Biopharmaceutical Classification System In In Vitro In

A comprehensive introduction to using modeling and simulationprograms in drug discovery and development Biopharmaceutical modeling has become integral to the design anddevelopment of new drugs. Influencing key aspects of thedevelopment process, including drug substance design, formulationdesign, and toxicological exposure assessment, biopharmaceuticalmodeling is now seen as the linchpin to a drug's future success.And while there are a number of commercially available softwareprograms for drug modeling, there has not been a single resourceguiding pharmaceutical professionals to the actual tools

andpractices needed to design and test safe drugs. A guide to the basics of modeling and simulation programs,Biopharmaceutics Modeling and Simulations offerspharmaceutical scientists the keys to understanding how they workand are applied in creating drugs with desired medicinalproperties. Beginning with a focus on the oral absorption of drugs,the book discusses: The central dogma of oral drug absorption (the interplay ofdissolution, solubility, and permeability of a drug), which formsthe basis of the biopharmaceutical classification system (BCS) The concept of drug concentration How to simulate key drug absorption processes The physiological and drug property data used forbiopharmaceutical modeling Reliable practices for reporting results With over 200 figures and illustrations and a peerlessexamination

of all the key aspects of drug research—includingrunning and interpreting models, validation, and compound andformulation selection—this reference seamlessly bringstogether the proven practical approaches essential to developingthe safe and effective medicines of tomorrow.

Oral Drug AbsorptionPrediction and Assessment, Second EditionCRC Press

This fully revised edition of Handbook of Pharmaceutical Granulation Technology covers the rapid advances in the science of agglomeration, process control, process modelling, scale-up, emerging particle engineering technologies, along with current regulatory changes presented by some of the prominent scientist and subject matter experts around the globe. Learn from more than 50 global subject matter experts who share their years of experience in areas

ranging from drug delivery and pharmaceutical technology to advances in nanotechnology. Every pharmaceutical scientist should own a copy of this fourth edition resource. Key Features: Theoretical discussions covering granulation and engineering perspectives. Covers new advances in expert systems, process modelling and bioavailability Chapters on emerging technologies in particle engineering Updated Current research and developments in granulation technologies This book discusses novel techniques of solubility & dissolution enhancement of -poorly water soluble drug- Olmesartan medoxomil. Olmesartan medoxomil is a selective Angiotensin II receptor blocker drug used in the treatment of hypertension. It is a model drug of the Biopharmaceutical Classification System (BCS) class II which is characterized by

poor water solubility and good permeability.It suffers from low bioavailability following oral administration using traditional dosage forms due to its poor aqueous solubility and efflux by drug resistance pumps in the gastrointestinal tract. It needs to be incorporated into a dosage form that enhances its solubility and overcomes these limitations.However, formulating olmesartan medoxomil as immediate release dosage forms, possess great challenge due to its poor aqueous solubility.

A Pragmatic Approach

Biopharmaceutics Modeling and Simulations

The Influence of Simulated Intestinal Fluids on Drug Solubility and Permeability

In-Vitro In-Vivo Correlation (IVIVC) for Poorly Soluble Drugs

6. Computer-aided biopharmaceutical characterization: gastrointestinal absorption simulation
Perspectives from Pharmacokinetics and Pharmacodynamics
The pharmaceutical industries are hungry to speed up formulation development process. In Vitro-In Vivo Correlation (IVIVC) modeling fulfills this objective efficiently. The objective of this book is to provide a systematic approach to develop level A correlation for the poorly soluble drugs leading to development of a suitable dosage forms of biopharmaceutical classification System (BCS) Class II drugs by reducing

time and cost i.e. research and development (R & D) work. This book is also helpful for the postgraduate students of pharmacy and allied sciences to get basic guidelines for pre-clinical and clinical studies of developed formulations.
The third edition of this introductory text covers the factors which influence the release of the drug from the drug product and how the body handles the drug. A stronger focus has been placed on the basics with clear explanations and illustrated examples. There is also more information on statistics and population pharmacokinetics and new

