

Oral Drug Absorption

Prediction and Assessment



edited by
Jennifer B. Dressman
Hans Lennernäs

Oral Drug Absorption Prediction And Assessment Drugs And The Pharmaceutical Sciences

**Yihong Qiu, Yisheng Chen, Geoff G.Z.
Zhang, Lirong Liu, William Porter**



Oral Drug Absorption Prediction And Assessment Drugs And The Pharmaceutical Sciences:

Oral Drug Absorption Jennifer B. Dressman, Christos Reppas, 2010-03-25 Oral Drug Absorption Second Edition thoroughly examines the special equipment and methods used to test whether drugs are released adequately when administered orally The contributors discuss methods for accurately establishing and validating in vitro in vivo correlations for both MR and IR formulations as well as alternative approaches for MR and IR formulations This practical hands on guide includes an interactive CD ROM that helps pharmaceutical industry personnel model their own testing data They will learn how to identify formulations that will produce the best clinical results and verify batch to batch reproducibility They will also understand how to identify whether changes in formulation or manufacturing procedure after marketing approval affect clinical performance and how to determine if a generic version of the medicine can be approved This edition includes information about bioequivalence studies biowaiving formulation screening and different approaches from U S industry and European industry perspectives It also reviews major advances in pharmacokinetic modeling and profiling Case based examples are included to clarify the material

Oral Drug Delivery for Modified Release Formulations Edmund S. Kostewicz, Maria Vertzoni, Heather A. E. Benson, Michael S. Roberts, 2022-04-26 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 **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 s 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

Neuropsychopharmacology Jahangir Moini,Anthony LoGalbo,Jennifer G. Schnellmann,2023-05-10 Neuropsychopharmacology reviews the principles of pharmacology with a focus on the central nervous system and autonomic nervous system Beyond autonomic and central nervous system pharmacology this volume uniquely discusses psychiatric disorders and the pharmacological interventions that are available for conditions including depression schizophrenia and anxiety disorders With a focus on these specific body systems readers will see end of chapter questions that offer real world case studies as well as multiple choice questions for further learning Beneficial features and content also include two extensive examination tests which each contain 100 questions for better learning or to be used in teaching and a glossary Helpful appendices cover high alert medications and toxicology effects on the nervous system Each chapter will contain classifications of medications pharmacokinetics mechanism of action clinical indications and toxicities Describes pharmacology principles pertaining to the central and autonomic nervous system Identifies pharmacological interventions for psychiatric disorders including current evidence based interventions for depression schizophrenia and anxiety disorders Features chapter outlines end of chapter questions real world case studies and examinations for deeper learning or teaching

Handbook of Pharmacokinetics and Toxicokinetics Mehdi Boroujerdi,2023-08-22 This fully revised and expanded volume is an effort to blend the common approaches to pharmacokinetics and toxicokinetics It integrates the principles held in

common by both fields through a logical and systematic approach which includes mathematical descriptions of physical and physiological processes employed in the approaches to pharmacokinetics and toxicokinetics modeling It emphasizes general principles and concepts and related isolated applications and case study observations The systematic compilation of mathematical concepts and methodologies allows readers to decide on relevant concepts and approaches for their research scientific or regulatory decisions or for offering advanced courses workshops and seminars Features Comprehensive handbook on principles and applications of PK TK appealing to a diverse audience including scientists and students An excellent text fully revised and fully updated for anyone interested in the theoretical and practical pharmacokinetics The systematic compilation of mathematical concepts and methodologies allows readers to decide on relevant concepts and approaches for their research Incorporates research relevant to SDGs and of interest to industrial and regulatory environmental scientists involved in chemical contamination research and regulatory decision making related to soil water and ocean Includes sections on applications and case studies

