

Formulation Development and in Vitro Evaluation of Capecitabine Immediate Release Tablets

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ABSTRACT

The aim of this study is to formulate and significantly improve the bioavailability and reduce the side effects of immediate release tablets Capecitabine. The precompression blends of Capecitabine were characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio. The precompression blend of all the batches indicates good to fair flowability and compressibility. Immediate release tablets were prepared with various disintegrants like PEG 6000, Croscarmellose sodium and Sodium- starch glycolate at different concentration ratios and were compressed into tablets. The formulated tablets were evaluated for various quality control parameters. The tablets were passed all tests. Among all the formulations F7 formulation containing, drug and Croscarmellose sodium showed good result that is 98.12 % in 45 min. Hence from the dissolution data it was evident that F7 formulation is the better formulation.

KEYWORDS: Capecitabine, PEG 6000, Croscarmellose sodium and Sodium-starch glycolate, Immediate release

Development

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INTRODUCTION:

Oral route is the most convenient and extensively used for drug administration. Oral administration is the most popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly, patient compliance suitable for industrial production, improved stability and bioavailability. The concept of immediate release tablets emerged from the desire to provide patient with more conventional means of taking their medication when emergency treatment is required. Recently, immediate release tablets have gained prominence of being new drug delivery systems. The oral route of administration has so far received the maximum attention with respect to research on physiological and drug constraints as well as design and testing of product. Drug delivery systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. Most immediate release tablets are intended to disintegrate in the stomach, where the pH is acidic. Several orally disintegrating

tablet (ODT) technologies based on direct compression. In pharmaceutical formulation includes any formulation in which the rate of release of drug from the formulation is at least 70% (preferably 80%) of active ingredient within 4 hours, such as within 3 hours, preferably 2 hours, more preferably within 1.5 hours, and especially within an hour (such as within 30 minutes) of administration. In Formulation of immediate release the commonly Superdisintegrants used are Croscarmellose, sodium, Sodium Starch glycolate and Crospovidone.¹

Oral route of administration is the most popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly, patient compliance. Also solid oral delivery systems does not need sterile conditions and are therefore, less expensive to manufacture. Patient compliance, high precision dosing, and manufacturing efficiency make tablets the solid dosage form of choice. There is

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Drug Discovery and Evaluation: Methods in Clinical Pharmacology H.Gerhard Vogel,Jochen Maas,Alexander Gebauer,2010-12-15 Drug Discovery and Evaluation has become a more and more difficult expensive and time consuming process The effect of a new compound has to be detected by in vitro and in vivo methods of pharmacology The activity spectrum and the potency compared to existing drugs have to be determined As these processes can be divided up stepwise we have designed a book series Drug Discovery and Evaluation in the form of a recommendation document The methods to detect drug targets are described in the first volume of this series Pharmacological Assays comprising classical methods as well as new technologies Before going to man the most suitable compound has to be selected by pharmacokinetic studies and experiments in toxicology These preclinical methods are described in the second volume Safety and Pharmacokinetic Assays Only then are first studies in human beings allowed Special rules are established for Phase I studies Clinical pharmacokinetics are performed in parallel with human studies on tolerability and therapeutic effects Special studies according to various populations and different therapeutic indications are necessary These items are covered in the third volume *Methods in Clinical Pharmacology Oral Drug Delivery for Modified Release Formulations* Edmund S. Kostewicz,Maria Vertzoni,Heather A. E. Benson,Michael S. Roberts,2022-04-04 ORAL DRUG DELIVERY FOR MODIFIED RELEASE FORMULATIONS Provides pharmaceutical development scientists with a detailed reference guide for the development of MR formulations Oral Drug Delivery for Modified Release Formulations is an up to date review of the key aspects of oral absorption from modified release MR dosage forms This edited volume provides in depth coverage of the physiological factors that influence drug release and of the design and evaluation of MR formulations Divided into three sections the book begins by describing the gastrointestinal tract GIT and detailing the conditions and absorption processes occurring in the GIT that determine a formulation s oral bioavailability The second section explores the design of modified release formulations covering early drug substance testing the biopharmaceutics classification system an array of formulation technologies that can be used for MR dosage forms and more The final section focuses on in vitro in silico and in vivo evaluation and regulatory considerations for MR formulations Topics include biorelevant dissolution testing preclinical evaluation and physiologically based pharmacokinetic modelling PBPK of in vivo behaviour Featuring contributions from leading researchers with expertise in the different aspects of MR formulations this volume Provides authoritative coverage of physiology physicochemical determinants and in vitro in vivo correlation IVIVC Explains the different types of MR formulations and defines the key terms used in the field Discusses the present status of MR technologies and identifies current gaps in research Includes a summary of regulatory guidelines from both the US and the EU Shares industrial experiences and perspectives on the evaluation of MR dosage formulations Oral Drug Delivery for Modified Release Formulations is an invaluable reference and guide for researchers industrial scientists and graduate students in general