chapters on drug distribution, computer applications, enzyme kinetics and pharmacokinetics models. Specifically geared to personnel in the pharmaceutical and biotechnology industries, this book describes the basics and challenges of oral bioavailability - one of the most significant hurdles in drug discovery and development. • Describes approaches to assess pharmacokinetics and how drug efflux and uptake transporters impact oral bioavailability • Helps readers reduce the failure rate of drug candidates when

transitioning from the bench to the clinic during development • Explains how preclinical animal models - used in preclinical testing - and in vitro tools translate to humans, which is an underappreciated and complicated area of drug development • Includes chapters about pharmacokinetic modelling, the Biopharmaceutics Drug Disposition Classification System (BDDCS), and the Extended Clearance Classification System (ECCS) • Has tutorials for applying strategies to medicinal chemistry practices of drug discovery/development
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
Estimation of Solubility, Permeability, Absorption and Bioavailability
Recent Advances in Novel Drug Carrier Systems
Pharmacokinetic Optimization in Drug Research
Excipient Development for

Pharmaceutical, Biotechnology, and Drug Delivery Systems
In Vitro-In Vivo Correlations
Biopharmaceutics
In the pharmaceutical industrial application field, hot-melt extrusion (HME) has been recently introduced to develop new solid dosage forms and products. By dissolving the poorly–soluble active pharmaceutical ingredients (API) into water-soluble polymers, the bioavailability of the Class II (with low solubility and high permeability in water) API in Biopharmaceutical

Classification System (BCS) could be significantly improved in the body. For readily water-soluble API, HME provides a new approach to produce a controlled release drug system. Hence, pharmaceutical HME is a promising processing method in the pharmaceutical industry. However, HME has not been widely applied into the pharmaceutical industry. The thermal degradation of the polymer (and/or other excipients) and API are major concerns in the pharmaceutical HME process: researchers aim to dissolve

the total loading of the API into the excipient within the short residence time with minimal API degradation. Therefore, the kinetics of the dissolving process should be known. In this work, the expression of dissolution process and the impact of shear rate, API concentration and API species in dissolution kinetics are determined. The viscosities of the mixture at different shear rates are also measured. A model API shall be dissolved into a polymeric excipient by conducting melt-mixing experiments using the Brabender Batch Mixer.

Pharmaceutics is one of the most diverse subject areas in all of pharmaceutical science. In brief, it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms or medicines. An understanding of pharmaceutics is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely, effectively and conveniently to the patient. Now in its fourth edition, this best-selling

textbook in pharmaceutics has been brought completely up to date to reflect the rapid advances in delivery methodologies by eye and injection, advances in drug formulations and delivery methods for special groups (such as children and the elderly), nanomedicine, and pharmacognosy. At the same time the editors have striven to maintain the accessibility of the text for students of pharmacy, preserving the balance between being a suitably pitched introductory text and a clear reflection of the state of the art. provides a

logical, comprehensive account of drug design and manufacture includes the science of formulation and drug delivery designed and written for newcomers to the design of dosage forms New to this edition New editor: Kevin Taylor, Professor of Clinical Pharmaceutics, School of Pharmacy, University of London. Twenty-two new contributors. Six new chapters covering parenteral and ocular delivery; design and administration of medicines for the children and elderly; the latest in plant medicines; nanotechnology

and nanomedicines, and the delivery of biopharmaceuticals. Thoroughly revised and updated throughout.
As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct efficient and successful bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence, and advances in the analytical technology used to detect drug and metabolite levels have made
Mathematical and Statistical

Skills in the Biopharmaceutical Industry: A Pragmatic Approach describes a philosophy of efficient problem solving showcased using examples pertinent to the biostatistics function in clinical drug development. It was written to share a quintessence of the authors' experiences acquired during many years of relevant work in the biopharmaceutical industry. The book will be useful will be useful for biopharmaceutical industry statisticians at different seniority levels and for graduate students who

consider a biostatistics-related career in this industry. Features: Describes a system of principles for pragmatic problem solving in clinical drug development. Discusses differences in the work of a biostatistician in small pharma and big pharma. Explains the importance/relevance of statistical programming and data management for biostatistics and necessity for integration on various levels. Describes some useful statistical background that can be capitalized upon in the drug development enterprise. Explains some hot topics and

current trends in biostatistics in simple, non-technical terms. Discusses incompleteness of any system of standard operating procedures, rules and regulations. Provides a classification of scoring systems and proposes a novel approach for evaluation of the safety outcome for a completed randomized clinical trial. Presents applications of the problem solving philosophy in a highly problematic transfusion field where many investigational compounds have failed. Discusses realistic planning of open-ended projects.

