Formulation Development and Characterization of Liquisolid Tablets Containing Clozapine

Psychiatric Diagnosis Revisited

Essential Chemistry for Formulators of Semisolid and Liquid Dosages

The Future of Pharmaceutical Product Development and Research examines the latest developments in the pharmaceutical sciences, also highlighting key developments, research and future opportunities. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of the product development phase of drug discovery and drug development. Each chapter covers fundamental principles, advanced methodologies and technologies employed by pharmaceutical scientists, researchers and the pharmaceutical industry. The book focuses on excipients, radiopharmaceuticals, and how manufacturing should be conducted in an environment that follows Good Manufacturing Practice (GMP) guidelines. Researchers and students will find this book to be a comprehensive resource for those working in, and studying, pharmaceuticals, cosmetics, biotechnology, foods and related industries. Provides an overview of practical information for clinical trials Outlines how to ensure an environment that follows Good Manufacturing Practice (GMP) Examines recent developments and suggests future directions for drug production methods and techniques

Pharmaceutical Formulation Development of Peptides and Proteins

Drug Delivery Aspects

The rapid advances in recombinant DNA technology and the increasing availability of peptides and proteins with therapeutic potential are a challenge for pharmaceutical scientists who have to formulate these compounds as drug products. Pharmaceutical Formulation Development of Peptides and Proteins, Second Edition discusses the development of therapeutics for peptides and proteins, focusing on the challenges and opportunities associated with their formulation. The book covers the latest advances in the field, including the use of novel delivery systems, the impact of biopharmaceutical and pharmacokinetic factors, and the importance of understanding the properties of the peptides and proteins themselves. It also provides guidance on how to optimize the formulation process to ensure the best possible outcomes for patients. The book is written in an accessible and practical style, making it a valuable resource for researchers, practitioners, and students in the field of pharmaceutical sciences.

Model Formulation, Development and Validation for the San Bernadino Forest Ecosystem Study

Formulation Development of Taste Masked Cefuroxime Axetil

Pharmaceutical Quality by Design

Formulating Poorly Water Soluble Drugs

Paediatric Formulation

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Formulation Of Dual Release Dosage Form By Mixed Solvency Concept

Advances and Challenges in Pharmaceutical Technology

The Future of Pharmaceutical Product Development and Research

Oral Controlled Release Formulation Design and Drug Delivery
Dosage Forms: Design and Development at Early Stage provides valuable benefits to interdisciplinary drug discovery teams working in industry and academia and will appeal to medicinal chemists, pharmaceutical chemists, and pharmacologists.

- Includes case studies from recent drug development programs to illustrate the practical challenges of preformulation design
- Innovative nanosuspensions, micelles, and cocrystals
- Describes current approaches in early pre-formulation to achieve the best in vivo results
- Addresses regulatory and safety aspects, which are key considerations for pharmaceutical companies

The book starts with a look at the impact of the polymorphic form of drugs on the preformulation and formulation development. It then offers readers reliable strategies for formulating drug candidates using functional excipients to enhance solubility and stability.

- Covers regulatory filing, drug metabolism and physical and chemical properties, toxicology formulation, biopharmaceutics classification system (BCS), screening 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 approaches by stage of discovery to early development

This book gives a "playbook" of practical and efficient strategies to test the formulation of 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

Developing Solid Oral Dosage Forms

- Teaches future and current drug developers the latest innovations in drug formulation design and optimization
- This highly accessible, practice-oriented book examines current approaches in the development of drug formulations for preclinical and clinical studies, including the use of functional excipients to enhance solubility and stability.
- It covers oral, intravenous, topical, and parenteral administration routes. The book also discusses safety aspects of drugs and excipients, as well as regulatory issues relevant to formulation.

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Pharmaceutical Preformulation and Formulation

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.

Biopharmaceutics and Pharmacokinetics Considerations

This book describes the theories, applications, and challenges for different oral controlled release formulations. This book differs from most in its focus on oral controlled release formulation design and process development. It also covers the related areas like preformulation, biopharmaceutics, in vitro-in vivo correlations (IVIVC), quality by design (QbD), and regulatory issues.

How to Develop Robust Solid Oral Dosage Forms

Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process, as well as the shift from developing small molecules to the growth of biopharmaceuticals. The book meets the need for advanced information for drug preformulation and formulation and addresses the current trends in the continually evolving pharmaceutical industry. Topics include: Candidate drug selection, Drug discovery and development, Preformulation predictions and drug selections, Product design to commercial dosage form, Biopharmaceutical support in formulation development. The book is ideal for practitioners working in the pharmaceutical arena—including R&D scientists, technicians, and managers—as well as for undergraduate and postgraduate courses in industrial pharmacy and pharmaceutical technology.