areas of drug delivery including pharmaceuticals pharmaceutical sciences biomedical engineering polymer and materials science and chemical and biochemical engineering Handbook of Bioequivalence Testing Sarfaraz K. Niazi, 2014-10-29 As the generic pharmaceutical industry continues to grow and thrive so does the need to conduct adequate efficient bioequivalence studies In recent years there have been significant changes to the statistical models for evaluating bioequivalence In addition advances in the analytical technology used to detect drug and metabolite levels have m

Artificial Intelligence in the Production of Biotherapeutics Alok Kumar Srivastav, Priyanka Das, 2025-08-29 The transformative role of artificial intelligence AI in modern biomanufacturing focuses on key areas such as process analytical technology PAT Good Manufacturing Practice GMP compliance predictive analytics and AI driven quality systems It bridges cutting edge AI applications with the complexities of biotherapeutic production offering insights into automation real time monitoring and process optimization Delving into the core of biomanufacturing the book provides a structured journey through its critical phases It begins with an introduction to modern biomanufacturing principles quality by design approaches and the integration of AI Subsequent chapters examine raw material management lean manufacturing practices and the application of predictive analytics to optimize supply chains Readers will explore advanced tools such as AI enhanced data acquisition in PAT automated standard operating procedures SOPs and AI driven process controls for fermenters and chromatography systems The text also addresses GMP essentials including personnel management hygienic facility design and pharmaceutical water systems Key chapters highlight AI s role in validation processes sterile packaging and regulatory compliance referencing global guidelines from organizations such as the WHO FDA and ICH Real world case studies featuring therapeutic proteins monoclonal antibodies and vaccines underscore the practical applications of AI in scaling and maintaining biotherapeutic production This book equips readers with a comprehensive understanding of AI s potential to enhance efficiency accuracy and compliance in biomanufacturing Whether you are a professional researcher or student this guide offers actionable insights into leveraging AI to revolutionize biotherapeutic production while adhering to the highest industry standards What You Will Learn Understand how AI enhances every phase of biotherapeutic production from raw material management to regulatory compliance optimizing efficiency accuracy and quality Explore the role of AI in advanced data acquisition process control and continuous improvement including applications in fermenters flow filtration and chromatography systems Gain insights into leveraging AI for automating standard operating procedures SOPs predictive maintenance quality assurance and adhering to global GMP standards like WHO and FDA guidelines Learn how AI transforms upstream and downstream processes ensures sterility in packaging and supports case studies on therapeutic proteins monoclonal antibodies and human vaccines Discover the potential of AI in shaping the future of biomanufacturing including challenges data security and the ethical implications of AI driven automation **Formulation Development of Candesartan Immediate Release Tablets** Tentu Nageswara Rao, Sharadha Devi Kappari, Murthy Snvs, 2015-10-30 Oral

drug delivery is the most desirable and preferred method of administering therapeutic agents for their systemic effects. In addition, the oral medication is generally considered as the first avenue investigated in the discovery and development of new drug entities and pharmaceutical formulations mainly because of patient acceptance, convenience in administration, and cost-effective manufacturing process. For many drug substances, conventional immediate release formulations provide clinically effective therapy while maintaining the required balance of pharmacokinetic and pharmacodynamic profiles with an acceptable level of safety to the patient.

Herstellung fester Dispersionen durch Covermahlung in einer Luftstrahlmühle
Christian Mühlenfeld, 2013-11-18

Die perorale Wirkstoffadministration stellt aufgrund der vergleichsweise günstigen Herstellung und hohen Akzeptanz bei Patienten die bevorzugte Applikationsart für die meisten Arzneistoffe dar. Die Formulierung fester Darreichungsformen schwerlöslicher Arzneistoffe zur oralen Verabreichung ist von besonderem Interesse für die pharmazeutische Industrie. Die Herstellung fester Dispersionen bei denen der Arzneistoff in einem hydrophilen Träger homogen verteilt ist, gehört dabei zu einem vielversprechenden Ansatz. Neben den klassischen Schmelz- und Lösungsmethoden lassen sich feste Dispersionen auch durch Covermahlung herstellen. Hier bietet die Luftstrahlmahlung gegenüber anderen Mahlverfahren den Vorteil, dass sie einen kontinuierlichen Prozess ermöglicht. Ziel der Arbeit war es, die Eignung der kontinuierlichen Covermahlung mittels Luftstrahlmühle als Verfahren zur Herstellung fester Dispersionen schwerlöslicher Arzneistoffe zu untersuchen.