Theory and Practice
Solvent Systems and Their Selection in Pharmaceutics and Biopharmaceutics
Oral Bioavailability Assessment
Theory, Practice, Methods, and Applications
Dissolution and Drug Release
Pharmaceutical Theory and Practice

In recent years, emerging trends in the design and development of drug products have indicated ever greater need for integrated characterization of excipients and in-depth understanding of their roles in drug delivery applications. This book presents a concise summary of relevant scientific and mechanistic information that can aid the use of excipients in formulation design and drug

delivery applications. Each chapter is contributed by chosen experts in their respective fields, which affords truly in-depth perspective into a spectrum of excipient-focused topics. This book captures current subjects of interest – with the most up to date research updates – in the field of pharmaceutical excipients. This includes areas of interest to the biopharmaceutical industry users, students, educators, excipient manufacturers, and regulatory bodies alike. This book is the first text to provide a comprehensive assessment of the application of fundamental principles of dissolution and drug release testing to poorly soluble compounds and formulations. Such drug products are, vis-à-vis their physical and chemical properties, inherently incompatible with aqueous dissolution. However, dissolution methods are required for product development and selection, as well as for the fulfillment of regulatory

obligations with respect to biopharmaceutical assessment and product quality understanding. The percentage of poorly soluble drugs, defined in classes 2 and 4 of the Biopharmaceutics Classification System (BCS), has significantly increased in the modern pharmaceutical development pipeline. This book provides a thorough exposition of general method development strategies for such drugs, including instrumentation and media selection, the use of compendial and non-compendial techniques in product development, and phase-appropriate approaches to dissolution development. Emerging topics in the field of dissolution are also discussed, including biorelevant and biphasic dissolution, the use on enzymes in dissolution testing, dissolution of suspensions, and drug release of non-oral products. Of particular interest to the industrial pharmaceutical professional, a

brief overview of the formulation and solubilization techniques employed in the development of BCS class 2 and 4 drugs to overcome solubility challenges is provided and is complemented by a collection of chapters that survey the approaches and considerations in developing dissolution methodologies for enabling drug delivery technologies, including nanosuspensions, lipid-based formulations, and stabilized amorphous drug formulations.

Drug Metabolism and Pharmacokinetics Quick Guide covers a number of aspects of drug assessment at drug discovery and development stages, topics such as pharmacokinetics, absorption, metabolism, enzyme kinetics, drug transporters, drug interactions, drug-like properties, assays and in silico calculations. It covers key concepts, with useful tables on physiological parameters (eg. blood flow to organs in x-species, expression and localization of

enzymes and transporters), chemical structure, nomenclature, and moieties leading to bioactivation (with examples). Overall it includes a number of key topics useful at the drug discovery stage, which would serve as a quick reference with several examples from the literature to illustrate the concept.

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 an

From Fundamentals to Industrial Practice

Solubility, Permeability, and Charge State

Generic Drug Product Development

Aulton's Pharmaceutics

The Design and Manufacture of Medicines

Mathematical and Statistical Skills in the Biopharmaceutical Industry

Solvent systems are integral to drug development and pharmaceutical technology. This single topic encompasses numerous allied subjects running the gamut from recrystallization solvents to biorelevant media. The goal of this contribution to the AAPS Biotechnology: Pharmaceutical Aspects series is to generate both a practical handbook as well as a reference allowing the reader to make effective decisions

concerning the use of solvents and solvent systems. To this end, the monograph was created by inviting recognized experts from a number of fields to author relevant sections. Specifically, 15 chapters have been designed covering the theoretical background of solubility, the effect of ionic equilibria and pH on solubilization, the use of solvents to effect drug substance crystallization and polymorph selection, the use of solvent systems in high throughput screening and early

discovery, solvent use in preformulation, the use of solvents in bio-relevant dissolution and permeation experiments, solvents and their use as toxicology vehicles, solubilizing media and excipients in oral and parenteral formulation development, specialized vehicles for protein formulation and solvent systems for topical and pulmonary drug administration. The chapters are organized such that useful decision trees are included together with the scientific underpinning

