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Pharmaceutical formulations have evolved from simple and traditional forms to more modern and complex novel dosage forms. Formulation development is a tedious process and requires an enormous amount of effort from many different people. Developing a stable novel dosage form and further targeting it to the desired site inside the body has always been a challenge. The purpose of this book is to bring together authors who have written regularly articles that highlight recent developments and trends in pharmaceutical formulation science. Each article has been written by experts in the subject area and has been selected from top journals around the world. This book has been written in a systematic and lucid style explaining all basic concepts and fundamentals in a very simple way. This book aims to serve the need of all individuals involved in any level in the pharmaceutical dosage form development. I sincerely hope that the book will be liked by inquisitive students and learned colleagues.

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. Innovative Dosage Forms: Design and Development at Early Stage starts with a look at the impact of the polymorphic form of drugs on the formulation and formulation development. It then offers readers relatable strategies for the formulation development of poorly soluble drugs. The book also studies the role of reactive impurities from the excipients on the formulation shelf life; preclinical formulation assessment of new chemical entities; and regulatory aspects for formulation design. Other chapters cover innovative formulations for special indications, including oncology injectables, delayed release and depot formulations; accessing pharmacokinetics of various dosage forms; physical characterization techniques to assess amorphous nature; novel formulations for protein oral dosage; and more. Provides information that is essential for the drug development effort - Presents the latest advances in the field and describes in detail innovative formulations, such as nanosuspensions, micelles, and coacrylates - 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 - Includes case studies from recent drug development programs to illustrate the practical challenges of preformulation design Innovative 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.

This comprehensive book encompasses various facets of sterile product development. Key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book: • Formulation approaches that discuss a variety of dosage forms including protein therapeutics, lipid-based controlled delivery systems, PEGylated biotherapeutics, nasal dosage form, and vaccines • Process, container closure and delivery considerations including freeze-thaw process challenges, best practices for technology transfer to enable commercial product development, innovations and advancement in aseptic fill-finish operations, approaches to manufacturing lyophilized parenteral products, pen / auto-injector delivery devices, and associated container closure integrity testing hurdles for sterile product closures • Regulatory and quality aspects in the areas of particulate matter and appearance evaluation, sterile filtration, admixture compatibility considerations, sterilization process considerations, microbial contamination investigations and validation of rapid microbiological methods, and dry and moist heat sterilizers This book is a useful resource to scientists and researchers in both industry and academia, and it gives process and product development engineers insight into current industry practices and evolving regulatory expectations for sterile product development.

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 affecting the blood, lungs, brain, and kidneys. The research presented in this book includes international collaborations in the area of novel drug delivery for the treatment of cancer. Cancer therapy remains one of the greatest challenges in modern medicine, as successful treatment requires the elimination of malignant cells that are closely related to normal cells within the body. Advanced drug delivery systems are carriers for a wide range of therapeutics used in many applications, including cancer treatment. The use of such carrier systems in cancer treatment is growing rapidly as they help overcome the limitations associated with conventional drug delivery systems. Some of the conventional limitations that these advanced drug delivery systems help overcome include nonspecific targeting, systemic toxicity, poor oral bioavailability, reduced efficacy, and low therapeutic index. This book begins with a broad introduction to cancer biology. This is followed by an overview of the current landscape in pharmacotherapy for the cancer management. The need for advanced drug delivery systems in oncology and cancer treatment is established, and the systems that can be used for several specific cancers are discussed. Several chapters of the book are devoted to discussing the latest technologies and advances in nanotechnology. These include 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. Advanced Drug Delivery Systems in the Management of Cancer is a valuable resource for anyone working in the fields of cancer biology and drug delivery, whether in academia, research, or industry. The book will be especially useful for researchers in drug formulation and drug delivery as well as for biological and translational researchers working in the field of cancer. Presents an overview of the recent perspectives and challenges within the management and diagnosis of cancer Provides insights into how advanced drug delivery systems can effectively be used in the management of a wide range of cancers Includes up-to-date information on diagnostic methods and treatment strategies using controlled drug delivery systems

