Comparative In Vitro Dissolution Study Of Aceclofenac

In Vitro-In Vivo Correlations
Applied Biopharmaceutics & Pharmacokinetics, Sixth Edition
Media for in Vitro Dissolution Testing of Polysaccharide Based CDDS
Oral Drug Absorption
Applied Biopharmaceutics and Pharmacokinetics
Handbook of Bioequivalence Testing
Dissolution Technology
Oral Controlled Release Formulation Design and Drug Delivery
Amorphous Solid Dispersions
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Testing Statistical Hypotheses of Equivalence and Noninferiority
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A Novel Approach to in Vitro Dissolution Testing

SHANIA REILLY

In Vitro-In Vivo Correlations ScholarlyEditions
Guides readers on the proper use of in vitro drug release methodologies in order to evaluate the performance of special dosage forms In the last decade, the application of drug release testing has widened to a variety of novel/special dosage forms. In order to predict the in vivo behavior of such dosage forms, the design and development of the in vitro test methods need to take into account various aspects, including the dosage form design and the conditions at the site of application and the site of drug release. This unique book is the first to cover the field of in vitro release testing of special dosage forms in one volume. Featuring contributions from an international team of experts, it presents the state of the art of the use of in vitro drug release methodologies for assessing special dosage forms' performances and describes the different techniques required for each one. In Vitro Drug Release Testing of Special Dosage Forms covers the in vitro release testing of: lipid based oral formulations; chewable oral drug products; injectables; drug eluting stents; inhalation products; transdermal formulations; topical formulations; vaginal and rectal delivery systems and ophthalmics. The book concludes with a look at regulatory aspects. Covers both oral and non-oral dosage forms Describes current regulatory conditions for in vitro drug release testing Features contributions from well respected global experts in dissolution testing In Vitro Drug Release Testing of Special Dosage Forms will find a place on the bookshelves of anyone working with special dosage forms, dissolution testing, drug formulation and delivery, pharmaceutics, and regulatory affairs.
Applied Biopharmaceutics & Pharmacokinetics, Sixth Edition World Health Organization
This book represents the invited presentations and some of the posters presented at the conference entitled "In Vitro-In Vivo Relationship (IVIVR) Workshop" held in Sep tember, 1996. The workshop was organized by the IVIVR Cooperative Working Group which has drawn together scientists from a number of organizations and institutions, both academic and industrial. In addition to Elan Corporation, which is a drug delivery com pany specializing in the development of ER (Extended Release) dosage forms, the IVIVR Cooperative Working Group consists of collaborators from the University of Maryland at Baltimore, University College Dublin, Trinity College Dublin, and the University of Not tingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. lain Cumming, Elan Corporation Dr. John Devane, Elan Corporation Dr. Adrian Dunne, University College Dublin Dr. Stuart Madden, Elan Corporation Dr. Colin Melia, University of Nottingham Mr. Tom O'Hara, Elan Corporation Dr. Deborah Piscitelli, University of Maryland at Baltimore Dr. Araz Raoof, Elan Corporation Mr. Paul Stark, Elan Corporation Dr. David Young, University of Maryland at Baltimore The purpose of the workshop was to discuss new concepts and methods in the devel opment of in vitro-in vivo relationships for ER products. The original idea went back ap proximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development.
Media for in Vitro Dissolution Testing of Polysaccharide Based CDDS Royal Society of Chemistry
This volume offers a comprehensive guide on the theory and practice of amorphous solid dispersions (ASD) for handling challenges associated with poorly soluble drugs. In twenty-three inclusive chapters, the book examines thermodynamics and kinetics of the amorphous state and amorphous solid dispersions, ASD technologies, excipients for stabilizing amorphous solid dispersions such as polymers, and ASD manufacturing technologies, including spray drying, hot melt extrusion, fluid bed layering and solvent-controlled micro-precipitation technology (MBP). Each technology is illustrated by specific case studies. In addition, dedicated sections cover analytical tools and technologies for characterization of amorphous solid dispersions, the prediction of long-term stability, and the development of suitable dissolution methods and regulatory aspects. The book also highlights future technologies on the horizon, such as supercritical fluid processing, mesoporous silica, KinetiSol®, and the use of non-salt-forming organic acids and amino acids for the stabilization of amorphous systems. Amorphous Solid Dispersions: Theory and Practice is a valuable reference to pharmaceutical scientists interested in developing bioavailable and therapeutically effective formulations of poorly soluble molecules in order to advance these technologies and develop better medicines for the future.
Oral Drug Absorption Cuvillier Verlag
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
Applied Biopharmaceutics and Pharmacokinetics Springer Science & Business Media
This book describes the theories, applications, and challenges for different oral controlled release formulations. This book differs from most in its focus on oral controlled release formulation design and process development. It also covers the related areas like preformulation, biopharmaceutics, in vitro-in vivo correlations (IVIVC), quality by design (QbD), and regulatory issues.
Handbook of Bioequivalence Testing Mack Publishing Company
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