Exploring Computational Pharmaceutics
Defang Ouyang, 2024-06-21

Provides an extensive and up-to-date overview of the theory and application of computational pharmaceutics in the drug development process. *Exploring Computational Pharmaceutics: AI and Modeling in Pharma 4.0* introduces a variety of current and emerging computational techniques for pharmaceutical research. Bringing together experts from academia, industry, and regulatory agencies, this edited volume also explores the current state, key challenges, and future outlook of computational pharmaceutics while encouraging development across all sectors of the field. Throughout the text, the authors discuss a wide range of essential topics from molecular modeling and process simulation to intelligent manufacturing and quantitative pharmacology. Building upon *Exploring Computational Pharmaceutics: AI and Modeling in Pharma 4.0*, this new edition provides a multi-scale perspective that reveals the physical, chemical, mathematical, and data-driven details of pre-formulation, formulation, process, and clinical studies, in addition to in vivo prediction in the human body and precision medicine in clinical settings. Detailed chapters address both conventional dosage forms and the application of computational technologies in advanced pharmaceutical research, such as dendrimer-based delivery systems, liposome and lipid membrane research, and inorganic nanoparticles. A major contribution to the development and promotion of computational pharmaceutics, this important resource discusses the development track, achievements, and prospects of computational pharmaceutics. Presents multidisciplinary research to help physicists, chemists, mathematicians, and computer scientists locate problems in the field of drug delivery. Covers a wide range of technologies, including complex formulations for water-insoluble drugs, protein, peptide

formulations nanomedicine and gene delivery systems Focuses on the application of cutting edge computational technologies and intelligent manufacturing of emerging pharmaceutical technologies Includes a systematic overview of computational pharmaceuticals and Pharma 4.0 to assist non specialist readers Covering introductory advanced and specialist topics Exploring Computational Pharmaceuticals AI and Modeling in Pharma 4.0 is an invaluable resource for computational chemists computational analysts pharmaceutical chemists process engineers process managers and pharmacologists as well as computer scientists medicinal chemists clinical pharmacists material scientists and nanotechnology specialists working in the field Developing Solid Oral Dosage Forms Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lirong Liu, William

Porter, 2009-03-10 Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms It covers essential principles of physical pharmacy biopharmaceutics and industrial pharmacy as well as various aspects of state of the art techniques and approaches in pharmaceutical sciences and technologies along with examples and or case studies in product development The objective of this book is to offer updated or current knowledge and skills required for rational oral product design and development The specific goals are to provide readers with Basics of modern theories of physical pharmacy biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation formulation process design characterization and scale up in pharmaceutical sciences and technologies New developments challenges trends opportunities intellectual property issues and regulations in solid product development The first book ever that provides comprehensive and in depth coverage of what is required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market including the most updated science and technologies practice applications regulation intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well established authors co authors of diverse background knowledge skills and experience from industry academia and regulatory agencies **Handbook of Pharmaceutical Manufacturing**

Formulations, Third Edition Sarfaraz K. Niazi, 2019-12-06 The Handbook of Pharmaceutical Manufacturing Formulations Third Edition Volume One Compressed Solid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing With thoroughly revised and expanded content this first volume of a six volume set compiles data from FDA new drug applications patent applications and other sources of generic and proprietary formulations to cover the broad spectrum of GMP formulations and issues in using these formulations in a commercial setting A must have collection for pharmaceutical manufacturers educational institutions and regulatory authorities this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent **ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS** DR A. BHARATH KUMAR, DR. JITEN