BIOPHARMACEUTICS AND PHARMACOKINETICS Dr. Chatlapelli Kishore, Mr. PAVAN KUMAR KROSURI, Prof. (Dr.) AJIT KUMAR ACHARYA, Dr. L. MATSYAGIRI, Welcome to the world of biopharmaceutics and pharmacokinetics This book aims to provide a comprehensive understanding of the principles concepts and applications of these intertwined disciplines that play a vital role in modern pharmaceutical sciences Biopharmaceutics explores the relationship between the formulation of a drug product and the pharmacokinetic behavior it exhibits in the human body It delves into the intricate processes of drug absorption distribution metabolism and excretion unraveling the factors that influence the drug's fate and therapeutic effectiveness Pharmacokinetics on the other hand focuses on the quantitative study of the drug's movement in the body employing mathematical models to predict drug concentrations at different sites and time points The field of biopharmaceutics and pharmacokinetics has witnessed remarkable advancements in recent years driven by technological innovations the emergence of novel drug delivery systems and a deeper understanding of physiological processes This book is designed to be a comprehensive guide for students researchers and professionals seeking to navigate the complexities of this rapidly evolving field Throughout the chapters we delve into the fundamental principles underlying drug absorption distribution metabolism and excretion providing a solid foundation for understanding drug kinetics We explore various mathematical models and equations used in pharmacokinetic analysis enabling readers to quantitatively evaluate drug behavior in different physiological compartments In addition to the theoretical aspects this book also emphasizes practical applications We discuss the development and optimization of drug formulations the influence of physiological and pathological factors on drug disposition and the application of pharmacokinetic principles in individualizing drug therapy and designing dosage regimens Real world examples and case studies are integrated to illustrate the relevance and impact of biopharmaceutics and pharmacokinetics in clinical practice I would like to express my sincere gratitude to all the contributors who have shared their expertise and insights in the creation

of this book Their invaluable contributions have helped shape a comprehensive resource that reflects the latest advancements in the field Pharmacokinetics and Toxicokinetics Mehdi Boroujerdi,2015-02-24 Pharmacokinetics and Toxicokinetics provides an overview of pharmacokinetics and toxicokinetics in a comprehensible interrelated and applied manner It integrates the principles held in common by both fields through a logical and systematic approach The book presents mathematical descriptions of physiological processes employed in different appr **Pharmacology** Carol T. Walsh,Rochelle D. Schwartz-Bloom,2004-12-22 Completely revised and updated this is the seventh edition of Levine s classic pharmacology textbook Known for it s thorough coverage and intelligent organization the book covers the basic principles of pharmacological interactions on the human body in a way that is useful for both undergraduate and graduate students Beginning with historical perspectives nomenclature and definitions the topics broaden to include sites and mechanisms of drug actions and travel to sites of action as well as termination and elimination The book also includes drug response and time response relationships response variability drug toxicity drug abuse drug dependence and more **Pharmacokinetics in Drug Development** Peter L. Bonate,Danny R. Howard,2005-12-05 These volumes are designed to be the most complete guide to pharmacokinetics PK and its role in drug development The volumes fill a gap between the academic science and the practical application of that knowledge in drug development Volume 1 discusses the role that PK plays in selected clinical study designs Volume 2 details the key regulatory and development paradigms in which PK supplements decision making during drug development *Modified-Release Drug Delivery Technology* Michael Rathbone,Jonathan Hadgraft,Michael S. Roberts,Majella E. Lane,2008-05-28 This two volume Second Edition describes the anatomical physiological pharmaceutical and technological aspects of delivery routes found in areas like Oral Ocular Dermal and transdermal VaginalColonic Oral mucosal Nasal PulmonaryProviding insight and critical assessment of the many available and emerging modified release drug delivery systems fo **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 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

Drug Discovery and Evaluation: Safety and Pharmacokinetic Assays Franz J.