for their application. In addition, trends in the use of solvent systems and a balance of current views make this monograph useful to both the novice and experienced researcher and to scientists at all developmental stages from early discovery to late pharmaceutical operations. Provides a comprehensive review of all types of medical therapeuticdelivery solutions from traditional pharmaceutical therapydevelopment to innovative medical device therapy treatment to

therecent advances in cellular and stem cell therapy development • Provides information to potentially allow futuredevelopment of treatments with greater therapeutic potential andcreativity • Includes associated regulatory requirements for thedevelopment of these therapies • Provides a comprehensive developmental overview ontherapeutic delivery solutions • Provides overview information for both the general reader as well as more detailed

references forprofessionals and specialists in the field 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 Detailing formulation approaches by stage of

discovery to early development, this book gives a "playbook" of practical and efficient strategies to formulate drug candidates with the least chance of failing in clinical development. • Comes from contributing authors with experience developing formulations on the frontlines of the pharmaceutical industry • Focuses on pre (or non-) clinical and early stage development, the phases where most compounds are used in drug research • Features case studies to illustrate practical

challenges and solutions in formulation selection • Covers regulatory filing, drug metabolism and physical and chemical properties, toxicology formulation, biopharmaceutics classification system (BCS), screening approaches, early stage clinical formulation development, and outsourcing
Computer-aided applications in pharmaceutical technology
Remington Education Pharmaceutics
IVIVC Modeling and

Biopharmaceutical Classification System (BCS) Prediction and Assessment, Second Edition
Biological, Physicochemical, and Computational Strategies In Situ, In Vitro and In Silico Models
A comprehensive introduction to using modeling and simulation programs in drug discovery and development Biopharmaceutical modeling has become integral to the design and development of new drugs. Influencing key aspects of the development process, including drug substance design, formulation design, and

toxicological exposure assessment, biopharmaceutical modeling is now seen as the linchpin to a drug's future success. And while there are a number of commercially available software programs for drug modeling, there has not been a single resource guiding pharmaceutical professionals to the actual tools and practices needed to design and test safe drugs. A guide to the basics of modeling and simulation programs, Biopharmaceutics Modeling and Simulations offers pharmaceutical scientists the keys to understanding how they work and are applied in creating drugs with desired medicinal properties.

Beginning with a focus on the oral absorption of drugs, the book discusses: The central dogma of oral drug absorption (the interplay of dissolution, solubility, and permeability of a drug), which forms the basis of the biopharmaceutical classification system (BCS) The concept of drug concentration How to simulate key drug absorption processes The physiological and drug property data used for biopharmaceutical modeling Reliable practices for reporting results With over 200 figures and illustrations and a peerless examination of all the key aspects of drug research—including running and interpreting models,

validation, and compound and formulation selection—this reference seamlessly brings together the proven practical approaches essential to developing the safe and effective medicines of tomorrow.
Hot-melt extrusion (HME) - melting a substance and forcing it through an orifice under controlled conditions to form a new material - is an emerging processing technology in the pharmaceutical industry for the preparation of various dosage forms and drug delivery systems, for example granules and sustained release tablets. Hot-Melt Extrusion: Pharmaceutical Applications covers the main

instrumentation, operation principles and theoretical background of HME. It then focuses on HME drug delivery systems, dosage forms and clinical studies (including pharmacokinetics and bioavailability) of HME products. Finally, the book includes some recent and novel HME applications, scale -up considerations and regulatory issues. Topics covered include: principles and die design of single screw extrusion twin screw extrusion techniques and practices in the laboratory and on production scale HME developments for the pharmaceutical industry solubility

parameters for prediction of drug/polymer miscibility in HME formulations the influence of plasticizers in HME applications of polymethacrylate polymers in HME HME of ethylcellulose, hypromellose, and polyethylene oxide bioadhesion properties of polymeric films produced by HME taste masking using HME clinical studies, bioavailability and pharmacokinetics of HME products injection moulding and HME processing for pharmaceutical materials laminar dispersive & distributive mixing with dissolution and applications to HME technological considerations related to scale-up of HME processes devices and

