Comparative In Vitro Dissolution Study Of Aceclofenac

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DAYTON CASSANDRA

Clinical Study Design and Analysis
ScholarlyEditions
OmeprazoleA Comparative in Vitro Dissolution Study of Different Brands of Omeprazole Magnesium with Reference Product Losec 20Validation and Comparative In-vitro Dissolution Studies of Cefaclor in Their Powder for Oral Suspension Dosage FormsGeneric Drug Product DevelopmentSolid Oral Dosage Forms, Second EditionCRC Press
Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence BoD – Books on Demand
Drug Delivery Systems examines the current state of the field within pharmaceutical science and concisely explains the history of drug delivery systems, including key developments. The book translates the physicochemical properties of drugs into drug delivery systems administered via various routes, such as oral, parenteral, transdermal and inhalational. Regulatory and product development topics are also explored. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of drug delivery systems within the pharmaceutical sciences industry and research, as well as in chemical engineering. Each chapter delves into a particular aspect of this fundamental field to cover the principles, methodologies and technologies employed by pharmaceutical scientists. This book provides a comprehensive examination that is suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnologies, and related industries. Provides up-to-date information on how to translate the physicochemical properties of drugs into drug delivery systems Explores how drugs are administered via various

routes, such as oral, parenteral, transdermal and inhalational Contains extensive references and further reading for course and self-study
Code of Federal Regulations McGraw Hill Professional
The pace of new research and level of innovation repeatedly introduced into the field of drug delivery to the lung is surprising given its state of maturity since the introduction of the pressurized metered dose inhaler over a half a century ago. It is clear that our understanding of pulmonary drug delivery has now evolved to the point that inhalation aerosols can be controlled both spatially and temporally to optimize their biological effects. These abilities include controlling lung deposition, by adopting formulation strategies or device technologies, and controlling drug uptake and release through sophisticated particle technologies. The large number of contributions to the scientific literature and variety of excellent texts published in recent years is evidence for the continued interest in pulmonary drug delivery research. This reference text endeavors to bring together the fundamental theory and practice of controlled drug delivery to the airways that is unavailable elsewhere. Collating and synthesizing the material in this rapidly evolving field presented a challenge and ultimately a sense of achievement that is hopefully reflected in the content of the volume.
Applied Biopharmaceutics & Pharmacokinetics
Government Printing Office
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
Developing Solid Oral Dosage Forms World Health Organization
Dissolution in different steps of pharmaceutical drug development was considered in this work. Dissolution is used as informative tool throughout the entire development process: After identification of a possible drug candidate, intrinsic dissolution in different buffer media is tested for physicochemical characterization. In galenics dissolution is used to develop and optimize formulations by comparative release studies. During scale-up dissolution testing is used to observe influence of process or parameter changes. For regulatory affairs all of these dissolution studies are of interest and many have to be presented to the authorities. Most of the dissolution testing designs in pharmaceutical development are following pharmacopoeial monographs or general chapters and official guidelines. In addition these “official” dissolution testing setups, a progression of more innovative dissolution methods closer to physiological conditions are used. Devices simulating movement and flow of the GIT combined with media simulating the gastrointestinal fluids are often used. Disadvantages of these methods are that they are time-consuming and expensive, both of which limit throughput. The aims of this thesis were to (a) reduce time consumption regarding preparation of

biorelevant dissolution, (b) increase biorelevance of the media FaSSIF and FeSSIF by substituting the non-physiological buffer systems for bicarbonate and (c) to increase throughput by miniaturization of dissolution devices. To meet the first goal a novel preparation method for the biorelevant media FaSSIF and FeSSIF was established. The conventional method uses chlorinated organic solvent, is time-consuming in preparation (approx. 2 hours) and needs to be done daily. The investigated method uses freeze-drying for the preparation of instant biorelevant media. The instant media only consist of bile salt and lecithin in mixed micelles. In situ preparation is done by simply adding blank buffer to the rapidly dissolving lyophilisate. Freeze-dried product gave comparable results to freshly prepared media and improved reproducibility. Comparison to commercial available instant media indicated superiority of the freeze-drying method. Next, a buffer system based on the more physiological bicarbonate buffer was investigated. A method to maintain a stable buffer system throughout the dissolution testing. The buffer therefore was created by sparging carbon dioxide into alkali saline solution to forming carbonate and bicarbonate as buffer system. At equilibrium the media was transferred to the vessels and supply of carbon dioxide continued by sparging the gas above the solution. Therewith bubble formation could be minimized, although not excluded. Only a small range of buffer strength and pH combinations was possible. The lowest pH still providing effective buffer capacity (5 mmol/l/ΔpH) was 5.5. Physiologically relevant buffer capacities of 10 and 30 mmol/l/ΔpH were tested at pH 6.5. The buffer turned out to be very sensitive against pH modifying agents by loosening its buffer capacity and strength. Standard deviations were generally higher. No superiority over conventional buffer systems like phosphate or acetate buffer regarding IVIVC was given. Therefore it is concluded that bicarbonate buffer is not a suitable medium for in vitro dissolution testing. Subsequently methods for small scale dissolution testing were established. Improvement of throughput in dissolution testing was achieved. The investigated BI miniDiss method can be used to test release profiles of small particulate formulations or intermediates. High throughput excipient screening for early formulation is possible by using the well-plate method. In the first series of tests, downscaling by factor 10 was conducted by miniaturizing and automating standard dissolution apparatus. Small vessels of 20 ml volume and paddles of about 8 mm diameter were used. Automating was done by sampling through paddle hollow shafts and online UV/VIS measurement. Since no filtration was possible due to the small sample volume, the true % dissolved was calculated using mathematical scatter correction of spectra from turbid solutions. In this way, release profiles comparable to standard dissolution testing were obtained. Cleaning and restart is accelerated and therewith throughput increased. The 10fold reduced consumption of drug formulation reduces API consumption, so that

