Oral Lipid Based Formulations Enhancing The Bioavailability Of Poorly Water Soluble Drugs Drugs And The Pharmaceutical Sciences

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GEORGE SANTOS

Antifungal Therapy William Andrew
Oral Delivery of Therapeutic Peptides and Proteins provides a complete overview of the journey scientists pursue to attain protein and peptide oral delivery. Oral delivery of therapeutic peptides and proteins requires deep understanding of the physiological barriers and disruptive approaches to overcome them in an integrated fashion. This book highlights that the physiological challenges are manifold and must be accounted for in addition to overcoming protease inhibition and acid stability issues that are commonly mentioned for this area of research. Primary topics include formulation technologies being adopted for oral delivery of proteins and peptides, modification of actives to make them more suited for oral delivery, animal models and their shortcomings in assessing oral bioavailability, and in vitro models to simulate drug absorption and transport. Academics and industry researchers working in formulation development and researchers and advanced students in biotechnology and pharmacy will find this a useful resource. Demonstrates how proteins and peptides transport throughout the gastrointestinal tract and how to evaluate their biological fate when encapsulated into certain delivery systems Examines developing technologies to improve future oral bioavailability Includes in vitro and preclinical techniques needed for development
Warts and All Springer Science & Business Media
Molecular modeling techniques have been widely used in drug

discovery fields for rational drug design and compound screening. Now these techniques are used to model or mimic the behavior of molecules, and help us study formulation at the molecular level. Computational pharmaceutics enables us to understand the mechanism of drug delivery, and to develop new drug delivery systems. The book discusses the modeling of different drug delivery systems, including cyclodextrins, solid dispersions, polymorphism prediction, dendrimer-based delivery systems, surfactant-based micelle, polymeric drug delivery systems, liposome, protein/peptide formulations, non-viral gene delivery systems, drug-protein binding, silica nanoparticles, carbon nanotube-based drug delivery systems, diamond nanoparticles and layered double hydroxides (LDHs) drug delivery systems. Although there are a number of existing books about rational drug design with molecular modeling techniques, these techniques still look mysterious and daunting for pharmaceutical scientists. This book fills the gap between pharmaceutics and molecular modeling, and presents a systematic and overall introduction to computational pharmaceutics. It covers all introductory, advanced and specialist levels. It provides a totally different perspective to pharmaceutical scientists, and will greatly facilitate the development of pharmaceutics. It also helps computational chemists to look for the important questions in the drug delivery field. This book is included in the Advances in Pharmaceutical Technology book series.

Biomedical and Food Applications CRC Press

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

In Vitro-In Vivo Correlations John Wiley & Sons

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.

In Vitro Drug Release Testing of Special Dosage Forms Mdpi AG

Presenting breakthrough research pertinent to scientists in a wide range of disciplines-from medicine and biotechnology to cosmetics and pharmacy-this Second Edition provides practical approaches to complex formulation problems encountered in the development of particulate delivery systems at the micro- and nano-size level. Completely revised and e

Advanced Technology for Delivering Therapeutics IGI Global

Properties and Formulation: From Theory to Real-World Application Scientists have attributed more than 40 percent of the failures in new drug development to poor biopharmaceutical properties, particularly water insolubility. Issues surrounding water insolubility can postpone or completely derail important new drug development. Even the much-needed reformulation of currently marketed products can be significantly affected by these challenges. More recently it was reported that the percentage increased to 90% for the candidates of new chemical entities in the discovery stage and 75% for compounds under development. In the most comprehensive resource on the topic, this third edition of Water-Insoluble Drug Formulation brings together a distinguished team of experts to provide the scientific background and step-by-step guidance needed to deal with solubility issues in drug development. Twenty-three chapters systematically describe the detailed discussion on solubility theories, solubility prediction models, the aspects of preformulation, biopharmaceutics, pharmacokinetics, regulatory, and discovery support of water-insoluble drugs to various techniques used in developing delivery systems for water-insoluble drugs. This book includes more than 15 water-insoluble drug delivery systems or technologies, illustrated with case studies and featuring oral and parenteral applications. Highlighting the most current information and data available, this seminal volume reflects the significant progress that has been made in nearly all aspects of this field. The aim of this book is to provide a handy reference for pharmaceutical scientists in the handling of formulation issues related to water-insoluble drugs. In addition, this book may be useful to pharmacy and chemistry undergraduate students and pharmaceutical and biopharmaceutical graduate students to enhance their knowledge in the techniques of drug solubilization and dissolution enhancement.