Advances and Challenges in Pharmaceutical Technology: Materials, Process Development and Drug Delivery Strategies examines recent advancements in pharmaceutical technology. The book discusses common formulation strategies, 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. Innovative Dosage Forms: Design and Development at Early Stage starts with a look at the impact of the polymorphic form of drugs on the formulation and formulation development. It then offers readers relatable strategies for the formulation development of poorly soluble drugs. The book also studies the role of reactive impurities from the excipients on the formulation shelf life; preclinical formulation assessment of new chemical entities; and regulatory aspects for formulation design. Other chapters cover innovative formulations for special indications, including oncology injectables, delayed release and depot formulations; accessing pharmacokinetics of various dosage forms; physical characterization techniques to assess amorphous nature; novel formulations for protein oral dosage; and more. Provides information that is essential for the drug development effort - Presents the latest advances in the field and describes in detail innovative formulations, such as nanosuspensions, micelles, and coacrylates - 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 - Includes case studies from recent drug development programs to illustrate the practical challenges of preformulation design Innovative 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.

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Advances and Challenges in Pharmaceutical Technology: Materials, Process Development and Drug Delivery Strategies examines recent advancements in pharmaceutical technology. The book discusses common formulation strategies, including the use of tools for statistical formulation optimization, Quality by design (QbD), process analytical technology, and the uses of various pharmaceutical biomaterials, including natural polymers, synthetic polymers, modified natural polymers, bioceramics, and other biomaterials. In addition, the book provides rapid advancements in the field by projecting a thorough understanding of various pharmaceutical developments, explorations, and exploitation of various pharmaceutical biomaterials to formulate pharmaceutical dosage forms. Provides extensive information and analysis on recent advancements in the field of pharmaceutical technology Includes contributions from global leaders and experts in academia, industry and regulatory agencies Uses high quality illustrations, flow charts and tables to explain concepts and text to readers, along with practical examples and research case studies

The development of paediatric medicines can be challenging since there is a specific patient population with specific needs. A medicine designed for use in paediatric patients must consider the following aspects: patient population variability; the pharmaceutical biomaterials to formulate pharmaceutical dosage forms. Provides extensive information and analysis on recent advancements in the field of pharmaceutical technology Includes contributions from global leaders and experts in academia, industry and regulatory agencies Uses high quality illustrations, flow charts and tables to explain concepts and text to readers, along with practical examples and research case studies

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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.

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. More featuring 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 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 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.

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 statistical 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.

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-CADE 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.

The main objective of present study was to explore mixed solvency concept in preparation of dual release tablet dosage form of indomethacin. The aim is to make water a strong solvent for the indomethacin for preparation of solid dispersion of drug using mixed solvency concept by use of safe solubilizers (niacinamide, sodium benzoate and sodium citrate) and preclude the use of toxic organic solvents used in solvent evaporation technique. Indomethacin is a non-steroidal anti-inflammatory drug (NSAID) It is indicated for moderate to severe rheumatoid arthritis including acute flares of chronic disease, ankylosing spondylitis, osteoarthritis, acute painful shoulder (bursitis and/or tendinitis) and acute gouty arthritis. The objective of the present research work is to develop once a day dual release tablet dosage form of the drug, to overcome gastric irritation caused by repeated use of NSAID in short duration of time. The immediate release is rapidly absorbed from the stomach to provide a bocus dose of active agent. The sustained release indomethacin is gradually released over time to maintain the blood level at effective concentrations for long period of time.

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 Featuring 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 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 therap
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.

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.

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 sequence 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 chemical, 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 rapid advance in recombinant DNA technology and the increasing availability of peptides and proteins with therapeutic potential for pharmaceutical scientists who have to formulate these compounds as drug products.

Preformulation Development of Peptides and Proteins, Second Edition discusses the development of therapeutic peptides and proteins, from the production of active compounds via basic pre-formulation and formulation to the registration of the final product. Providing integrated solutions, this book discusses: The synthesis of peptides and the biotechnological production of proteins by recombinant DNA technology; The physicochemical characteristics and stability of peptides and proteins; The formulation of proteins as suspensions, solutions, and (mostly freeze-dried) solids; The opportunities and challenges of non-parenteral delivery of peptides and proteins; Risk factors, specifically the development of an unwanted immune response; A simulation approach to describe the fate of peptides and proteins upon administration to a biological system. The documentation required to register a protein-based drug Scientists in the pharmaceutical industry and academia as well as postgraduate students in pharmaceutical science will find this a valuable resource.

