Dissolution Test For Extended Release Tablets

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Handbook of Pharmaceutical Controlled Release Technology OUP Oxford

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.

Oral Drug Delivery for Modified Release Formulations Springer Science & Business Media

The Handbook of Pharmaceutical Controlled Release Technology reviews the design, fabrication, methodology, administration, and classifications of various drug delivery systems, including matrices, and membrane controlled reservoir, bioerodible, and pendant chain systems. Contains cutting-edge research on the controlled delivery of biomolecules! Discussing the advantages and limitations of controlled release systems, the Handbook of Pharmaceutical Controlled Release Technology covers oral, transdermal, parenteral, and implantable delivery of drugs discusses modification methods to achieve desired release kinetics highlights constraints of system design for practical clinical application analyzes diffusion equations and mathematical modeling considers environmental acceptance and tissue compatibility of biopolymeric systems for biologically active agents evaluates polymers as drug delivery carriers describes peptide, protein, micro-, and nanoparticulate release systems examines the cost, comfort, disease control, side effects, and patient compliance of numerous delivery systems and devices and more!

Protein Purification Applications CRC Press

Since the earliest dosage forms to modern drug delivery systems, came a great development and growth of knowledge with respect to drug delivery. Strategies to Modify the Drug Release from Pharmaceutical Systems will address principles, systems, applications and advances in the field.It will be principally a textbook and a reference source of strategies to modify the drug release. Moreover, the characterization, mathematical and physicochemical

models, applications and the systems will be discussed. Addresses the principles, systems, applications and advances in the field of drug delivery Highlights the mathematical and physicochemical principles related to strategies Discusses drug release and its possible modifications

Biopharmaceutics Applications in Drug Development McGraw-Hill/Appleton & Lange

Dissolution has emerged as a key method during development of medicines and for quality control of marketed products. At the early stage of development, dissolution guides the selection of toxicology and first test in man formulations. At later stages of development, dissolution tests are performed to compare prototype formulations, the robustness of the manufacturing process, to indicate stability and to assure safe release and reproductibility of the products to the market. However despite they wide use in pharmaceutical development, several challenges still exist. In particular, there is a lack of thorough identification and understanding of the critical quality attributes that control dissolution of Active Pharmaceutical Ingredient and Drug Product. Dissolution exhibits clearly a higher predictability if it can be extrapolated directly to in vivo behavior. Thepresent work focuses on the optimization of the existing and alternative dissolution techniques to lay a foundation for Quality by Design (QbD) principles, In Vitro/In Vivo Correlation (IVIVC) and In Vitro/In Vivo Relationship (IVIVR). The dissolution applied on API and on differente formulations types (Immediate release and extended release form) during the different development phases as well as for generic has been explored. Simple and cost effective dissolution methods were shown to be potential surrogate for in vivo performance and serve as well for strong quality control method. The future perspectives and central role of dissolution testing are presented and discussed.

Aarhuus Stiftstidendes Lommebog for Avislæsere CRC Press

Introduction, Historical Highlights, and the Need for Dissolution Testing Theories of Dissolution Dissolution Testing Devices Automation in Dissolution Testing, by William A. Hanson and Albertha M. Paul Factors That Influence Dissolution Testing Interpretation of Dissolution Rate Data Techniques and of In Vivo Dissolution, by Umesh V. Banakar, Chetan D. Lathia, and John H. Wood Dissolution of Dosage Forms Dissolution of Modified-Release Dosage Forms Dissolution and Bioavailability Dissolution Testing and the Assessment of Bioavailability/Bioequivalence, by Santosh J. Vetticaden Dissolution Rediscovered, by John H. Wood Appendix: USP/NF Dissolution Test.

Controlled Release in Oral Drug Delivery CRC Press

Pharmaceutical Dosage Forms: Capsules covers the development, composition, and manufacture of capsules. Despite the important role that capsules play in drug delivery and product development, few comprehensive texts on the science and technology of capsules have been available for the research and academic environments. This text addresses this gap, discussing how capsules provide unique capabilities and options for dosage form design and formulation.

Generic Drug Product Development Elsevier

In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of

patent infringement and other legal and regulatory concerns.Generic Drug Product Development: Solid Oral Excipient Applications in Formulation Design and Drug Delivery Woodhead Publishing Compassion of the dissolution data obtained in this study with the results from other dissolution studies allows conclusions to be drawn regarding the appropriate conditions for dissolution testing of sustained-release dosage forms.

Oral Drug Absorption Springer 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

Controlled Release Veterinary Drug Delivery Mack Publishing Company "Pharmaceutics is the art of pharmaceutical preparations. It encompasses design of drugs, their manufacture and the elimination of micro-organisms from the products. This book encompasses all of these areas."--Provided by publisher.

In Vitro Drug Release Testing of Special Dosage Forms Springer Dextromethorphan is a highly potent and commonly used anitussive agent. At present there are no extended release dextromethorphan matrix tablets available in the USA. The objective of this dissertation to develop and evaluate extended release dextromethorphan matrix tablets manufactured by the direct compression method. Formulation and process variables on the