Role of Lipid Excipients in Modifying Oral and Parenteral Drug Delivery Elsevier

Biodrug Delivery Systems: Fundamentals, Applications and Clinical Development presents the work of an international group of leading experts in drug development and biopharmaceutical science who discuss the latest advances in biodrug delivery systems and associated techniques. The book discusses components of successful formulation, delivery, and p

The Impact of Food Bioactives on Health CRC Press

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 preformulation and formulation development. It then offers readers reliable 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 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 -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.

Computational Pharmaceutics William Andrew

This thesis has explored the use of lipid-based formulations (LBF) to enhance the oral bioavailability of the cholesteryl ester transfer protein (CETP) inhibitor CP-532,623, used here as a model poorly water soluble drug (PWSD), and the impact of dispersion and digestion on formulation performance. A particular focus has been the use of the in vitro lipid digestion model as a tool to predict the oral bioavailability of PWSDs, by investigating the relationship between drug solubilisation after in vitro digestion and in vivo exposure after oral administration.Dispersion and digestion of LBFs are both events that challenge the solubilisation of a co-administered drug. The data show that the development of LBFs can be informed by the dispersion and solubilisation properties of individual excipients after in vitro digestion. Different patterns of solubilisation were observed with changes in the type of excipient employed. Lipids and lipophilic co-surfactants retained drug in an oily phase but were nonetheless resistant to drug precipitation. Hydrophilic surfactants (particularly Kolliphor RH 40) maintained higher drug solubilisation levels after digestion, a characteristic that was maintained within composite formulations containing Kolliphor and additional excipients. Conversely, co-solvents supported high initial drug loading, but provided no ongoing solubilisation when introduced to aqueous media. A series of formulations based on medium chain (MC) lipids and were initially developed to provide for effective drug loading and good dispersion properties. Assessment of these MC-LBFs using the in vitro digestion model revealed varying degrees of susceptibility to precipitation during in vitro digestion, and a broad correlation between drug solubilisation after in vitro digestion and drug absorption after oral administration in beagle dogs.Subsequent modification of the formulations to include long chain (LC) lipids rather than MC lipids generally resulted in higher levels of CP-532,623 solubilisation after in vitro digestion. In all cases the LBFs greatly enhanced in vitro solubilisation and in vivo oral bioavailability of CP-532,623 in fasted beagle dogs when compared to a simple powder formulation. Within related groups of formulations in vitro solubilisation on lipid digestion was also found to correlate with in vivo exposure. Notably, formulations based on LC-LBFs required higher levels of drug solubilisation to achieve similar levels of in vivo exposure, when compared to MC-LBFs. Re-evaluation of the in vitro data to measure drug supersaturation rather than drug solubilisation, however, resulted in improved correlations, especially for formulations containing a common surfactant. Thus, formulations containing Kolliphor RH 40 were absorbed more readily at lower supersaturation levels than formulations containing polysorbate 80 or vitamin E TPGS. The data suggest that the degree of drug solubilisation and supersaturation during in vitro lipid digestion provides some indication of formulation performance but that this alone is insufficient to completely explain patterns of drug absorption. Further investigations into the factors contributing to the high bioavailability obtained in beagle dogs also suggested that drug absorption from LBFs may vary in beagle and greyhound dogs, with drug absorption typically being higher in beagles.In summary, the studies presented here further demonstrate the utility of the in vitro digestion model in formulation development. In conjunction with solubility studies, calculation of drug supersaturation, and characterisation of the physical state of precipitated drug, in vitro lipolysis tests provide useful in vitro indicators of formulation performance. Interestingly, the current studies suggest that whilst the overall patterns of in vitro-in vivo correlation that have previously been described in the literature, may be maintained, they appear to exist in parallel with excipient specific effects on drug absorption and bioavailability. Thus, in addition to concentration or thermodynamic activity, the nature of the solubilised phases formed on lipid formulation digestion appears to be a significant driver of differences in patterns of drug absorption from LBF.