implant systems by HME an FDA perspective on HME product and process understanding improved process understanding and control of an HME process with near-infrared spectroscopy Hot-Melt Extrusion: Pharmaceutical Applications is an essential multidisciplinary guide to the emerging pharmaceutical uses of this processing technology for researchers in academia and industry working in drug formulation and delivery, pharmaceutical engineering and processing, and polymers and materials science. This is the first book from our brand new series Advances in Pharmaceutical Technology. Find out more about

the series here.
Remington Education: Pharmaceutics covers the basic principles of pharmaceutics, from dosage forms to drug delivery and targeting. It addresses all the principles covered in an introductory pharmacy course. As well as offering a summary of key information in pharmaceutics, it offers numerous case studies and MCQs for self assessment.
This contribution book collects reviews and original articles from eminent experts working in the interdisciplinary arena of novel drug delivery systems and their uses. From their direct and recent experience, the readers can achieve a wide vision on the new

and ongoing potentialities of different drug delivery systems. Since the advent of analytical techniques and capabilities to measure particle sizes in nanometer ranges, there has been tremendous interest in the use of nanoparticles for more efficient methods of drug delivery. On the other hand, this reference discusses advances in the design, optimization, and adaptation of gene delivery systems for the treatment of cancer, cardiovascular, pulmonary, genetic, and infectious diseases, and considers assessment and review procedures involved in the development of gene-based pharmaceuticals.

The Science and Technology of Dosage Forms
Developing Solid Oral Dosage Forms
Hot-Melt Extrusion
Absorption and Drug Development
Dissolution Kinetics of Model Api in Molten Polymer Excipients During Batch Processing
Pharmaceutical Applications
Guides readers on the proper use of in vitro drug release methodologies in order to evaluate the performance of special dosage forms In the last decade, the application of drug release testing has widened to a variety of novel/special dosage forms. In order to predict the in vivo behavior of such dosage forms, the design and

development of the in vitro test methods need to take into account various aspects, including the dosage form design and the conditions at the site of application and the site of drug release. This unique book is the first to cover the field of in vitro release testing of special dosage forms in one volume. Featuring contributions from an international team of experts, it presents the state of the art of the use of in vitro drug release methodologies for assessing special dosage forms' performances and describes the different techniques required for each one. In Vitro Drug Release Testing of Special Dosage Forms covers the in vitro release testing of: lipid based oral formulations;

chewable oral drug products; injectables; drug eluting stents; inhalation products; transdermal formulations; topical formulations; vaginal and rectal delivery systems and ophthalmics. The book concludes with a look at regulatory aspects. Covers both oral and non-oral dosage forms Describes current regulatory conditions for in vitro drug release testing Features contributions from well respected global experts in dissolution testing In Vitro Drug Release Testing of Special Dosage Forms will find a place on the bookshelves of anyone working with special dosage forms, dissolution testing, drug formulation and delivery, pharmaceutics, and regulatory

affairs.
Explore the latest research in biopharmaceutics from leading contributors in the field In Biopharmaceutics - From Fundamentals to Industrial Practice, distinguished Scientists from the UK's Academy of Pharmaceutical Sciences Biopharmaceutica Focus Group deliver a comprehensive examination of the tools used within the field of biopharmaceutics and their applications to drug development. This edited volume is an indispensable tool for anyone seeking to better understand the field of biopharmaceutics as it rapidly develops and evolves. Beginning with an expansive introduction to the basics of

biopharmaceutics and the context that underpins the field, the included resources go on to discuss how biopharmaceutics are integrated into product development within the pharmaceutical industry. Explorations of how the regulatory aspects of biopharmaceutics function, as well as the impact of physiology and anatomy on the rate and extent of drug absorption, follow. Readers will find insightful discussions of physiologically based modeling as a valuable asset in the biopharmaceutics toolkit and how to apply the principles of the field to special populations. The book goes on to discuss: Thorough introductions to biopharmaceutics, basic

pharmacokinetics, and biopharmaceutics measures Comprehensive explorations of solubility, permeability, and dissolution Practical discussions of the use of biopharmaceutics to inform candidate drug selection and optimization, as well as biopharmaceutics tools for rational formulation design In-depth examinations of biopharmaceutics classification systems and regulatory biopharmaceutics, as well as regulatory biopharmaceutics and the impact of anatomy and physiology Perfect for professionals working in the pharmaceutical and biopharmaceutical industries, Biopharmaceutics - From Fundamentals to Industrial

Practice is an incisive and up-to-date resource on the practical, pharmaceutical applications of the field.

