaceutics pharmaceutical sciences biomedical engineering polymer and materials

science and chemical and biochemical engineering ADME Processes in Pharmaceutical Sciences Alan Talevi, Pablo A. M. Quiroga, 2018-11-30 Absorption Distribution Metabolism and Excretion ADME processes and their relationship with the design of dosage forms and the success of pharmacotherapy form the basis of this upper level undergraduate graduate textbook As an introduction oriented to pharmacy students it is also written for scientist from different fields outside of pharmaceuticals e g material scientist material engineers medicinal chemists who might be working in a positions in pharmaceutical companies or whose work might benefit from basic training in the ADME concepts and some biological background Pedagogical features such as objectives keywords discussion questions summaries and case studies add valuable teaching tools This book will provide not only general knowledge on ADME processes but also an updated insight on some hot topics such as drug transporters multi drug resistance related to pharmacokinetic phenomena last generation pharmaceutical carriers nanopharmaceuticals in vitro and in vivo bioequivalence studies biopharmaceuticals pharmacogenomics drug drug and food drug interactions and in silico and in vitro prediction of ADME properties In comparison with other similar textbooks around half of the volume would be focused on the relationship between expanding scientific fields and ADME processes Each of these burgeoning fields has a separate chapter in the second part of the volume and was written with leading experts on the correspondent topic including scientists and academics from USA and UK Duquesne University School of Pharmacy Indiana University School of Medicine University of Utah College of Pharmacy University of Maryland University of Bath Additionally each of the initial chapters dealing with the generalities of drug absorption distribution metabolism and excretion would include relevant classic examples related to each topic with appropriate illustrations e g importance of active absorption of levodopa implications in levodopa administration drug drug interactions and food drug interactions emerging from the active uptake intoxication with paracetamol as a result of glutathione depletion CYP induction and its relationship with acute liver failure caused by paracetamol etc ADME Processes and Pharmaceutical Sciences is written as a core textbook for ADME processes pharmacy pharmacokinetics drug delivery biopharmaceutics drug disposition drug design and medicinal chemistry courses Aulton's Pharmaceutics Michael E. Aulton, Kevin Taylor, 2013 Pharmaceutics is the art of pharmaceutical preparations It encompasses design of drugs their manufacture and the elimination of micro organisms from the products This book encompasses all of these areas Provided by publisher *Pharmaceutical Dosage Forms and Drug Delivery* Ram I. Mahato, Ajit S. Narang, Virender Kumar, 2024-11-22 Completely revised and updated this fourth edition elucidates the principles of pharmaceuticals biopharmaceutics dosage form design and drug delivery including emerging new biotechnology based treatment modalities The authors integrate aspects of physical pharmacy chemistry biology and biopharmaceutics into drug delivery With the expiration of older patents and generic competition the biopharmaceutical industry is evolving faster than ever Consequently this edition of the book emphasizes the heightened focus that the recent remarkable progress in gene editing immunotherapy and nanotechnology

has brought to the design of new drugs and diagnostic approaches along with novel dosage forms Apart from new chapters this edition highlights the emerging emphasis on the role of artificial intelligence AI in drug discovery mRNA and antibody based therapies genome editing immunotherapy chemical kinetics and the stability of drug products Features Includes new chapters on antibody therapeutics gene editing and immunotherapy Explains newer approaches and future methods and the significance of artificial intelligence AI in drug discovery Updated sections on pharmacy mathematics chemical kinetics and the stability of medicinal products Important updates on parenteral drug products protein and peptide treatments and biotechnology based pharmaceuticals to provide a contemporary perspective on drug development delivery and pharmaceutical sciences Expansion of review questions and answers to clarify concepts for students and add to their grasp of key concepts covered in this book Although there are numerous books on pharmaceutics and dosage forms most cover different areas of the discipline and do not provide an integrated approach The integrated approach of this book not only provides a singular perspective of the overall field but also supplies a unified source of information for students instructors and professionals saving their time and money

Pharmaceutical Dosage Forms Larry L. Augsburger, Stephen W. Hoag, 2017-10-30 Pharmaceutical Dosage Forms Capsules covers the development composition and manufacture of capsules Despite the important role that capsules play in drug delivery and product development few comprehensive texts on the science and technology of capsules have been available for the research and academic environments This text addresses this gap discussing how capsules provide unique capabilities and options for dosage form design and formulation

Dosage Form Design Parameters , 2018-07-25 Dosage Form Design Parameters Volume II examines the history and current state of the field within the pharmaceutical sciences presenting key developments Content includes drug development issues the scale up of formulations regulatory issues intellectual property solid state properties and polymorphism Written by experts in the field this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters Chapters delve into a particular aspect of this fundamental field covering principles methodologies and the technologies employed by pharmaceutical scientists In addition the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals cosmetics biotechnology and related industries Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects preformulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates graduate students and those interested in drug dosage design