Dissolution Technology CRC Press

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.

Oral Controlled Release Formulation Design and Drug Delivery Springer

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools. The Expert Committee develops standards through worldwide consultation and an international consensus-building process. The following new guidance texts were adopted and recommended for use: WHO good manufacturing practices for excipients used in pharmaceutical products (revision); IAEA/WHO good manufacturing practices for in-house cold kits for radiopharmaceutical preparations (new); WHO good practices for pharmaceutical quality control laboratories (revision); WHO/UNFPA female condom generic specification (new); WHO Biowaiver List: proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines

immediate-release (updated), solid oral dosage forms; WHO guideline on Biopharmaceutics Classification System-based biowaivers (revision); and Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (republished). All of the above are included in this report and recommended for implementation.

Amorphous Solid Dispersions Springer

Till date, pursuit for cost effective and animal sparing colon specific bio-relevant dissolution media has been a foremost challenge facing pharmaceutical scientists over many decades.It is problematic to mimic the dynamic and ecologically diverse features of the colon in dissolution vessel.With the knowledge of enormous colonic microflora, the predominant species Bacteroides, Bifidobacterium, Eubacterium, Streptococcus and Lactobacillus species were cultured in 12% w/v skimmed milk powder and 5%w/v grade "A" honey. Probiotic culture was added to the dissolution media in order to test the drug release of polysaccharide based formulations. USP dissolution apparatus I/II with gradient pH dissolution method were used to evaluate the drug release from formulations meant for colonic drug delivery. Drug release from 5-fluorouracil granules and metronidazole tablets were assed under gastric, small intestine conditions and also within a simulated colonic environment involving existing rat caecal, human fecal media and compared with novel probiotic media. The present method can be successfully applied for the drug release testing of any oral formulations meant for colonic delivery.

Poorly Soluble Drugs John Wiley & Sons

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/.

Testing Statistical Hypotheses of Equivalence and Noninferiority CRC Press

Although the Bioequivalence (BE) requirements in many global jurisdictions have much in common, differences in certain approaches and requirements such as definitions and terms, choice of comparator (reference) product, acceptance criteria, fasted and fed studies, single and multi-dose studies, biowaivers and products not intended for absorption into the systemic circulation (locally acting medicines and dosage forms), amongst others, provide food for thought that standardisation should be a high priority objective in order to result in a harmonized international process for the market approval of products using BE. An important objective of Bioequivalence Requirements in Various Global Jurisdictions is to attempt to gather the various BE requirements used in different global jurisdictions to provide a single source of relevant information. This information from, Brazil, Canada, China, European Union, India, Japan, MENA, Russia South Africa, the USA and WHO will be of value to drug manufacturers, regulatory agencies, pharmaceutical scientists and related health organizations and governments around the world in the quest to harmonize regulatory requirements for the market approval of generic products.