In this age of combinatorial chemistry and high-throughput technologies, bioactive compounds called hits are discovered by the thousands. However, the road that leads from hits to lead compounds and then to pharmacokinetically optimized clinical and drug candidates is very long indeed. As a result, the screening, design, and optimization of pharmacokinetic properties has become the bottleneck and a major challenge in drug research. To shorten the time-consuming develop-ment and high rate of attrition of active compounds

ultimately doomed by hidden pharmacokinetic defects, drug researchers are coming to incorporate structure-permeation, structure-distribution, structure-metabolism, and structure-toxicity relations into drug-design strategies. To this end, powerful biological, physicochemical, and computational approaches are being developed whose objectives are to increase the clinical relevance of drug design, and to eliminate as soon as possible compounds with unfavorable physicochemical properties and pharmacokinetic profiles. Toxicological issues are also of utmost importance in this paradigm. There was, hence, an urgent need for a book covering this field in an authoritative,

didactic, comprehensive, factual, and conceptual manner. In this work of unique breadth and depth, international authorities and practicing experts from academia and industry present the most modern biological, physicochemical, and computational strategies to optimize gastrointestinal absorption, protein binding and distribution, brain permeation, and metabolic profile. The biological strategies emphasized in the book include cell cultures and high-throughput screens. The physicochemical strategies focus on the determination and interpretation of solubility, lipophilicity, and related molecular properties as factors and predictors of pharmacokinetic

bahavior. Particular attention is paid to the lipophilicity profiles of ionized compounds, to lipophilicity measurements in anisotropic media (liposomes/water, IAM columns), and to permeability across artificial membranes. Computational strategies comprise virtual screening, molecular modelling, lipophilicity, and H-bonding fields and their importance for structure-disposition relations. This book is both about theoretical and technological breakthroughs. Thus, molecular properties are contemplated from a dual perspective, namely a) their interpretation in biological and/or physicochemical terms, and b) their value in screening, lead

optimization, and drug-candidate selection. In addition to its 33 chapters, the book includes a CD-ROM containing the invited lectures, oral communications and posters (in full version) presented at the Second LogP Symposium, 'Lipophilicity in Drug Disposition—Practical and Computational Approaches to Molecular Properties Related to Drug Permeation, Disposition and Metabolism', held at the University of Lausanne in March 2000.

Many times drugs work fine when tested outside the body, but when they are tested in the body they fail. One of the major reasons a drug fails is that it cannot be absorb by the body in a way to have the effect it was intended to

have. Permeability, Solubility, Dissolution, and Charged State of Ionizable Molecules: Helps drug discovery professionals to eliminate poorly absorbable molecules early in the drug discovery process, which can save drug companies millions of dollars. Extensive tabulations, in appendix format, of properties and structures of about 200 standard drug molecules.

Oral Drug Absorption

In Vitro Drug Release Testing of Special Dosage Forms

Oral Formulation Roadmap from Early Drug Discovery to Development

Therapeutic Delivery Solutions

Solid Oral Dosage Forms, Second Edition

Pharmaceutical Formulation

This volume offers a comprehensive guide on the theory and practice of amorphous solid dispersions (ASD) for handling challenges associated with poorly soluble drugs. In twenty-three inclusive chapters, the book examines thermodynamics and kinetics of the amorphous state and amorphous solid dispersions, ASD technologies, excipients for stabilizing amorphous solid dispersions such as polymers, and ASD manufacturing technologies, including spray drying, hot melt extrusion, fluid bed layering and solvent-controlled micro-precipitation technology (MBP).