Aulton's Pharmaceutics E-Book Kevin M.G. Taylor, Michael E. Aulton, 2017-07-07 From a review of the previous edition For all the pharmacy students out there part of your pharmacy degree will be to study formulation design and pharmaceutics This is the holy grail of pharmaceutical technology books The text reads well and introduces difficult concepts in a more easy to understand way it is definitely worth the money to help you get through the

module if you're doing a research project in pharmaceutical design then this would also be an excellent buy. This is essential for passing exams and developing professional competence. This is the best known text on pharmaceuticals. Its strength lies mainly in being a complete course in one book. Reviewers consistently praise its comprehensiveness and its extremely high quality content. Pharmaceuticals is one of the most diverse subject areas in pharmaceutical science and an understanding of it is vital for all pharmacists and scientists involved in converting drugs to medicines that can be safely delivered to a patient. The editorial and author team deliver a tour de force of accessibility coverage and currency in this new edition of a world class textbook. Relevant chemistry covered throughout. Reflects current and future use of biotechnology products throughout. Covers ongoing changes in our understanding of biopharmaceuticals, certain areas of drug delivery and the significance of the solid state. Includes the science of formulation and drug delivery. Designed and written for newcomers to the design of dosage forms. Key points boxes throughout. Summaries at the end of each chapter. Fully updated throughout with particular focus on delivery of biopharmaceuticals, nanotechnology and nanomedicines, parenteral and ocular drug delivery mechanisms. Now comes with online access on StudentConsult. **Oral Bioavailability** Xiaoling Li, 2011-08-04

Understand and assess the design, delivery and efficacy of orally administered drugs. A practical guide to understanding oral bioavailability, one of the major hurdles in drug development and delivery. **Oral Bioavailability: Basic Principles, Advanced Concepts and Applications** is designed to help chemists, biologists, life science researchers, pharmaceutical scientists, pharmacologists, clinicians and graduate students become familiar with the fundamentals and practices of the science of oral bioavailability. The difference in rate and extent between a drug taken orally and the actual amount of a drug reaching the circulatory system, oral bioavailability, is an essential parameter for determining the efficacy and adverse effects of new and developing medications as well as finding an optimal dosing regimen. This book provides a much needed one stop resource to help readers better understand and appreciate the many facets and complex problems of oral bioavailability, including the basic barriers to oral bioavailability, the methods used to determine relevant parameters and the challenges of drug delivery. In addition, this comprehensive book discusses biological and physicochemical methods for improving bioavailability, integrates physicochemistry with physiology and molecular biology, and includes several state of the art technologies and approaches: Caco-2 cell culture model, MDCK and other related cell culture models which are used to study the science of oral bioavailability. *Micro- and Nanotechnologies-Based Product Development* Neelesh Kumar

Mehra, Arvind Gulbake, 2021-09-06. This book provides comprehensive information of the nanotechnology based pharmaceutical product development including a diverse range of arenas such as liposomes, nanoparticles, fullerenes, hydrogels, thermally responsive, externally activated theranostics, TREAT hydrogels, microspheres, micro and nanoemulsions and carbon nanomaterials. It covers the micro and nanotechnological aspects for pharmaceutical product development with the product development point of view and also covers the industrial aspects, novel technologies, stability studies, validation

safety and toxicity profiles regulatory perspectives scale up technologies and fundamental concept in the development of products Salient Features Covers micro and nanotechnology approaches with current trends with safety and efficacy in product development Presents an overview of the recent progress of stability testing reverse engineering validation and regulatory perspectives as per regulatory requirements Provides a comprehensive overview of the latest research related to micro and nanotechnologies including designing optimisation validation and scale up of micro and nanotechnologies Is edited by two well known researchers by contribution of vivid chapters from renowned scientists across the globe in the field of pharmaceutical sciences Dr Neelesh Kumar Mehra is working as an Assistant Professor of Pharmaceutics Biopharmaceutics at the Department of Pharmaceutics National Institute of Pharmaceutical Education Research NIPER Hyderabad India He received TEAM AWARD for successful commercialisation of an ophthalmic suspension product He has authored more than 60 peer reviewed publications in highly reputed international journals and more than 10 book chapter contributions He has filed patents on manufacturing process and composition to improved therapeutic efficacy for topical delivery He guided PhD and MS students for their dissertations research projects He has received numerous outstanding awards including Young Scientist Award and Team Award for his research output He recently published one edited book Dendrimers in Nanomedicine Concept Theory and Regulatory Perspectives in CRC Press Currently he is editing books on nano drug delivery based products with Elsevier Pvt Ltd He has rich research and teaching experience in the formulation and development of complex innovative ophthalmic and injectable biopharmaceutical products including micro and nanotechnologies for regulated market Dr Arvind Gulbake is working as an Assistant Professor at the Faculty of Pharmacy School of Pharmaceutical Population Health Informatics at DIT University Dehradun India He has authored more than 40 peer reviewed publications in highly reputed international journals four book chapters and a patent contribution He has received outstanding awards including Young Scientist Award and BRG Travel Award for his research He is an assistant editor for IJAP He guided PhD and MS students for their dissertations research projects He has successfully completed extramural project funded by SERB New Delhi Government of India He has more than 12 years of research and teaching experience in the formulation and development of nanopharmaceuticals