In Vitro Drug Release Testing of Special Dosage Forms CRC Press

The oral bioavailability of a drug substance is strongly related to its aqueous solubility. Only complete dissolution during the GI-passage can maintain an optimal bioavailability. Poor aqueous drug solubility results, according to the Nernst-Brunner equation into a slow dissolution rate, sometimes too slow for complete dissolution in the GI tract. The dissolution rate increases with decreasing particle size and therefore increasing surface area of the drug particles. In consequence,, micronization of the drug is applied to increase oral bioavailability, but often meets with modest success. Recently developed techniques were applied to decrease the particle size into the nanometer range. For some substances, pharmacokinetic parameters could be influenced decisively, e.g. the obviation of a food effect for the drugs aprepitant and fenofibrate. The assessment of a dosage form is investigated by dissolution testing. For a reasonable assessment of such tests, a separation of solid and liquids has to be ensured within an appropriate time frame. For particle sizes of about 150 nm it appears questionable whether such separation can be succeeded by classical techniques, e.g. the use of syringe filters with a pore size of 0.45 µm. The aims of this thesis were to investigate the suitability of various analytical techniques in analysis of dissolution tests containing nanosized drug substance. Furthermore, a suitable analytical tool is applied to establish an in vitro – in vivo correlation of the nanosized drug fenofibrate. At first, several techniques were investigated in theory to assess their ability to ensure a rapid and complete separation of solids and liquids. The classical dialysis, turbidity measurement and UV-measurement via fiber optics were excluded from further investigation due to various reasons, e.g. the speed of separation for dyialisis. The asymmetrical flow field-flow fractionation appeared to be a promising tool, but lack of equipment precluded further investigation. The ultrasonic resonance technology (ResoScan), the microdialysis and the use of centrifugal filter devices have shown to be inappropriate for the analytics of nanosized drugs in dissolution test. The use of syringe filters with various pore sizes and the ionselective electrode (ISE) was promising, so these techniques were examined more intensively. The syringe filters with various filter pore sizes were investigated for their ability to hold back colloidal drug. Fenofibrate was chosen as model drug, since this is commercially available both as micronized and nanosized formulation (Lipidil TerR and Lipidil 145 ONER), enabling direct comparison. The experiments with micronized fenofibrate which contains little or no colloidal fenofibrate yielded similar dissolution profiles, irrespective of filter pore size; f2 was always greater than 65, indicating less than 5% difference between the dissolution profiles in any medium. Using a pore size of 0.1 µm or less, the maximum concentration of drug achieved in solution from the nanosized formulation was commensurate with the saturation solubility of fenofibrate in all tested media. Filtration with a pore size of 0.2 µm or 0.45 µm generated concentrations exceeding the saturation solubility. These results, in combination with higher standard deviations of the analytical results, indicate that the apparent “supersaturation” is caused by colloidal fenofibrate, which is too fine to be held back by these filters. The f2-value of less than 50 when comparing the profiles