Each technology is illustrated by specific case studies. In addition, dedicated sections cover analytical tools and technologies for characterization of amorphous solid dispersions, the prediction of long-term stability, and the development of suitable dissolution methods and regulatory aspects. The book also highlights future technologies on the horizon, such as supercritical fluid processing, mesoporous silica, KinetiSol®, and the use of non-salt-forming organic acids and amino acids for the stabilization of amorphous systems. Amorphous Solid Dispersions: Theory and Practice

is a valuable reference to pharmaceutical scientists interested in developing bioavailable and therapeutically effective formulations of poorly soluble molecules in order to advance these technologies and develop better medicines for the future.

This book represents the invited presentations and some of the posters presented at the conference entitled "In Vitro-In Vivo Relationship (IVIVR) Workshop" held in Sep tember, 1996. The workshop was organized by the IVIVR Cooperative Working Group which has drawn together

scientists from a number of organizations and institutions, both academic and industrial. In addition to Elan Corporation, which is a drug delivery com pany specializing in the development of ER (Extended Release) dosage forms, the IVIVR Cooperative Working Group consists of collaborators from the University of Maryland at Baltimore, University College Dublin, Trinity College Dublin, and the University of Not tingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. lain Cumming, Elan Corporation Dr. John

Devane, Elan Corporation Dr. Adrian Dunne, University College Dublin Dr. Stuart Madden, Elan Corporation Dr. Colin Melia, University of Nottingham Mr. Tom O'Hara, Elan Corporation Dr. Deborah Piscitelli, University of Maryland at Baltimore Dr. Araz Raoof, Elan Corporation Mr. Paul Stark, Elan Corporation Dr. David Young, University of Maryland at Baltimore The purpose of the workshop was to discuss new concepts and methods in the devel opment of in vitro-in vivo relationships for ER products. The original idea went back ap proximately 15 months prior to the workshop itself. For

some time, the principal collaborators had been working together on various aspects of dosage form development.
To facilitate the development of novel drug delivery systems and biotechnology-oriented drugs, the need for new excipients to be developed and approved continues to increase. Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems serves as a comprehensive source to improve understanding of excipients and forge new avenue
The highly experienced authors here present readers with step-wise, detail-conscious information

to develop quality pharmaceuticals. The book is made up of carefully crafted sections introducing key concepts and advances in the areas of dissolution, BA/BE, BCS, IVIC, and product quality. It provides a specific focus on the integration of regulatory considerations and includes case histories highlighting the biopharmaceutics strategies adopted in development of successful drugs.

Development, Implementation, and Growth

Role in the Biopharmaceutical Classification System

A Pharmaceutical Study on an Antihypertensive Drug

Applied Biopharmaceutics and Pharmacokinetics

Drug Delivery Approaches

Drug Bioavailability

Formulation is a key step in the drug design process, where the active drug is combined with other substances that maximise the therapeutic potential, safety and stability of the final medicinal product. Modern formulation science deals with biologics as well as small molecules. Regulatory and quality demands, in addition to advances in processing technologies, result in growing challenges as well as possibilities for the

field. Pharmaceutical Formulation provides an up to date source of information for all who wish to understand the principles and practice of formulation in the drug industry. The book provides an understanding of the links between formulation theory and the practicalities of processing in a commercial environment, giving researchers the knowledge to produce effective pharmaceutical products that can be approved and manufactured. The first chapters introduce readers to different dosage forms, including oral liquid products, topical products

and solid dosage forms such as tablets and capsules. Subsequent chapters cover pharmaceutical coatings, controlled release drug delivery and dosage forms designed specifically for paediatric and geriatric patients. The final chapter provides an introduction to the vital role intellectual property plays in drug development. Covering modern processing methods and recent changes in the regulatory and quality demands of the industry, Pharmaceutical Formulation is an essential, up to date resource for students and researchers working in academia and in the

pharmaceutical industry. Novel Drug Delivery Systems for Phytoconstituents discusses general principles of drug targeting, construction material and technological concerns of different phytoconstituent in delivery systems. It focuses on the development of novel herbal formulations and summarizes their method of preparation, type of active ingredients, route of administration, biological activity and their applications. It dicusses therapeutic activities of plant derived chemicals, their limitations in clinical applications and novel drug delivery

solutions to overcome them to provide better therapeutic effects with controlled and targeted drug delivery. Focus on drug delivery of phytomolecules Act as bridge between natural product scientist and clinical doctors Discusses mechanism of poor bioavailability of herbal molecules Increases awareness towards phytochemical efficacy Summarizes efficient novel delivery systems-based formulations. It extensively covers the applications of novel drug delivery systems including polymeric nanoparticles, solid lipid nanoparticles,

nanostructured lipid capsules, liposomes, phytosomes, microsphere, transferosomes, and ethosomes. Some chapters are especially focused on anticancer phytodrugs, silymarin, andrographolide, berberine, and curcumin delivery with special emphasis on their application.