a larger variety of formulations can be prepared and tested with the same amount of API. The BI miniDiss is limited to multiparticulates like pellets, extrudates, minitablets, granules or intermediates. Downscaling of matrix or IR tablets will likely result in different results due to changed surface to volume ratio. The well-plate method offers a miniaturization of factor 100. Dissolution of multiparticulates showed significant differences compared to standard methods. However, ranking of formulations was possible in several cases. The well-plate method is not suitable for conducting comparative release profiles. However, it can be used for selection of excipients by supersaturation testing. It is an informative tool in early formulation screening helping to optimize formulation of poorly soluble compounds. As last part of the work, the BI miniDiss was used to screen various buffers to finding the best media for IVIVC, retrospectively. The BI miniDiss proved to be useful as a fast and cost and effective screening method. In summary, several improvements in dissolution for pharmaceutical development purposes have been developed regarding consumption of API, costs and efficiency. An easy and rapid preparation of biorelevant media was established making their use in pharmaceutical development and routine quality control more feasible. The miniaturized dissolution methods and the improved high-throughput fulfil demands from pharmaceutical industries to facilitate API-saving methods in development.

Code of Federal Regulations Title 21 Food and Drugs Cuvillier Verlag

The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume Two, Uncompressed 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 second volume of a six-volume set, compiles data from FDA and EMA new drug applications, patents and patent applications, and other sources of generic and proprietary formulations including author's own experience, to cover the broad spectrum of cGMP 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. Features: Largest source of authoritative and practical formulations, cGMP compliance guidance and self-audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing, bioequivalence testing, and full compliance with drug product safety elements Written by a well-recognized authority on drug and dosage form development including biological drugs and alternative medicines

Parts 300 to 499: Revised As of April 1,

2011 Springer Science & Business Media
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-à-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.

Shape Memory Alloys for Biomedical Applications CRC Press
The World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations advises the Director-General of WHO in the area of medicines quality assurance. It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality safety and efficacy in all WHO Member States. Its advice is developed through a broad consensus-building process and covers all areas of quality assurance of medicines from their development to their distribution to patients. In the area of quality control the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia and received the annual report of the European Directorate for the Quality of Medicines & HealthCare (EDQM) the custodian centre for International Chemical Reference Substances (ICRS). The Committee adopted a number of monographs general texts and ICRS. It noted the report on Phase 5 of the External Quality Assurance Assessment Scheme (EQAAS) and on new approaches to ensure sustainability of this scheme through user fees. The Committee further received a concept paper on the benefits of good pharmacopoeial

practices (GPhP) and was informed of progress achieved with developing a comprehensive document on GPhP through discussions at consecutive international meetings of world pharmacopoeias. In the various quality assurance-related areas the Expert Committee was presented with a number of new and revised guidelines related to good manufacturing practices (GMP) distribution and trade of pharmaceuticals and regulatory practice. It adopted eight guidelines and 16 technical supplements as listed below including a new guidance text on good review practice prepared under the leadership of the Asian-Pacific Economic Cooperation Regulatory Harmonization Steering Committee. The Committee took note of ongoing work to promote collaboration and information exchange through the good regulatory practice project and welcomed the development of a comprehensive set of guidelines for all national regulatory authorities through this project. The report includes the following annexes which are recommended as new WHO guidelines: . Annex 1. Procedure of the development of monographs for inclusion in The International Pharmacopoeia (revision); . Annex 2. Updating mechanism for the section on radiopharmaceuticals in The International Pharmacopoeia (revision); . Annex 3. Supplementary guidelines on good manufacturing practices: validation; Appendix 7: non-sterile process validation (revision); . Annex 4. General guidance for inspectors on hold-time studies (new); . Annex 6. Recommendations for quality requirements when plant-derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients (revision); . Annex 7. Guidelines on registration requirements to establish interchangeability (revision); . Annex 8. Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products (revision); . Annex 9: Good review practices guidelines for regulatory authorities (new). In addition 16 technical supplements to the WHO model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products were adopted for publication in a format which is appropriate to the large volume of this guidance (Annex 5). The newly adopted monographs were adopted for inclusion in The International Pharmacopoeia. Following the implementation of the revised general monograph on parenteral preparations the Committee adopted the proposed endotoxin limits for 11 parenteral dosage form monographs lacking such specification together with related updates to relevant monographs. The Committee adopted 12 ICRS newly characterized by the custodian centre EDQM. The Committee further adopted the workplan for new monographs to be included in The International Pharmacopoeia.