obtained from 0.1 µm and 0.2 µm filter pore size indicates that the choice of filter pore size is crucial to the interpretation of the dissolution profiles. To separate nanosized drug from molecularly dissolved fenofibrate in Lipidil 145 ONER, a filter pore size of 0.1 µm or less appears to be appropriate. It was observed that the experimental increase of dissolution rate is not congruent with common hypothesis regarding the boundary layer h for decreasing particle sizes and subsequent application of the Nernst-Brunner equation. The initial dissolution rates of both formulations were investigated by using a filter pore size of 0.1 µm. The results were utilized in an in silico model (STELLAc) to correlate the in vitro results with in vivo data (Model A). In the preprandial state a good in correlation was established for the micronized fenofibrate, while for the nanosized fenofibrate the plasma levels were overpredicted. The model was expanded to investigate the impact of an absorption step at the intestinal membrane on the in vitro – in vivo correlation. It was found that even a minor deceleration of absorption results in varied plasma profiles caused by a lagged appearance of drug in the blood. For both formulations the rate determining step was identified: When changing from the micronized to the nanosized formulation, the rate-determining step for absorption may change from completely dissolution-controlled to at least partly permeationcontrolled in the fasted state. In the fed state, gastric emptying appears to be rate-determining for absorption of fenofibrate from both the micronized and the nanosized formulation. Another technique appears to be suitable for analysis of nanosized drugs in dissolution testing. The Ion-selective electrode (ISE) is a recently developed analytical system measuring the changes of the electrochemical potential in solutions. A transformation via the Nikolski – Eisenmann equation results into the concentration of the respective drug in solution. Since only dissolved drug is detected, obviating the need for separation of dissolved from undissolved drug, this system appears to be very promising in the analytics of nanocrystalline drugs. Diphenhydramine_HCl was chosen as model substance for the ISE studies. It was the goal of investigation to test compatibility of the ISE with complex media, e.g. all biorelevant dissolution media. This is done in advance of application of the ISE in these media for nanocrystalline drug substance. The results were compared to manual sampling, filtration and subsequent HPLC-UV analysis. The results demonstrate that the ion-selective electrode is suitable for measurements of diphenhydramine HCl in fasted state biorelevant media (FaSSGF, FaSSIF, FaSSIF-V2) as both a stand-alone system (Method A) and in conjunction with a single point conventional assay (Method B). The results acquired are similar to those obtained by manual sampling and subsequent HPLC-UV analysis. The ISE also delivers satisfactory results in a milk-based medium (FeSSGF), in which it has distinct advantages over manual sampling with HPLC-UV analysis by obviating the need for sample preparation. The application of the ISE in FeSSIF type media will need further study. Finally, as an on-line technology, ISE offers more efficient generation of dissolution profiles than conventional sample-based methods.

Limited in Vitro/in Vivo Correlation Study of Rifampicin in a Fixed Dose Combination Tablet CRC Press

Explore the cutting-edge of dissolution testing in an authoritative, one-stop resource In Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence: Science, Applications, and Beyond, distinguished pharmaceutical advisor and consultant Dr. Umesh Banakar delivers a comprehensive and up-to-date reference covering the established and emerging roles of dissolution testing in pharmaceutical drug development. After discussing the fundamentals of the subject, the included resources go on to explore common testing practices and methods, along with their associated challenges and issues, in the drug development life cycle. Over 19 chapters and 1100 references allow practicing scientists to fully understand the role of dissolution, apart from mere quality control. Readers will discover a wide range of topics, including automation, generic and biosimilar drug development, patents, and clinical safety. This volume offers a one-stop resource for information otherwise scattered amongst several different regulatory regimes. It also includes: A thorough introduction to the fundamentals and essential applications of pharmaceutical dissolution testing Comprehensive explorations of the foundations and drug development applications of bioavailability and bioequivalence Practical discussions about solubility, dissolution, permeability, and classification systems in drug development In-depth examinations of the mechanics of dissolution, including mathematical models and simulations An elaborate assessment of biophysiologically relevant dissolution testing and IVIVCs, and their unique applications A complete understanding of the methods, requirements, and global regulatory expectations pertaining to dissolution testing of generic drug products Ideal for drug product development and formulation scientists, quality control and assurance professionals, and regulators, Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence is also the perfect resource for intellectual property assessors.

Validation and Comparative In-vitro Dissolution Studies of Cefaclor in Their Powder for Oral Suspension Dosage Forms Elsevier

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.