This is a well thought-out, highly practical text covering contemporary 'in vitro' techniques for drug absorption studies. Starting at the molecular level of investigation, it continues with cell monolayer models (both primary and cell lines) and culminates with

in situ techniques as a final testing format. In addition, chapters on high-throughput assays, in vitro-in vivo correlation, bioinformatics and regulatory issues are covered, giving a comprehensive overview of available models and techniques. Moreover, an appendix consisting of a number of practical protocols is available online, updated as needed, and should prove very helpful to apply the techniques directly to the benchside.

A comprehensive resource on the biopharmaceutics classification system (BCS),

this book includes expert views from scientists and industry professionals, case studies, and examples - illustrating the BCS benefits and helping readers optimize drug candidates. • Overviews BCS fundamentals, scientific framework, development, and implementation • Acts as a reference guide to help readers understand oral drug absorption and apply the BCS guidelines in the most efficient way • Includes recent research, up-to-date methods, and approaches, like novel dissolution techniques and new cell line models • Evaluates worldwide regulations and up-to-date

global perspectives on the topic

Basics and Strategies for Drug Discovery and Development
Drug Absorption Studies
Biopharmaceutics Applications in Drug Development
Amorphous Solid Dispersions
Biopharmaceutics Classification System (BCS)

This chapter introduces the concept of gastrointestinal absorption simulation using in silico methodology. Parameters used for model construction and the sensitivity predicted pharmacokinetic responses to various input parameters are

described. Virtual trials for in silico modeling of drug absorption are presented. The influence of food on drug absorption, as well as correlation between the in vitro and in vivo results, are also addressed, followed by biowaiver considerations. Numerous examples are provided throughout the chapter. Explore this comprehensive discussion of the application of physiologically- and physicochemical-based models to guide drug delivery edited by leading experts in the field Drug Delivery Approaches: Perspectives from Pharmacokinetics and

Pharmacodynamics delivers a thorough discussion of drug delivery options to achieve target profiles and approaches as defined by physical and pharmacokinetic models. The book offers an overview of drug absorption and physiological models, chapters on oral delivery routes with a focus on both PBPK and multiple dosage form options. It also provides an explanation of the pharmacokinetics of the formulation of drugs delivered by systemic transdermal routes. The distinguished editors have included practical and accessible resources that address the biological and

delivery approaches to pulmonary and mucosal delivery of drugs. Emergency care settings are also described, with explorations of the relationship between parenteral infusion profiles and PK/PD. The future of drug delivery is addressed via discussions of virtual experiments to elucidate mechanisms and approaches to drug delivery and personalized medicine. Readers will also benefit from the inclusion of: A thorough introduction to the utility of mathematical models in drug development and delivery An exploration of the techniques and applications of

physiologically based models to drug delivery Discussions of oral delivery and pharmacokinetic models and oral site-directed delivery A review of integrated transdermal delivery and pharmacokinetics in development An examination of virtual experiment methods for integrating pharmacokinetic, pharmacodynamic, and drug delivery mechanisms Alternative endpoints to pharmacokinetics for topical delivery Perfect for researchers, industrial scientists, graduate students, and postdoctoral students in the area of pharmaceutical science and

engineering, Drug Delivery Approaches: Perspectives from Pharmacokinetics and Pharmacodynamics will also earn a place in the libraries of formulators, pharmacokineticists, and clinical pharmacologists.
Drug Metabolism and Pharmacokinetics Quick Guide
Novel Drug Delivery Systems for Phytoconstituents
Excipient Applications in Formulation Design and Drug Delivery
Poorly Soluble Drugs
Handbook of Bioequivalence Testing
Handbook of Pharmaceutical Granulation Technology