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.

Although the United States (U.S.) and the more developed nations of the world are blessed with a variety of pharmaceuticals, feed additives, and biological products to treat, prevent, and control animal diseases, there is a healthy desire among persons involved in animal health issues to increase our animal medicine chest. The interest stems from the desire to efficiently produce food that is safe and plentiful and from the desire to have more and better government-approved products available for the prevention and treatment of diseases of dogs, cats, and horses and for an increasing variety of minor animal species. For the animal health industry, increased drug availability means broader markets, increased revenues, and an opportunity to better serve their customers. For the veterinarian, more animal health products means that he or she is better able to treat the usual and the unusual conditions, and to prevent animal disease and suffering. No doubt, we are all winners when new technology and industrial and regulatory initiatives hasten the availability of safe and effective animal health products.

"The review on Quinazoline Heterocycle: A Pharmacophoric Scaffold book has been written, keeping in view the needs and interest of student, teachers and researchers in pharmaceutical Science field. The prime aim and objective of the authors has always been to keep transparency in the subject matter, the various terminologies and texts which have been introduced and defined in a precise and articulate manner. Besides this the entire text has been substantiated with the chemical structure of synthesized Quinazoline derivatives and their pharmacological significance. All the authors communicate their interest of the subject matter by reviewing through various literatures. This book appears to be blend of synthesis, physico-chemical characterisation and pharmacological activity of various Quinazoline derivatives synthesised by different scientists. Heterocyclic compounds have broad spectrum of application in the field of medicinal chemistry due to potent pharmacological activity which has been recognized and has been studied experimentally. Quinazoline and its derivatives have received considerable attention due to their synthetic and effective biological importance. The connection between a wide spectrum of biological activities and compounds containing quinazoline moiety has been known and it clearly demonstrate the remarkable potential of quinazoline derivatives as source of useful pharmacophore for the new drug discovery. This book is about several structural modifications on the quinazoline nucleus which were done by different scientists to evaluate the enhancement in the biological activities like anti-convulsant, CNS depressant, anti-microbial, analgesic and anti-inflammatory, anti-tubercular, anti-cancer, anti-HIV activity. Any constructive criticism, comments and suggestions for further improvement from the readers are always welcome. We wish to thank the publishers for showing the interest by them for publication. The authors acknowledge the help and excellent co-operation from editors of Books Clinic publications for bringing out this book in a record time frame."

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.

This book is a Academic Gernal Book By Author Dr. Reenu Yadav, Dr.Ankur Choubey, Mr Ashutosh Mishra

This book explores the purpose of clinical psychological and psychiatric diagnosis, and provides a persuasive case for moving away from the traditional practice of 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. Starting from literature on qualitative research the author makes clear how to guarantee the quality of clinical case formulations.

Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies

A needed resource for pharmaceutical scientists and cosmetic chemists, Essential Chemistry for Formulators of Semisolid and Liquid Dosages provides insight into the basic chemistry of mixing different phases and test methods for the stability study of nonsolid formulations. The book covers foundational surface/colloid chemistry, which forms the necessary background for making emulsions, suspensions, solutions, and nano drug delivery systems, and the chemistry of mixing, which is critical for further formulation of drug delivery systems into semisolid (gels, creams, lotions, and ointments) or liquid final dosages. Expanding on these foundational principles, this useful guide explores stability testing methods, such as particle size-microscopy/viscosity, microscopy, and chemical, and closes with a valuable discussion of regulatory issues. Essential Chemistry for Formulators of Semisolid and Liquid Dosages offers scientists and students the foundation and practical guidance to make and analyze semisolid and liquid formulations. Unique coverage of the chemistry of mixing that makes possible stable dosage Quality content written by experts from the drug delivery industry Valuable information for academic and industrial scientists developing topical and liquid dosage formulations for pharmaceutical as well as skin care and cosmetic products

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.