MISHRA,MR. DIGAMBAR BISOI,DR. MADHU SAHU, Advanced Biopharmaceutics Pharmacokinetics is born out of a desire to provide a comprehensive and integrated understanding of the principles that govern the fate of drugs in the human body In the rapidly evolving world of pharmaceutical sciences the ability to accurately predict assess and apply pharmacokinetic and biopharmaceutical data is not only vital for drug development but also critical in clinical decision making and personalized medicine This book aims to bridge the gap between theoretical foundations and practical applications offering a nuanced perspective tailored for students educators researchers and professionals Over the years pharmacokinetics has emerged as a cornerstone in drug discovery and development influencing every stage from preclinical studies to post marketing surveillance At the same time the principles of biopharmaceutics dealing with the absorption distribution metabolism and excretion of drugs have proven essential in understanding drug performance and therapeutic outcomes Recognizing the intertwined nature of these disciplines this book brings them together in a cohesive narrative enriched with real world case studies graphical models equations and problem solving approaches This book has been written keeping in mind the curriculum needs of undergraduate and postgraduate students in pharmacy and related fields However its practical orientation and research based content make it equally useful for industry professionals involved in formulation clinical pharmacology and regulatory affairs Numerous illustrative examples practice questions and reference materials have been incorporated to make the learning experience more interactive and insightful As scientific knowledge continues to advance it is hoped that this book serves as a reliable resource and foundational guide for all those seeking to deepen their understanding of drug kinetics and biopharmaceutical principles I welcome feedback and suggestions from readers that could help improve future editions and enhance the utility of this work DR A BHARATH KUMAR DR JITEN MISHRA MR DIGAMBAR BISOI DR MADHU SAHU

Pharmaceutical Preformulation and Formulation Mark Gibson,2016-04-19
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 ne

Oral Drug Absorption Jennifer B. Dressman,Christos Reppas,2016-04-19 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 Pharmaceutical Dosage Forms - Parenteral Medications Sandeep Nema,John D. Ludwig,2016-04-19 This three volume set of Pharmaceutical Dosage Forms Parenteral Medications is an authoritative comprehensive reference work on the formulation and manufacture of parenteral dosage forms effectively balancing theoretical considerations with the practical aspects of their development As such it is recommended for scientists and engineers in the **Polymers in Drug Delivery** Ijeoma F. Uchegbu,Andreas G.

Schatzlein,2006-05-19 Together the nano explosion and the genomic revolution are ushering in a new frontier in drug delivery In recent years we ve seen how polymers can play a crucial role in controlling the rate of drug release enhancing solubility and uptake and limiting degradation and toxicity In the very near future they may well be used to deliver gene therapeutics

Pharmaceutical Dosage Forms Sandeep Nema,John D. Ludwig,2010-08-26 Pharmaceutical Dosage Forms Parenteral Medications explores the administration of medications through other than the enteral route First published in 1984 as two volumes and then last revised in 1993 this three volume set presents the plethora of changes in the science and considerable advances in the technology associated with these products

System Engineering Analysis, Design, and Development Charles S. Wasson,2015-11-16 Praise for the first edition This excellent text will be useful to every system engineer SE regardless of the domain It covers ALL relevant SE material and does so in a very clear methodical fashion The breadth and depth of the author s presentation of SE principles and practices is outstanding Philip Allen This textbook presents a comprehensive step by step guide to System Engineering analysis design and development via an integrated set of concepts principles practices and methodologies The methods presented in this text apply to any type of human system small medium and large organizational systems and system development projects delivering engineered systems or services across multiple business sectors such as medical transportation financial educational governmental aerospace and defense utilities political and charity among others Provides a common focal point for bridging the gap between and unifying System Users System Acquirers multi discipline System Engineering and Project Functional and Executive Management education knowledge and decision making for developing systems products or services Each chapter provides definitions of key terms guiding principles examples author s notes real world examples and exercises which highlight and reinforce key SE specification development system architecture development User Centric System Design UCSD interface definition system integration and Verification Life Cycle requirements Phases Modes SE Process Requirements Derivation System Architecture Development User Centric System Design UCSD Engineering Standards Coordinate Systems and Conventions et al Thoroughly illustrated with end of chapter exercises and numerous case studies and examples Systems Engineering Analysis Design and Development Second Edition is a primary textbook for multi discipline engineering system analysis and project management undergraduate graduate level students and a valuable reference for professionals

Poorly Soluble Drugs Gregory K. Webster,Robert G. Bell,J. Derek Jackson,2017-01-06 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 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 **Federal Register**,2001-06-27 *Design Science Research for a Resilient Future* Munir Mandviwalla,Matthias Söllner,Tuure Tuunanen,2024-05-26 This book constitutes the proceedings of the 19th International Conference on Design Science Research in Information Systems and Technology DESRIST 2024 which was held in Trollh ttan Sweden during June 3 5 2024 The 30 full papers presented in this book were carefully reviewed and selected from 69 submissions The papers are divided into the following topical sections DSR for a resilient world theme track general track DSR methods and education DSR in practice and emerging topics in DSR **Western Aviation, Missiles, and Space** ,1963

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web use a pencil to mark the mounting holes 3 remove the wall plate from the wall and drill two holes in the wall as marked gently tap anchors provided into the drilled holes until flush with the wall 4 position the wall plate over the holes pulling wires through the wiring opening see fig 5 5

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