INDUSTRIAL PHARMACY Mr. Navneet Pandey, Dr. Matsyagiri Lenkalapally, Dr. Kiran Kumar G B, Dr. Madhu B K, Dr. Paresh Kumar N. Patel, A crucial course in the pharmaceutical sciences Industrial Pharmacy focuses on the concepts procedures and methods used in the creation production and quality assurance of pharmaceutical goods From medication formulation and dosage forms to the complexities of large scale manufacture in the pharmaceutical industry this book aims to provide students a thorough understanding of all the different facets of pharmaceutical production The availability of safe and efficient drugs for the treatment and prevention of illnesses is greatly influenced by the pharmaceutical sector As science and technology continue to progress the sector encounters new opportunities and difficulties that call for a thorough comprehension of both academic knowledge and practical abilities By

providing an organized approach to the core ideas in industrial pharmacy this book seeks to close the knowledge gap between classroom instruction and actual pharmaceutical manufacture The fundamentals of pharmaceutical manufacture such as drug formulation excipient selection and dosage form design are covered in the first part of this book As they advance students will learn more about subjects like regulatory frameworks quality control and the production procedures of different dosage forms such as injectables pills and capsules Current Good Manufacturing Practices cGMP and the legal requirements that control the manufacturing of pharmaceuticals are emphasized Pharmacy students researchers and pharmaceutical industry professionals looking for a strong foundation in industrial pharmacy are the target audience for this book It seeks to equip the upcoming generation of pharmaceutical scientists to contribute to the constantly changing field of drug manufacture and to satisfy the rising need for high quality reasonably priced medications by offering a blend of theory real world applications and case studies We hope that this book will be a useful tool for your academic and professional endeavors giving you the information and abilities you need to succeed in the exciting and influential subject of industrial pharmacy Mr Navneet Pandey Dr Matsyagiri Lenkalapally Dr Kiran Kumar G B Dr Madhu B K Dr Paresh Kumar N Patel

Dosage Form Design Considerations ,2018-07-28 Dosage Form Design Parameters Volume I examines the history and current state of the field within the pharmaceutical sciences presenting key developments Content includes drug development issues the scale up of formulations regulatory issues intellectual property solid state properties and polymorphism Written by experts in the field this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters Chapters delve into a particular aspect of this fundamental field covering principles methodologies and the technologies employed by pharmaceutical scientists In addition the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals cosmetics biotechnology and related industries Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects prefomulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates graduate students and those interested in drug dosage design **Fundamentals of Drug Development** Jeffrey S.

Barrett,2022-09-07 Fundamentals of DRUG DEVELOPMENT Enables readers to understand the process of pharmaceutical research its regulatory basis and how it fits into the global healthcare environment This book discusses how to conduct pharmaceutical research and the context for how the industry fits into global healthcare Holistically the well qualified author helps readers and students of drug development appreciate the time and expense of the process Specifically the work identifies the emerging trends shaping the future of drug development along with important related topics like generic drugs data sharing and collaboration To aid in seamless reader comprehension the book includes a glossary of terms and a self assessment quiz for each chapter at the end PowerPoint slides are also available as an online ancillary for adopting

professors Sample topics covered in the book include Drug development and its phases Decision making processes drug development milestones and compound progression metrics The various disciplines involved along with an assessment of the complexity and risks associated across the stages of development Differences in the nature and scope of development programs due to the therapeutic area of interest Associated costs and resources required Graduate students and professors teaching courses in drug development drug discovery pharmaceuticals medicinal chemistry and drug synthesis will be able to use this book as a complete resource for understanding all the complexities and nuances involved in the drug development process

Pharmaceutical Excipients Otilia M. Y. Koo,2016-10-03 This book provides an overview of excipients their functionalities in pharmaceutical dosage forms regulation and selection for pharmaceutical products formulation It includes development characterization methodology applications and up to date advances through the perspectives of excipients developers users and regulatory experts Covers the sources characterization and harmonization of excipients essential information for optimal excipients selection in pharmaceutical development Describes the physico chemical properties and biological effects of excipients Discusses chemical classes safety and toxicity and formulation Addresses recent efforts in the standardization and harmonization of excipients

Therapeutic Delivery Solutions Chung Chow Chan,Kwok Chow,Bill McKay,Michelle Fung,2014-06-27 Provides a comprehensive review of all types of medical therapeutic delivery solutions from traditional pharmaceutical therapy development to innovative medical device therapy treatment to the recent advances in cellular and stem cell therapy development Provides information to potentially allow future development of treatments with greater therapeutic potential and creativity Includes associated regulatory requirements for the development of these therapies Provides a comprehensive developmental overview on therapeutic delivery solutions Provides overview information for both the general reader as well as more detailed references for professionals and specialists in the field

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

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Developing Solid Oral Dosage Forms Pharmaceutical Theory Practice Introduction

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