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In Vitro Bioequivalence Studies of Topical Drug Products: Challenges and Promises of IVRT and IVPT EASY steps for In-vitro Skin Permeation Study using Franz Diffusion Cell ~~Webinar: Introduction to In Vitro Release Testing (IVRT)~~ ~~DDDPlus™ v6 Webinar: In Vitro Dissolution... Reimagined~~

BioEngineered Human Tissues for Skin, Cancer and Drug Metabolism ¦ REPROCELL webinar series*Dissolution-Part1 Utilization of PBBM/PBPK Models for Building a Safe Space and Regulatory Applications in Support of* ~~Interview Questions for Quality control Dissolution,Dissolution acceptance criteria as per USP~~ ~~Simple and effective design of SEDDS formulations~~ **SOTAX MPS Mobile Dissolution Media Preparation Station 8200-2 Demonstration** Top 20 interview questions answer on dissolution ¦ Acceptance criteria of dissolution as per USP

In Vitro Drug Release Testing for LA Drug Products QC (16of35) Complex Generics - Sep. 25-26, 2019~~Tutorial - DIY Aquarium Plant Tissue Cultures (Part 1)~~ *The missing link between conventional in vitro testing and preclinical models in drug development* Indivision - In Vitro Bioavailability \u0026 Bioequivalence ~~Calculation of dissolution / percentage release from Tablets~~ *All-In-One Grow Bags ¦ Grow Mushrooms FAST and EASY! ¦ No Experience Needed ¦ Virtually Error Proof Plant Tissue Culture in 3 minutes!*

CE 7smart – Large cell for tablets and capsules (22.6mm) Dissolution Testing USP4 ~~Lab Protocol - Dialysis Tubing Experiments (Unit 7 Diffusion)~~ *Bioequivalence ¦ Bioavailability and Bioequivalence ¦ Biopharmaceutics and Pharmacokinetics ¦ A Biologically-Relevant, Chronic, In-vitro Solid Tumor Model: Implications for Metastasis Research* ~~Dissolution Case Studies- FDA Generic Drug Forum 2019~~ Murashige and Skoog medium preparation - Virtual Lab ONLINE Micro Lab 9: Microbial Genetics, DNA Extraction, in vivo DNA Replication

Understanding dermal drug disposition using TCAT™ - a novel PBPK model **Development of a Unified Dissolution and Precipitation Model** *Why does osmolality matter? Observations, drift, explanations, and counter measures* FIP Guidelines for Dissolution Testing of Solid Oral Products **Dissolution Media For In Vitro**

The in vitro dissolution profile of crushed tegaserod ... The dissolution profiles of crushed tegaserod tablets in these media were not comparable to those of intact tablets, indicating incomplete ...

Stability and Compatibility of Tegaserod From Crushed Tablets Mixed in Beverages and Foods
Table 1. Summary of in vitro dissolution data: amount of omeprazole released after 30 minutes in phosphate buffer solution, pH 6.8, after pre-exposure to acidic media of different pH over 2 hours ...

Multiple-Dose Studies Can Be a More Sensitive Assessment for Bioequivalence Than Single-Dose Studies
Source: Shutterstock The biotechnology firm announced that in-vitro data shows Q-Sphera ... look to further optimize the drug loading and dissolution profile for encapsulated monoclonal antibodies.

MTP Stock: The Big Midatech Pharma News That Has Shares Rocketing Today
Zinc oxide slipped through the in vitro BBB with the greatest ease. The researchers found spherical and disc-like silver nanomaterials underwent different dissolution regimes - gradually transforming ...

Nanomaterials shape and form influences their ability to cross the blood brain barrier
Figure 3A. ACQUITY PREMIER LC System The messenger RNA that is manufactured for a vaccine or therapy is produced through a cell-free process known as in vitro transcription (IVT) synthesis ...

Analyzing Encapsulated mRNA with LC, MS, and Calorimetry
In vitro PK studies of drug properties, such as rates of dissolution, have also been required for drug-eluting stent approval. These critical laboratory and animal studies can also serve as the basis ...

Regulatory Strategy: Preclinical Testing of Combination Products
These amorphous mineral phases contain abundant water, which induces dissolution and recrystallization of the intermediate amorphous phases under P. By controlling the water content (n) within ...

Pressure-driven fusion of amorphous particles into integrated monoliths
that uses gene-editing tools to manipulate stem cells in vitro. This can generate disease models for scientific insight into human development and devising therapeutic strategies. She pioneered human ...

Indian stem cell, developmental biologist part of WHO Advisory Committee
Midatech Pharma PLC (AIM: MTPH.L; Nasdaq: MTP), an R&D biotechnology company focused on improving the bio-delivery and biodistribution of medicines, announces breakthrough in vitro data which ...

Midatech Pharma Regulatory News
ABINGDON, OXFORDSHIRE/ ACCESSWIRE / June 17, 2021 / Midatech Pharma PLC (AIM:MTPH.L)(NASDAQ:MTP), an R&D biotechnology company focused on improving the bio-delivery and biodistribution of medicines, ...

Midatech Pharma PLC Announces Breakthrough Data Using Q-Sphera Technology
ensuring and declaring that EsoGuard meets the essential requirements of Europe ' s In-Vitro Diagnostic Medical Devices Directive 98/79/EC (" IVDD "). EsoGuard may now be marketed in CE Mark ...

PAVmed Subsidiary Lucid Diagnostics Completes European CE Mark Certification of its EsoGuard Esophageal DNA Test
He said that cultural and historical change had led to a " dissolution " of morality in Catholicism. Pope Francis said the Catholic Church should not allow its bans on gay marriage, abortion and ...

Tag: homosexuality
Prosecutor Pérez is seeking 30 years and 10 months in prison for Fujimori and the dissolution of her political party, Onwards Peru, on charges that also include organized criminality and obstruction ...

Peruvian judge in Keiko Fujimori corruption case rejects call to return her to prison
Zinc oxide slipped through the in vitro BBB with the greatest ease. The researchers found spherical and disc-like silver nanomaterials underwent different dissolution regimes—gradually ...

Nanomaterials shape and form influences their ability to cross the blood brain barrier
Zinc oxide slipped through the in vitro BBB with the greatest ease. The researchers found spherical and disc-like silver nanomaterials that underwent different dissolution regimes - gradually ...

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.

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 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

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.

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.

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

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.

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,

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