Hock, Michael K. Pugsley, 2024-10-21 Many aspects of drug safety have become an outstanding and even persistent issue and may occur during the process of both drug discovery and development Until 15 years ago drug discovery and evaluation was primarily a sequential process starting with the selection of the most pharmacologically active compound from a series of newly synthesized small molecule chemical series by means of distinctive pharmacological assays Safety aspects were addressed by evaluation of the selected compound at high doses in a series of specific studies directed at indications other than the intended indication of the new compound These tests are then followed by pharmacokinetic studies which are primarily conducted to confirm whether the selected compound possesses a suitable half life for sufficient exposure and efficacy and whether it has the desired properties specificity to the intended route of administration Safety aspects relied predominantly on the conduct of single and repeat toxicology dose studies which inform changes in organ structure rather than organ function Both toxicological and pharmacokinetic studies are adapted to the progress of studies in clinical pharmacology and clinical trials The new edition of this well and broadly accepted reference work contains several innovative and distinguished chapters This sequential strategy has been abandoned with this new version of the book for several reasons Of the possible multitude of negative effects that novel drugs may impart on organ function e g ventricular tachy arrhythmia many are detected too late in non clinical studies to inform clinicians On the other hand negative findings in chronic toxicity studies in animals may turn out to be irrelevant for human beings New scientific approaches e g high throughput screening human pluripotent stem cells transgenic animals knock out animals in silico models pharmacogenomics and pharmacoproteomics as well as Artificial Intelligence AI methods offered new possibilities There are several examples that show that the druggability of compounds was considerably underestimated when the probability of success of a new project was assessed The success rate in the pharmaceutical industry and the introduction of new chemical entities to the market per year dropped dramatically whereas the development time for a new compound increased sometimes exceeding the patent protection Research and development scientists involving the following changes therefore adopted a change of strategy Parallel instead of sequential involvement of the various disciplines multidimensional compound optimization The term Safety Pharmacology was coined The International Conference on Harmonization ICH founded a Safety Pharmacology Working Group and the Safety Pharmacology Society SPS was launched The discipline provided for evaluation development and validation of a multitude of safety tests outlined in the Core Battery of Studies Characterizing the exposure profile of a drug by conducting pharmacokinetic studies that evaluates the absorption distribution metabolism and excretion should to be investigated at an early stage of development as results contribute to the selection of a compound

for further development Advancements in Toxicology were achieved by the introduction of new methods e g in silico methods genetic toxicology computational toxicology and AI The book is a landmark in the continuously changing world of drug research and developments As such it is essential reading for many groups not only for all students of pharmacology and toxicology but also for industry scientists and physicians especially those involved in clinical trials of drugs and for pharmacists who must know the safety requirements of drugs The book is essential for scientists and managers in the pharmaceutical industry who are involved in drug discovery drug development and decision making in the development process In particular the book will be of use to government institutions and committees working on official guidelines for drug evaluation worldwide

Oral Drug Absorption Jennifer B. Dressman,Hans Lennernäs,2000 Annotation A practical hands on guide for successfully developing oral drug products this comprehensive reference runs the gamut from theoretical stages of computer based calculations to practical guidelines for establishing in vitro in vivo correlations Coverage details the interrelationship between the physiology of the gastrointestinal tract and oral drug formulations and absorption and progresses to the latest applications of pharmacokinetic analysis

Pharmaceutical Amorphous Solid Dispersions Ann Newman,2015-02-27 Providing a roadmap from early to late stages of drug development this book overviews amorphous solid dispersion technology a leading platform to deliver poorly water soluble drugs a major hurdle in today s pharmaceutical industry Helps readers understand amorphous solid dispersions and apply techniques to particular pharmaceutical systems Covers physical and chemical properties screening scale up formulation drug product manufacture intellectual property and regulatory considerations Has an appendix with structure and property information for polymers commonly used in drug development and with marketed drugs developed using the amorphous sold dispersion approach Addresses global regulatory issues including USA regulations ICH guidelines and patent concerns around the world