effect of hydroxypropylmethylcellulose (HPMC K100LV) in combination with anionic methacrylic acid copolymer (Eudragit L100-55); and polyvinyl acetate/povidone (PVAP) (Kollidon SR) polymer concentrations in the tablet, filler excipient concentration, compression force, stability storage conditions and variable dissolution agitation rates were evaluated on the produced tablet characteristics. The extended release tablets were then compared to a marketed capsule product by applying the FDA dissolution recommended model independent f2 similarity test. Additionally, bioavailability and bioequivalence studies in healthy adult beagle dogs were performed. It was found that HPMC (K100LV) at 20% level in combination with methacrylic acid copolymer (Eudragit L100-55) at 20% level produced extended release dextromethorphan matrix tablets that are similar to the marketed capsule product according to the model independent FDA guidelines (f2 factor). Polyvinyl acetate/povidone (PVAP) (Kollidon SR) at 39.5% in combination with dibasic calcium phosphate also at 39.5% level produced extended release dextromethorphan tablets that are similar to the marketed capsule product according the model independent FDA guidelines (f2 factor). The extended release dextromethorphan matrix tablets followed square root of time dependent kinetics for drug release indicating a diffusion controlled release mechanism. The extended release dextromethorphan matrix tablets were not bioequivalent to the marketed capsule product, however, the tablets had higher bioavailability as shown by the AUC(0-inf). In vitro/invivo correlation between variable dissolution agitation rates and the dextromethorphan released and absorbed was not established for the extended release dextromethorphan matrix tablets. It was concluded that extended release dextromethorphan tablets were developed using HPMC (K100LV) in combination with methacrylic acid copolymer (Eudragit L100-55); and PVAP (Kollidon SR) as the release extending excipients. In vitro testing indicated that the produced tablets had similar dissolution behavior to the marketed capsule product according to the model independent FDA guideline (f2 factor).

Multiparticulate Drug Delivery CRC Press

First Published in 1987, this book offers a full, comprehensive guide to the process of administering the correct dosage in medicine. Carefully compiled and filled with a vast repertoire of notes, diagrams, and references this book serves as a useful reference for students of medicine, and other practitioners in their respective fields.

Analytical Method Development and Validation Pharmaceutical Dissolution Testing

In recent years, emerging trends in the design and development of drug products have indicated ever greater need for integrated characterization of

excipients and in-depth understanding of their roles in drug delivery applications. This book presents a concise summary of relevant scientific and mechanistic information that can aid the use of excipients in formulation design and drug delivery applications. Each chapter is contributed by chosen experts in their respective fields, which affords truly in-depth perspective into a spectrum of excipient-focused topics. This book captures current subjects of interest – with the most up to date research updates – in the field of pharmaceutical excipients. This includes areas of interest to the biopharmaceutical industry users, students, educators, excipient manufacturers, and regulatory bodies alike.

Applied Biopharmaceutics and Pharmacokinetics Elsevier

High pressure liquid chromatography–frequently called high performance liquid chromatography (HPLC or, LC) is the premier analytical technique in pharmaceutical analysis and is predominantly used in the pharmaceutical industry. Written by selected experts in their respective fields, the Handbook of Pharmaceutical Analysis by HPLC Volume 6, provides a complete yet concise reference guide for utilizing the versatility of HPLC in drug development and quality control. Highlighting novel approaches in HPLC and the latest developments in hyphenated techniques, the book captures the essence of major pharmaceutical applications (assays, stability testing, impurity testing, dissolution testing, cleaning validation, high-throughput screening). A complete reference guide to HPLC Describes best practices in HPLC and offers 'tricks of the trade' in HPLC operation and method development Reviews key HPLC pharmaceutical applications and highlights currents trends in HPLC ancillary techniques, sample preparations, and data handling

World Health Organization

Proteins are an integral part of molecular and cellular structure and function and are probably the most purified type of biological molecule. In order to elucidate the structure and function of any protein it is first necessary to purify it. Protein purification techniques have evolved over the past ten years with improvements in equipment control, automation, and separation materials, and the introduction of new techniques such as affinity membranes and expanded beds. These developments have reduced the workload involved in protein purification, but there is still a need to consider how unit operations linked together to form a purification strategy, which can be scaled up if necessary. The two Practical Approach books on protein purification have therefore been thoroughly updated and rewritten where necessary. The core of both

books is the provision of detailed practical guidelines aimed particularly at laboratory scale purification. Information on scale-up considerations is given where appropriate. The books are not comprehensive but do cover the major laboratory techniques and common sources of protein. Protein Purification Techniques focuses on unit operations and analytical techniques. It starts with an overview of purification strategy and then covers initial extraction and clarification techniques. The rest of the book concentrates on different purification methods with the emphasis being on chromatography. The final chapter considers general scale-up considerations. Protein Purification Applications describes purification strategies from common sources: mammalian cell culture, microbial cell culture, milk, animal tissue, and plant tissue. It also includes chapters on purification of inclusion bodies, fusion proteins, and purification for crystallography. A purification strategy that can produce a highly pure single protein from a crude mixture of proteins, carbohydrates, lipids, and cell debris to is a work of art to be admired. These books (available individually or as a set)are designed to give the laboratory worker the information needed to undertake the challenge of designing such a strategy.

The Impact of Food Bioactives on Health Academic Press

“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.

The Japanese Pharmacopoeia CRC Press

The field of encapsulation, especially microencapsulation, is a rapidly growing area of research and product development. The Handbook of Encapsulation and Controlled Release covers the entire field, presenting the fundamental processes involved and exploring how to use those processes for different applications in industry. Written at a level comp

Extended-Release Dosage Forms Springer

Pharmaceutical Dissolution TestingCRC Press

Poorly Soluble Drugs Springer Science & Business Media

First Published in 1987, this book offers a full, comprehensive guide to the process of administering the correct dosage in medicine. Carefully compiled and filled with a vast repertoire of notes, diagrams, and references this book serves as a useful reference for students of medicine, and other practitioners in their respective fields.

Basic Tests for Pharmaceutical Dosage Forms CRC Press

The highly experienced authors here present readers with step-wise, detail-conscious information to develop quality pharmaceuticals. The book is made up of carefully crafted sections introducing key concepts and advances in the areas of dissolution, BA/BE, BCS, IVIC, and product quality. It provides a specific focus on the integration of regulatory considerations and includes case histories highlighting the biopharmaceutics strategies adopted in development of successful drugs.