Formulation and Device Lifecycle Management of Biotherapeutics

The objective of the present study was to address challenges in research and development associated with the bitter taste and poor aqueous solubility of Cefuroxime Axetil. The inclusion complex of drug and HP-β-Cyclodextrin and mouth dissolving tablets were prepared. Bitter taste threshold, DSC, PXRD, saturation solubility, in-vitro dissolution studies were carried out for pure drug CA, commercial tablet CEFTUM and CA loaded MDTs. The results support an addition of banana starch to CA-HP CD inclusion complexes can efficiently aid as an antidiarrheal agent and mask the bitter taste of CA.

Metered Dose Inhaler Technology

Drug Delivery Aspects reviews additional features of drug delivery systems, along with the standard formulation development, like preclinical testing, conversion into solid dosage forms, roles of excipients and polymers used on stability and sterile processing. There is a focus on formulation engineering and related large scale (GMP) manufacturing, regulatory, and functional aspects of drug delivery systems. A detailed discussion on biologics and vaccines gives insights to readers on new developments in this direction. The series Expectations and Realities of Multifunctional Drug Delivery Systems examines the fabrication, optimization, biological aspects, regulatory and clinical success of wide range of drug delivery carriers. This series reviews multifunctionality and applications of drug delivery systems, industrial trends, regulatory challenges and in vivo success stories. Throughout the volumes discussions on diverse aspects of drug delivery carriers, such as clinical, engineering, and regulatory, facilitate insight sharing across expertise area and form a link for collaborations between industry-academic scientists and clinical researchers. Expectations and Realities of Multifunctional Drug Delivery Systems connects formulation scientists, regulatory experts, engineers, clinical experts and regulatory stakeholders. The wide scope of the book ensures it as a valuable reference resource for researchers in both academia and the pharmaceutical industry who want to learn more about drug delivery systems. Encompasses engineering and large-scale manufacturing of nanocarriers, Considers preclinical, regulatory and ethical guidelines on nanoparticles, Contains in-depth discussions on delivery of biologics, vaccines and sterilisation, Industrial view on solid dispersions, milling techniques.

Controlled Release in Oral Drug Delivery
Due to their synthetic and effective biological importance, quinazoline compounds have received considerable attention due to their wide spectrum of biological activities. The connection between various quinazoline derivatives synthesized by different scientists has been explored, and the pharmacological activity of these compounds has been characterized.

Heterocyclic compounds have a broad spectrum of applications in the pharmaceutical field. The review on Quinazoline Heterocycle: A Pharmacophoric Scaffold book has been written to address the needs and interests of students, teachers, and researchers in pharmaceutical science. The book includes contributions from global leaders and experts from academia, industry, and regulatory agencies, providing a comprehensive understanding of QbD concepts and their applications in various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk assessment, and clinical trials.

Hydrophobic base with suitable gelling agents containing mangostin and asiaticoside for the relief of oral lichen planus and aphthous ulcer was formulated using pectin, sodium xanthan gum, and chitosan salts prepared by spray-drying process with suitable conditions. The PE polymer in mineral oil was found to precipitate as small crystallites surrounded by long fibrous amorphous filaments which intermesh and produce a sponge-like structure resulting in a three-dimensional lattice. The percent contents of mangostin and asiaticoside in the hydrophobic base were found to be stable over a period of 4 months at 30°C. This research study tended to develop hydrophobic base with suitable gelling agents containing mangostin and/or asiaticoside for the relief of oral lichen planus and aphthous ulcer.
Formulation Development And Evaluation Of Quinazoline Derivatives

Known compounds clearly demonstrate the remarkable potential of quinazoline derivatives as a source of useful pharmacophore for new drug discovery. This book focuses on several structural modifications on the quinazoline nucleus done by different scientists to evaluate enhancements in biological activities such as anti-convulsant, CNS depressant, anti-microbial, analgesic, anti-inflammatory, anti-tubercular, anti-cancer, and anti-HIV activity. We welcome constructive criticism, comments, and suggestions for further improvement from readers.

We wish to thank the publishers for showing interest in publishing this book. The authors acknowledge the help and excellent cooperation from the editors of Books Clinic Publications for bringing out this book in a record time frame.

Oral Formulation Roadmap from Early Drug Discovery to Development

This is an academic general book by authors Dr. Reenu Yadav, Dr. Ankur Choubey, and Mr. Ashutosh Mishra.

Formulation tools for Pharmaceutical Development

Controlled Release in Oral Drug Delivery provides focus on specific topics, complementing other books in the CRS series. Each chapter sets the context for the inventions described and describes the latitude that the inventions allow. The coverage includes historical overview, candidate drugs, factors influencing design and development, formulation and manufacturing, and delivery system design.