Controlled Release in Oral Drug Delivery provides focus on specific topics, complementing other books in the initial CRS series. Each chapter sets the context for the inventions described and describe the latitude that the inventions allow. In order to provide some similar look to each chapter, the coverage includes the historical overview, candidate drugs, factors influencing design and development, formulation and manufacturing and delivery system design. This volume was written along three main sections: the relevant anatomy and physiology, a discussion on candidates for oral drug delivery and the major three groups of controlled release systems: diffusion control (swelling and inert matrices); environmental control (pH sensitive coatings, time control, enzymatic control, pressure control) and finally lipidic systems.

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-HPC inclusion complexes can efficiently aid as an antidiarrheal agent and mask the bitter taste of CA."

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 the reader 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 whilst 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. This text addresses the dearth of expertise and discusses how skin can be a route of delivery and the processes in formulation development, but how such an application is very different to that used for oral, IV, and other administration routes. Key Features: Presents a practical guide for both industry and academia Focuses on and draws together the fundamental principles behind transdermal and topical drug delivery development explores the practicalities of formulation design using key case studies Gives an understanding of the skin as a route of delivery and how formulation development for such application differs from that for other administration routes

Today, the pressure on healthcare costs and resources is increasing, and especially for biopharmaceuticals that require parenteral administration, the inherent complex and invasive dosing procedure adds to the demand for efficient medical management. In light of the COVID-19 pandemic the value of drug delivery technologies in enabling a flexible care setting is broadly recognized. In such a setting, patients and their caregivers can choose the place of drug administration based on individual preferences and capabilities. This includes not only dosing in the clinic but also supervised at-home dosing and self-administration for eligible patients. Formulation and Device Lifecycle Management of Biotherapeutics: A Guidance for managed care. In light of the COVID-19 pandemic the value of drug delivery technologies in enabling a flexible care setting is broadly recognized. In such a setting, patients and their caregivers can choose the place of drug administration based on individual preferences and capabilities. This includes not only dosing in the clinic but also supervised at-home dosing and self-administration for eligible patients. Formulation and Device Lifecycle Management of Biotherapeutics: A Guidance for

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Controlled Release in Oral Drug Delivery provides focus on specific topics, complementing other books in the initial CRS series. Each chapter sets the context for the inventions described and describe the latitude that the inventions allow. In order to provide some similar look to each chapter, the coverage includes the historical overview, candidate drugs, factors influencing design and development, formulation and manufacturing and delivery system design. This volume was written along three main sections: the relevant anatomy and physiology, a discussion on candidates for oral drug delivery and the major three groups of controlled release systems: diffusion control (swelling and inert matrices); environmental control (pH sensitive coatings, time control, enzymatic control, pressure control) and finally lipidic systems.

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-HPC inclusion complexes can efficiently aid as an antidiarrheal agent and mask the bitter taste of CA."

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 the reader 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 whilst 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. This text addresses the dearth of expertise and discusses how skin can be a route of delivery and the processes in formulation development, but how such an application is very different to that used for oral, IV, and other administration routes. Key Features: Presents a practical guide for both industry and academia Focuses on and draws together the fundamental principles behind transdermal and topical drug delivery development explores the practicalities of formulation design using key case studies Gives an understanding of the skin as a route of delivery and how formulation development for such application differs from that for other administration routes