Controlled Pulmonary Drug Delivery McGraw-Hill Medical Publishing Annotation The primary emphasis of this book is on the application and understanding of concepts. Basic theoretical discussions of

the principles of biopharmaceutics and pharmacokinetics are provided, along with illustrative examples and practice problems and solutions to help the student gain skill in practical problem solving.
Dissolution and Drug Release CRC Press
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
In Vitro-In Vivo Correlations OmeprazoleA Comparative in Vitro Dissolution Study of Different Brands of Omeprazole Magnesium with Reference Product Losec 20Validation and Comparative In-vitro Dissolution Studies of Cefaclor in Their Powder for Oral Suspension Dosage FormsGeneric Drug Product DevelopmentSolid Oral Dosage Forms, Second Edition
Phenylacetates—Advances in Research and Application: 2012 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Phenylacetates. The editors have built Phenylacetates—Advances in Research and Application: 2012 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Phenylacetates in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Phenylacetates—Advances in Research and Application: 2012 Edition has been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.
Limited in Vitro/in Vivo Correlation Study of Rifampicin in a Fixed Dose Combination Tablet Office of the Federal Register
An expertly written source on the devices, systems, and technologies used in the dissolution testing of oral pharmaceutical dosage forms, this reference provides reader-friendly chapters on currently utilized equipment, equipment qualification, consideration of the gastrointestinal physiology in test design, the analysis and interpretation of data and procedure automation - laying the foundation for the creation of appropriate and useful dissolution tests according to the anticipated location and duration of drug release from the dosage form within the gastrointestinal tract.
Nonsteroidal Anti-Inflammatory Drugs Frontiers Media SA
An in-vitro dissolution study was conducted on two respirable oxidized depleted uranium samples. The dissolution rates generated from this study were then utilized in the International Commission on Radiological Protection Task Group lung clearance model and a lung clearance model

proposed by Cuddihy. Predictions from both models based on the dissolution rates of the amount of oxidized depleted uranium that would be cleared to blood from the pulmonary region following an inhalation exposure were compared. It was found that the predictions made by both models differed considerably. The difference between the predictions was attributed to the differences in the way each model perceives the clearance from the pulmonary region. 33 references, 11 figures, 9 tables.

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition CRC Press

Special edition of the Federal Register, containing a codification of documents of general applicability and future effect ... with ancillaries.

Drug Delivery Systems John Wiley & Sons

With contributions from leading researchers in the nanomedicine field from industry, academia, and government and private research institutions across the globe, the volume provides an up-to-date report on topical issues in nano-drug delivery and nanotechnological approaches to tissue engineering. The volume offers research on a variety of diverse nano-based drug delivery systems along with discussions of their efficacy, safety, toxicology, and applications for different purposes. Focusing on nanotechnology approaches to tissue engineering, this volume considers the use of hydrogel systems, nanoceria and micro- and nano-structured biomaterials for bone tissue engineering, mesenchymal stem cells, and more.

Guide to Strengthening Healthcare Systems Springer

Ophthalmic Preparations—Advances in Research and Application: 2012 Edition is a ScholarlyBrief™ that delivers timely, authoritative, comprehensive, and specialized information about Ophthalmic Preparations in a concise format. The editors have built Ophthalmic Preparations—Advances in Research and Application: 2012 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Ophthalmic Preparations in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Ophthalmic Preparations—Advances in Research and Application: 2012 Edition has been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.

Science, Applications, and Beyond Academic Press

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the United States Federal Government.

ScholarlyBrief John Wiley & Sons

Shape memory alloys are suitable for a wide range

of biomedical applications, such as dentistry, bone repair and cardiovascular stents. Shape memory alloys for biomedical applications provides a comprehensive review of the use of shape memory alloys in these and other areas of medicine. Part one discusses fundamental issues with chapters on such topics as mechanical properties, fabrication of materials, the shape memory effect, superelasticity, surface modification and biocompatibility. Part two covers applications of shape memory alloys in areas such as stents and orthodontic devices as well as other applications in the medical and dental fields. With its distinguished editors and international team of contributors, Shape memory alloys for biomedical applications is an essential reference for materials scientists and engineers working in the medical devices industry and in academia. A comprehensive review of shape memory metals and devices for medical applications Discusses materials, mechanical properties, surface modification and biocompatibility Chapters review medical and dental devices using shape memory metals, including stents and orthodontic devices

Title 21: Food and Drugs Elsevier

Dosage Form Design Parameters, Volume I, examines the history and current state of the field within the pharmaceutical sciences, presenting key developments. Content includes drug development issues, the scale up of formulations, regulatory issues, intellectual property, solid state properties and polymorphism. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters. Chapters delve into a particular aspect of this fundamental field, covering principles, methodologies and the technologies employed by pharmaceutical scientists. In addition, the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnology and related industries. Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects, prefomulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates, graduate students and those interested in drug dosage design

Generic Drug Product Development ScholarlyEditions

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the United States Federal Government.