Design and Development at Early Stage CRC Press

Biopolymer-Based Formulations: Biomedical and Food Applications presents the latest advances in the synthesis and characterization of advanced biopolymeric formulations and their state-of-the-art applications across biomedicine and food science. Sections cover the fundamentals, applications, future trends, environmental, ethical and medical considerations, and biopolymeric architectures that are organized in nano, micro and macro scales. The final section of the book focuses on novel applications and recent developments. This book is an essential resource for researchers, scientists and advanced students in biopolymer science, polymer science, polymer chemistry, polymer composites, plastics engineering, biomaterials, materials science, biomedical engineering, and more. It will also be of interest to R&D professionals, scientists and engineers across the plastics, food, biomedical and pharmaceutical industries. Provides in-depth coverage of methods for the characterization of the physical properties of biopolymeric architectures Supports a range of novel applications, including scaffolds, implant coatings, drug delivery, and nutraceutical encapsulation systems Includes the use of experimental data and mathematical modeling, thus enabling the reader to analyze and compare the properties of different polymeric gels

Lipid-Based Nano-Delivery for Oral Administration of Poorly Water Soluble Drugs (PWSDs): Design, Optimization and in Vitro Assessment Springer Science & Business Media

“Infogest” (Improving Health Properties of Food by Sharing our Knowledge on the Digestive Process) is an EU COST action/network in the domain of Food and Agriculture that will last for 4 years from April 4, 2011. Infogest aims at building an open international network of institutes undertaking multidisciplinary basic research on food digestion gathering scientists from different origins (food scientists, gut physiologists, nutritionists...). The network gathers 70 partners from academia, corresponding to a total of 29 countries. The three main scientific goals are: Identify the beneficial food components released in the gut during digestion; Support the effect of beneficial food components on human health; Promote harmonization of currently used digestion models Infogest meetings highlighted the need for a publication that would provide researchers with an insight into the advantages and disadvantages associated with the use of respective in vitro and ex vivo assays to evaluate the effects of foods and food bioactives on health. Such assays are particularly important in situations where a large number of foods/bioactives need to be screened rapidly and in a cost effective manner in order to ultimately identify lead foods/bioactives that can be the subject of in vivo assays. The book is an asset to researchers wishing to study the health benefits of their foods and food bioactives of interest and highlights which in vitro/ex vivo assays are of greatest relevance to their goals, what sort of outputs/data can be generated and, as noted above, highlight the strengths and weaknesses of the