Formulation and Analytical Development for Low-Dose Oral Drug Products

The Art and Science of Dermal Formulation Development is a comprehensive guide to the theory and practice of transdermal and topical formulation development, covering preclinical studies, evaluation, and regulatory approval. It enables readers to understand the opportunities and challenges in developing products and how risks can be mitigated. Over the last 25 years, expertise in this area has declined while drug delivery systems for other administration routes have developed significantly. The advantages offered by transdermal and topical drug delivery remain compelling for sectors including the pharmaceutical industry, personal care, and cosmetics.

Pharmaceutical Experimental Design

This book explores the purpose of clinical psychological and psychiatric diagnosis and provides a persuasive case for moving away from traditional psychiatric classification. It discusses the validity and reliability of classification-based approaches to clinical diagnosis and frames them in their broader historical and societal context. The Diagnostic and Statistical Manual of Mental Disorders (DSM) is used across the world in research and a range of mental health settings; here, Stijn Vanheule argues that the diagnostic reliability of the DSM is overrated, built on a limited biomedical approach to mental disorders that neglects context, and ultimately breeds stigma. The book subsequently makes a passionate plea for a more detailed approach to the study of mental suffering by means of case formulation.

Pharmaceutical Formulation Development of Peptides and Proteins, Second Edition

This useful reference describes the statistical planning and design of pharmaceutical experiments, covering all stages in the development process—including preformulation, formulation, process study and optimization, scale-up, and robust process and formulation development. It shows how to overcome pharmaceutical, technological, and economic constraints on experiment design. Directly comparing the advantages and disadvantages of specific techniques, Pharmaceutical Experimental Design—offers broad, detailed, up-to-date descriptions of designs and methods not easily accessible in other books—reviews screening designs for qualitative factors at different levels—presents designs for predictive models and their use in optimization.
Advanced Drug Delivery Systems in the Management of Cancer discusses recent developments in nanomedicine and nano-based drug delivery systems used in the treatment of cancers. The book provides a comprehensive overview of the latest advancements in drug delivery system technologies and their applications in cancer management. It includes practical solutions on how to design more effective nanocarriers for the drugs used in cancer therapeutics. Each chapter is written with the goal of informing readers about the latest advancements in drug delivery system technologies while reinforcing understanding through various detailed tables, figures, and illustrations.

The formulation of proteins as suspensions, solutions, and (mostly freeze-dried) solids offers significant opportunities and challenges in terms of non-parenteral delivery of peptides and proteins. Adverse events, such as the development of an unwanted immune response, require a thorough understanding of how drugs are delivered to the body. The research presented in this book includes international collaborations in the area of novel drug delivery for the treatment of cancer.

The synthesis of peptides and the biotechnological production of proteins through recombinant DNA technology is a cornerstone of modern drug development. The physicochemical characteristics and stability of peptides and proteins are crucial for their therapeutic efficacy. Pharmaceutical scientists must consider these factors to formulate these compounds as drug products. Pharmaceutical Formulation Development of Peptides and Proteins, Second Edition discusses the development of therapeutic peptides and proteins, focusing on the formulation, analytical, and synthetic chemists and engineers, quality assurance personnel; all users of statistical experimental design in research and development; and postgraduate and postdoctoral research workers in these disciplines.

Pharmaceutical Experimental Design is suitable for industrial, research, and clinical pharmaceutical scientists, pharmacists, and pharmacologists; statisticians and biostatisticians; drug regulatory affairs personnel; biotechnologists; and anyone who needs to understand how one experimental design evolves from another - and more. Featuring over 700 references, tables, equations, and drawings, it reveals advanced approaches for robust scaling up and process transfer - details nonstandard designs and mixtures - analyzes factorial, D-optimal design, and offline quality assurance techniques - reveals optimization methods, such as steepest ascent, optimum path, canonical analysis, graphical analysis, and desirability - discusses the Taguchi method for quality assurance and more.
Formulation Development and Evaluation of Delivery Systems

Formulation Development of Taste Masked Cefuroxime Axetil

This book is based on the authors' significant practical experience partnering with scientists to develop strategies to accelerate the formulation (mixtures) development process. The authors not only explain the most important methods used to design and analyze formulation experiments, but they also present overall strategies to enhance both the efficiency and effectiveness of the development process.