Novel Carrier Systems for Targeted and Controlled Drug Delivery Awesh K. Yadav,Keerti Jain,2024-12-23 The book presents novel carrier systems for the targeted and controlled drug delivery for the treatment of various diseases which are difficult to be treated with conventional drug delivery systems like cancer autoimmune disorders and emerging infectious diseases It also reviews the origins and applications of stimuli responsive polymer systems and polymer therapeutics such as polymer protein and polymer drug conjugates The book also explores the potential applications of the parenteral route of administration for the delivery of active pharmaceutical substances with a narrow therapeutic index and poor bioavailability Further the book presents common routes of administration for the systemic delivery of peptides and proteins It also examines the applications of various implantable systems in drug delivery The book also covers the important colloidal drug delivery systems including liposomes and niosomes and solid lipid nanoparticles and nanostructured lipid carriers Towards the end the book discusses the therapeutic potential of biodegradable polymeric nanoparticles for controlled drug delivery Authoritative and thorough this book is a valuable resource for researchers working on a multidisciplinary approach to employing drug delivery systems

Handbook of Personalized Medicine Ioannis S. Vizirianakis, 2014-02-12 This book compiles multidisciplinary efforts to conceptualize the environment in research and clinical setting that creates the fertile ground for the practical utility of personalized medicine decisions and also enables clinical pharmacogenomics for establishing pharmacotyping in drug prescription. It covers innovative drug formulations and nanot

Concepts and Models for Drug Permeability Studies Bruno Sarmento, Catarina Leite Pereira, José Das Neves, 2024-02-23 Concepts and Models for Drug Permeability Studies Cell and Tissue Based in Vitro Culture Models Second Edition summarizes the most important developments in in vitro models for predicting the permeability of drugs. This book is structured around three different approaches summarizing the most recent achievements regarding models comprising i immortalized cells with an intrinsic ability to grow as monolayers when seeded in permeable supports ii primary cells isolated from living organisms and directly cultured as barrier monolayers and iii tissue based models constructed with cell lines and extracellular matrix that resembles the tridimensional structure of mucosae and other biological membranes or animal patient derived tissues. Each model is covered in detail including the protocol of generation and application for specific drugs drug delivery systems. The equivalence between in vitro cell and tissue models and in vivo conditions is discussed highlighting how each model may provisionally resemble different drug absorption route. Chapters included in the first edition were updated with relevant data published in recent years while four new chapters were included to reflect new emerging directions and trends in drug permeability models. Concepts and Models for Drug Permeability Studies Cell and Tissue Based in Vitro Culture Models Second Edition is a critical reference for drug discovery and drug formulation scientists interested in delivery systems intended for the administration of drugs through mucosal routes and other important tissue barriers e.g. the BBB. Researchers studying mucosal biology can use this book to familiarize themselves and exploit the synergic effect of mucosal delivery systems and biomolecules. Summarizes the current advances in the use of permeability models in drug transport. Covers the most important buccal gastric intestinal pulmonary nasal vaginal ocular renal skin and blood brain barrier in vitro models. Includes case studies to facilitate understanding of various concepts in computer aided applications. Updates in the second edition include organ on chip devices 3D advanced models multiple layered tissues organoids etc and multicompartmentalized tissue models

Frontiers in Medicinal Chemistry: Volume 1 Atta-ur Rahman, Allen B. Reitz, M. Iqbal Choudhary, Cheryl P. Kordik, 2004-01-15 Frontiers in Medicinal Chemistry is an Ebook series devoted to the review of areas of important topical interest to medicinal chemists and others in allied disciplines. Frontiers in Medicinal Chemistry covers all the areas of medicinal chemistry incl

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 Handbook of Drug Screening Ramakrishna Seethala,Litao Zhang,2016-04-19 Building upon the foundation of basics discussed in the previous edition the Second Edition provides a more in depth look at the latest methods and technologies of advanced drug screening an essential function of drug discovery With extensively updated content and 21 new chapters this text examines quality and efficiency of drug target validati

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