Dissolution, Bioavailability & Bioequivalence John Wiley & Sons

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

Handbook of Bioequivalence Testing Springer
This comprehensive reference provides an in-depth discussion on state-of-the-art regulatory science in bioequivalence. In sixteen chapters, the volume explores a broad range of topics pertaining to bioequivalence, including its origin and principles, statistical considerations, food effect studies, conditions for waivers of bioequivalence studies, Biopharmaceutics Classification Systems, Biopharmaceutics Drug Disposition Classification System, bioequivalence modeling/simulation and best practices in bioanalysis. It also discusses bioequivalence studies with pharmacodynamic and clinical endpoints as well as bioequivalence approaches for highly variable drugs, narrow therapeutic index drugs, liposomes, locally acting gastrointestinal drug products, topical products and nasal and inhalation products. FDA Bioequivalence Standards is written by FDA regulatory scientists who develop regulatory policies and conduct regulatory assessment of bioequivalence. As such, both practical case studies and fundamental science are highlighted in these chapters. The book is a valuable resource for scientists who work in the pharmaceutical industry, regulatory agencies and academia as well as undergraduate and graduate students looking to expand their knowledge about bioequivalence standards.
Characterization of Pharmaceutical Nano- and Microsystems Elsevier
As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct efficient and successful bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence, and advances in the analytical technology used to detect drug and metabolite levels have made
Biopharmaceutics and Clinical Pharmacokinetics McGraw-Hill/Appleton & Lange
This thesis describes a novel "Tablet-in-a-Bottle" oral suspension formulation. Ingredients with unstable physical or chemical characteristics can be placed in a core tablet, and then dry compression coated with an outer layer which provides separation from other components. The new suspension formulation comprises fast disintegrating clavulanic acid (KCA) tablets with a powder mixture containing amoxicillin. Hardness, friability, flow properties and weight uniformity of tablets for three different formulations were investigated and were all improved in a third formulation. Stability tests under different humidities were conducted. Amoxicillin and clavulanic acid in the new formulations showed the same stabilities when compared with the marketed product Augmentin®. Preliminary pharmacokinetics and bioavailability of one new formulation were evaluated by comparing in vitro release rates and in vivo urinary excretion rates. In vitro dissolution studies were carried out according to the USP XXIII paddle method. The new formulation showed faster release rates during the first hour when stirring speed was 25 rpm. However, when 75 rpm stirring speed was applied, the dissolution profiles for the new formulation and the reference marketed product were identical. A randomized two-way crossover bioequivalence study was designed to evaluate the bioavailabilities. Cmax, Tmax and AUC[subscript o--->t] of amoxicillin were within ±20% of the reference pharmacokinetic values. However, Cmax and Tmax of clavulanate were not within ±20%. Bioeqivalence between this new suspension formulation and the marketed product (Augmentin®) were evaluated using a two one-sided t-test. There is not sufficient statistical support with this test to conclude that the two products are bioequivalent. However, this is most likely due to small sample size and high intersubject variation and statistical support for bioequivalence is expected in a larger study group.
Clinically Relevant in Vitro Dissolution/release Testing for Parenteral Formulations Cuvillier Verlag
1. Evolution of dissolution testing 5; 2. Theory of dissolution 11; 3. Theoretical concepts for the release of a drug from dosage forms 37; 4. Effect of the physicochemical properties of the drug on dissolution rate 53; 5. Factors affecting the rate of dissolution of solid dosage forms 73; 6. Effects of storage and packaging on the dissolution of drug formulations 107; 7. Factors relating to the dissolution apparatus 115; 8. Effect of the test parameters on dissolution rate 145; 9. Dissolution of suspensions 173; 10. Dissolution of topical dosage forms (creams, gels, and ointments) 189; 11. Dissolutions of suppositories 205; 12. Dissolution characteristics of controlled-release systems 215; 13. Methods for enhancement of the drug-dissolution characteristics 265; 14. Developing a new dissolution method 285; 15. Bioavailability, definitions and historical perspective 297; 17. In vitro modeling for drug absorption 315; 18. Pharmacokinetic considerations in bioavailability studies 335; 19. Bioavailability and variations in drug blood levels 367; 20. Bioavailability and the biologic response 385; 21. Measurements of bioavailability 399; 22. General issues to be considered in conducting bioavailability studies 415; 23. Bioavailability of controlled-release dosage forms 425; 24. In vivo release and bioavailability of topical preparations 437; 25. Methods for enhancement of bioavailability 455; 26. Bioequivalence: general definitions 477; 27. Bioequivalence: case histories 481; 28. Correlation of in vitro rate of dissolution with in vivo bioavailability 491; 29. Determination of bioequivalence and its regulatory aspects 517; 30. The official bioequivalence protocols and therapeutic equivalence 533.
Predictive in Vitro Dissolution Tools John Wiley & Sons
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.

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