Pharmaceutical Quality by Design

The development of paediatric medicines can be challenging since this is a different patient population with specific needs. A medicine designed for use in paediatric patients must consider the following aspects: patient population variability; the need for dose flexibility; route of administration; patient compliance; excipient tolerability. For example, the toxicity of excipients may differ in children compared to adults and children have different taste preferences. Globally, about 75% of drugs do not carry regulatory approval for use in children; worldwide, many medications prescribed for the treatment of paediatric diseases are used off-label, and less than 20% of package inserts have sufficient information for treating children. This book provides an update on both state-of-the-art methodology and operational challenges in paediatric formulation design and development. It aims at re-evaluating what is needed for more progress in the design and development of age-appropriate treatments for paediatric diseases, focusing on: formulation development; drug delivery design; efficacy, safety, and tolerability of drugs and excipients.

Formulating Poorly Water Soluble Drugs

There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.

Paediatric Formulation

This volume is intended to provide the reader with a breadth of understanding regarding the many challenges faced with the formulation of poorly water-soluble drugs as well as in-depth knowledge in the critical areas of development with these compounds. Further, this book is designed to provide practical guidance for overcoming formulation challenges toward the end goal of improving drug therapies with poorly water-soluble drugs. Enhancing solubility via formulation intervention is a unique opportunity in which formulation scientists can enable drug therapies by creating viable medicines from seemingly undeliverable molecules. With the ever increasing number of poorly water-soluble compounds entering development, the role of the formulation scientist is growing in importance. Also, knowledge of the advanced analytical, formulation, and process technologies as well as specific regulatory considerations related to the formulation of these compounds is increasing in value. Ideally, this book will serve as a useful tool in the education of current and future generations of scientists, and in this context contribute toward providing patients with new and better medicines.

"INDUSTRIAL PHARMACOGNOSY"

Formulation Of Dual Release Dosage Form By Mixed Solvency Concept

Metered Dose Inhaler Technology explores the technologies of pressurized metered dose inhalation (MDI) delivery systems and provides practical, easy-to-use guidance to effective product formulation. With contributions from an international panel of authors, the book addresses the global phase-out of chloroflourocarbon chemicals (CFCs), the generation of propellant systems to replace them, and their associated new medications and therapies. Topics include the manufacture of metered dose inhalers, particle size analysis in inhalation therapy, development and testing, pharmcokinetics and metabolism of propellants, toxicology, and more.
Advances and Challenges in Pharmaceutical Technology

This useful reference describes the statistical planning and design of pharmaceutical experiments, covering all stages in the development process—including preformulation, formulation, process study and optimization, scale-up, and robust process and formulation development. Shows how to overcome pharmaceutical, technological, and economic constraints on experiment design! Directly comparing the advantages and disadvantages of specific techniques, Pharmaceutical Experimental Design offers broad, detailed, up-to-date descriptions of designs and methods not easily accessible in other books· reviews screening designs for qualitative factors at different levels· presents designs for predictive models and their use in optimization· highlights optimization methods, such as steepest ascent, optimum path, canonical analysis, graphical analysis, and desirability· discusses the Taguchi method for quality assurance and approaches for robust scaling up and process transfer· details nonstandard designs and mixtures· analyzes factorial, D-optimal design, and offline quality assurance techniques· reveals how one experimental design evolves from another· and more! Featuering over 700 references, tables, equations, and drawings, Pharmaceutical Experimental Design is suitable for industrial, research, and clinical pharmaceutical scientists, pharmacists, and pharmacologists; statisticians and biostatisticians; drug regulatory affairs personnel; biotechnologists; formulation, analytical, and synthetic chemists and engineers, quality assurance personnel; all users of statistical experimental design in research and development; and postgraduate and postdoctoral research workers in these disciplines.

The Future of Pharmaceutical Product Development and Research

A range of new and innovative tools used for preformulation and formulation of medicines help optimize pharmaceutical development projects. Such tools also assist with the performance evaluation of the pharmaceutical process, allowing any potential gaps to be identified. These tools can be applied in both basic research and industrial environment. Formulation tools for pharmaceutical development considers these key research and industrial tools. Nine chapters by leading contributors cover: Artificial neural networks technology to model, understand, and optimize drug formulations; ME_expert 2.0: a heuristic decision support system for microemulsions formulation development; Expert system for the development and formulation of push-pull osmotic pump tablets containing poorly water-soluble drugs; SeDeM Diagram: an expert system for preformulation, characterization and optimization of tablets obtained by direct compression; New SeDeM-ODT expert system: an expert system for formulation of orodispersible tablets obtained by direct compression; and 3D-cellular automata in computer-aided design of pharmaceutical formulations: mathematical concept and F-CAD software. Coverage of artificial intelligence tools, new expert systems, understanding of pharmaceutical processes, robust development of medicines, and new ways to develop medicines Development of drugs and medicines using mathematical tools Compilation of expert system developed around the world

Oral Controlled Release Formulation Design and Drug Delivery

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

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