various assays. It is also an important resource for undergraduate students in the ‘food and health’ arena.
Developing Solid Oral Dosage Forms CRC Press
Oral lipid-based formulations are attracting considerable attention due to their capacity to facilitate gastrointestinal absorption and reduce or eliminate the effect of food on the absorption of poorly water-soluble, lipophilic drugs. Despite the obvious and demonstrated utility of these formulations for addressing a persistent and growing problem of major significance, the pharmaceutical industry has been slow to apply and further develop this technology. This title provides a comprehensive summary of the theoretical and practical aspects of oral lipid-based formulations for use in industry, and provides further insights into a developing technology expected to assume increasing prominence in years to come.
Investigation of Formulation Variables and Physiological Processing on the Behaviour of Lipid-based Formulations for Poorly Water-soluble Drugs Academic Press
Oral lipid-based formulations are attracting considerable attention due to their capacity to facilitate gastrointestinal absorption and reduce or eliminate the effect of food on the absorption of poorly water-soluble, lipophilic drugs. Despite the obvious and demonstrated utility of these formulations for addressing a persistent and growing problem
Oral Delivery of Therapeutic Peptides and Proteins Academic Press
The present book volume presents a holistic view of the aspects of nanobiomaterials incl. their stellar merits and limitations, applications in diverse fields, their futuristic promise in the fields of biomedical science and drug delivery. The federal & regulatory issues on the usage of nanobiomaterials have been assigned due consideration.
NanoBioMaterials CRC Press
The creation of new and more efficient therapies for improving human health greatly depends on drug delivery systems. Nanotechnology has emerged as a powerful strategy for the development of nanoparticles, such as nanoemulsions, liposomes, nanocrystals, and nanocomplexes, applied in the diagnosis, treatment, or theranostics of several pathologies and diseases. This book reviews the most recent research and development in nanotechnology and, following a multidisciplinary approach, presents new strategies for drug delivery, including aspects from chemistry, physics, biology, and imaging methodologies and exploiting several administration routes, internalization pathways, site-specific delivery strategies, and the potential cytotoxicity of nanoparticles. Beginning with a description of the importance and application of nanotechnology for enhancing existing therapy, the book moves on to detailing oral, topical, pulmonary, brain, cancer, and anti-inflammatory drug delivery approaches; gene delivery approaches; theranostic approaches; and nanoparticle cytotoxicity. Practical and user friendly, it is suitable for advanced undergraduate, graduate, and postgraduate students of nanoscience and nanotechnology; researchers in nanoscience, nanotechnology, chemistry, biology, biochemistry, pharmaceutical sciences, medicine, and bioengineering, especially those with an interest in drug delivery or theranostics; and academia and university readership.
Recent Advances in Novel Drug Carrier Systems Baker's Plays
The World Malaria Report 2015 assesses global malaria disease trends and changes in the coverage and financing of malaria control programs between 2000 and 2015. It also summarizes progress towards international targets, and provides regional and country profiles that summarize trends in each WHO region and each country with malaria. The report is produced with the help of WHO regional and country offices, ministries of health in endemic countries, and a broad range of other partners. The data presented are assembled from the 96 countries and territories with ongoing malaria transmission, and a further five countries that have recently eliminated malaria. Most data are those reported for 2014 and 2015, although in some cases projections have been made into 2015, to assess progress towards targets for 2015.
Basic Principles and Biological Examples CRC Press
Background: The work presented in this thesis was designed as a part of an ongoing research project to develop a formulation strategy to enhance the oral bioavailability of lycopene. As a natural antioxidant derived from dietary sources, lycopene has attracted considerable attention as a potent chemo-preventative agent. Lycopene is an extremely lipophilic compound and absorption from dietary sources is estimated to be low and highly variable. The purpose of this thesis is to perform a systematic assessment of lycopene absorption from the gastrointestinal tract and to design a novel oral formulation strategy of lycopene. Methods: A mechanistic evaluation of the route of absolute absorption and absolute bioavailability of lycopene was evaluated in the mesenteric lymph duct cannulated rat model. Lycopene was formulated in a range of self micro-emulsifying drug delivery system and then characterised. A solid dispersion was also investigated. Finally, the in vivo bioavailability was evaluated in conscious pig model. Results: The absolute bioavailability of lycopene is 1.85±0.39% and the intestinal lymphatic route is the major uptake mechanism of lycopene from gastrointestinal tract. A novel LBSDF formulation which developed resulted in a 2.2-fold higher bioavailability compared to the commercial lycopene product, lycovit®. Conclusion: The data obtained in this study illustrate a number of design concepts that might usefully be incorporated into formulation strategies for lipid-based formulations of poorly water soluble drugs. In the case of lycopene, an optimised formulation, which allows for efficient and reproducible dosing may serve as the basis for a prospective case controlled study into the potential benefits of this potent antioxidant.
Fundamentals, Applications and Clinical Development Springer
This comprehensive resource covers the fundamentals, formulation, and biopharmaceutical issues of lipid-based drug delivery. It presents the principles of lipid absorption and covers formulation issues, such as dissolution testing and stability testing, and physiological and biopharmaceutical issues, including the role of specific enzymes, the evaluation of transport systems in the body, and the mechanisms governing the transport of water-insoluble drugs.
Microencapsulation CRC Press
Drug delivery technologies represent a vast and vital area of Research and Development. The demand for innovative drug delivery systems continues to grow, and this growth continues to drive new developments. Building on the foundation provided by the first edition, Drug Delivery Systems, Second Edition covers the latest developments in both
Drug Delivery Systems BoD – Books on Demand
Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with:

Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design, characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges, trends, opportunities, intellectual property issues and regulations in solid product development The first book (ever) that provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice, applications, regulation, intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies

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