Today, the pressure on healthcare costs and resources is increasing, and especially for biopharmaceuticals that require parenteral administration, the inherent complex and invasive dosing procedure adds to the demand for efficient medical management. In light of the COVID-19 pandemic the value of drug delivery technologies in enabling a flexible care setting is broadly recognized. In such a setting, patients and their caregivers can choose the place of drug administration based on individual preferences and capabilities. This includes not only dosing in the clinic but also supervised at-home dosing and self-administration for eligible patients. Formulation and Device Lifecycle Management of Biotherapeutics: A Guidance for Researchers and Drug Developers covers the various aspects of improving drug delivery of biological medicines with the ultimate goal to reduce dosing complexity associated with parenteral administration and, thus, enhance patient experience and drug administration-related healthcare capacity. The target audience are multidisciplinary researchers and drug developers in the pharmaceutical industry, biotech companies, and academia involved in formulation and device development. This includes pharmacology and medical experts in charge of generating nonclinical and clinical data to support approval of novel dosing regimens, and drug delivery scientists and engineers responsible for technical particulars of product optimizations. Moreover, professionals in market access and commercial functions are expected to benefit from the discussions about the impact of patient and healthcare provider needs and country-specific reimbursement models on realizing a truly convenient and cost and resource efficient drug delivery solution. Summarizes formulation and device lifecycle management activities that enable customer-centric and sustainable drug delivery for biotechnologies Describes the pharmacokinetic-based clinical development pathway for subcutaneous dosing alternatives to established intravenous formulations for monoclonal antibodies Details established clinical development pathways supporting the approval of automated subcutaneous injection devices and pre-filled syringes Discusses how to realize hormone- and self-administration of biotechnologies in cancer care Highlights novel concepts in multidisciplinary formulation and device lifecycle management that can be leveraged across different disease areas and introduces a decision architecture on when and how drug developers should embark into related development activities

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 chlorofluorocarbon chemicals (CFCs), the generation of propellant systems to replace them, and their associated new medications and therapies. Topics include the manufacture of...
Biopharmaceutics and Pharmacokinetics Considerations examines the history of biopharmaceutics and pharmacokinetics. The book provides a biopharmaceutics and pharmacokinetics approach to addressing issues in formulation development and ethical considerations in handling animals. Written by experts in the field, this volume within the Advances in Pharmaceutical Product Development and Research series deepens understanding of biopharmaceutics and pharmacokinetics within drug discovery and drug development. Each chapter delves into a particular aspect of this fundamental field to cover the principles, methodologies and technologies employed by pharmaceutical scientists, researchers and pharmaceutical industries to study the chemical and physical properties of drugs and the biological effects they produce. Examines the most recent developments in biopharmaceutics and pharmacokinetics for pharmaceutical sciences Covers the principles, methodologies and technologies of biopharmaceutics and pharmacokinetics Focuses on the pharmaceutical sciences, but also encompasses aspects of toxicology, neuroscience, environmental sciences and nanotechnology

A real-world guide to the production and manufacturing of biopharmaceuticals While much has been written about the science of biopharmaceuticals, there is a need for practical, up-to-date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products. This book helps fill the gap in the field, examining all areas of biopharmaceuticals manufacturing, from development and formulation to production and packaging. Written by a group of experts from industry and academia, the book focuses on real-world methods for maintaining product integrity throughout the commercialization process, clearly explaining the fundamentals and essential pathways for all development stages. Coverage includes: Research and early development phase—appropriate approaches for ensuring product stability Development of commercially viable formulations for liquid and lyophilized dosage forms Optimal storage, packaging, and shipping methods Case studies relating to therapeutic monoclonal antibodies, recombinant proteins, and plasma fractions Useful analysis of successful and failed products Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries, for government and regulatory agencies, and for anyone with an interest in the latest developments in the field.

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. Hydrophobic base with good physical appearance was prepared from melting process of polyethylene polymer (PE) and mineral oil at about 80 degree Celsius. 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 responsible for stable gel structure. Among various percentages of PE in this study, it was found that the appropriate amount of PE polymer in hydrophobic base was 4.5 percent. From rheogram at various temperatures, hydrophobic base exhibits pseudoplastic behavior. Activation energy calculated from modified Arrhenius’s equation was about 12.45 kJ/mol. Gelatin, xanthan gum, pectin, sodium evaluated for suitable gelling agent in hydrophobic base. Chitosan salts prepared by spray-drying process with suitable conditions were fine yellowish powder with round shape. Among these gelling agents mixed with hydrophobic base, SCMC, pectin, chitosan glutamate molecular weight 227000, butylated hydroxytoluene (BHT) and active ingredient (either mangostin or asiaticoside) was suitable. From photoxidation study the result revealed that the percent contents of both mangostin and asiaticoside in formulation using BHT as antioxidant were slightly changed within acceptable limit. In addition, after 4 months of stability study at 30 degree Celsius the percent contents of mangostin and asiaticoside in formulation seem to be unchanged at various storage time intervals.

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