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In Vitro Drug Release Testing of Special Dosage Forms John Wiley & Sons

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.

The Japanese Pharmacopoeia CRC Press

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, pharmaceuticals, and regulatory affairs.

Media for in Vitro Dissolution Testing of Polysaccharide Based CDDS CRC Press

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

Developing Solid Oral Dosage Forms Elsevier

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.

Oral Drug Delivery for Modified Release Formulations CRC Press

Dissolution testing is routinely conducted in the pharmaceutical industry to provide in vitro drug release information for quality control purposes. The most common dissolution testing system for solid dosage forms is the United States Pharmacopeia (USP) Dissolution Testing Apparatus 2. In this work, a modified Apparatus 2, termed "OPI" System for "off-center paddle impeller," in which the impeller is placed 8 mm off center in the

vessel is tested to determine its sensitivity to differentiate between the dissolution profiles of differently formulated and manufactured tablets. Dissolution tests are conducted with both the OPI System and the Standard System using three different brands of aspirin at nine different tablet positions. The OPI system produces dissolution profiles that are highly dependent on the different brands of aspirin used, similarly to those generated in the Standard System. However, the dissolution profiles obtained with the OPI apparatus are found to be largely independent of the tablet location at the vessel bottom, whereas those obtained in the Standard System generate statistically different profiles depending on tablet location. It can be concluded that the newly proposed OPI system can effectively eliminate artifacts generated by random settling of the tablet at the vessel bottom, thus making the test more robust, while at the same time being just as sensitive as the Standard System to actual differences in differently manufactured tablets having intrinsically different dissolution profiles.

Handbook of Stability Testing in Pharmaceutical Development Elsevier

Updated and expanded second edition covers all aspects of capsule technology, including history, standards, methods and equipment used in manufacture, filling, printing, weighing, cleaning and inspecting of both hard and soft capsules.

Hydrodynamic Characterization of the USP Apparatus 2 Dissolution Test CRC Press

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, pharmaceuticals, and regulatory affairs.

Pharmaceutical Dissolution Testing CRC Press

Dissolution testing is routinely carried out in the pharmaceutical industry to determine the rate of dissolution of solid dosage forms. This test is one of the several tests that pharmaceutical companies typically conduct on oral dosage formulations (e.g., tablets) to determine compliance. The USP Dissolution Testing Apparatus 2 is the most common of the apparatuses listed in the USP. However, it has been shown previously that the dissolution profile of a tablet undergoing dissolution in the USP Dissolution Apparatus 2 can be affected by the tablet location in the apparatus. In this work, the dissolution rates of both non-disintegrating tablets (salicylic acid) and disintegrating tablets (Prednisone) were experimentally determined for many different tablet locations, both centered on the vessel bottom and off-center. The location of the tablet was experimentally varied in very small increments in order to determine the exact location where a transition in the dissolution profile occurred. It was found that in a small region (2-4 mm in radius) centered around the vessel centerline just below the impeller the dissolution profiles were similar to those observed with a centered tablet. However, outside this region the dissolution profiles were found to be significantly different, as indicated by the values of the Similarity Factor f_1 and the Difference Factor f_2 . These findings are consistent with previous hydrodynamic investigations that showed the existence of a poorly mixed zone below the USP Apparatus 2 impeller. The results of this work can guide the practitioner on

when to accept dissolution testing results based on tablet location.

Effect of Tablet Compression on the Dissolution of Aspirin Tablets Using a Novel Off-center Paddle Impeller (opi) Dissolution Testing System CRC Press

Regulatory Affairs in the Pharmaceutical Industry is a comprehensive reference that compiles all the information available pertaining to regulatory procedures currently followed by the pharmaceutical industry. Designed to impart advanced knowledge and skills required to learn the various concepts of regulatory affairs, the content covers new drugs, generic drugs and their development, regulatory filings in different countries, different phases of clinical trials, and the submission of regulatory documents like IND (Investigational New Drug), NDA (New Drug Application) and ANDA (Abbreviated New Drug Application). Chapters cover documentation in the pharmaceutical industry, generic drug development, code of Federal Regulation (CFR), the ANDA regulatory approval process, the process and documentation for US registration of foreign drugs, the regulation of combination products and medical devices, the CTD and ECTD formats, and much more. Updated reference on drug approval processes in key global markets. Provides comprehensive coverage of concepts and regulatory affairs. Presents a concise compilation of the regulatory requirements of different countries. Introduces the fundamentals of manufacturing controls and their regulatory importance.

Quaestio juris controversi an impubes negotiorum gestor esse possit LAP Lambert Academic Publishing. 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 biophysically 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.

Pharmaceutical Dissolution Testing Hydrodynamic Characterization of the USP Apparatus 2 Dissolution Test Pharmaceutical Dissolution Testing

Issues in National, Regional, and Environmental Health and Medicine: 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about National, Regional, and Environmental Health and Medicine. The editors have built *Issues in National, Regional, and Environmental Health and Medicine: 2011 Edition* on the vast information databases of ScholarlyNews.™ You can expect the information about National, Regional, and Environmental Health

and Medicine 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 *Issues in National, Regional, and Environmental Health and Medicine: 2011 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/>.

Statistical Design and Analysis of Stability Studies ScholarlyEditions

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 and

Dissolution of Different Commercial Aspirin Tablets Using a Novel Off-center Paddle Impeller (OPI) Dissolution Testing System John Wiley & Sons

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 Dosage Forms, Second Edition presents in-depth discussions from more than 30 noted specialists describing the development of generic drug products—from the raw materials to the development of a therapeutic-equivalent drug product to regulatory approval. Major topics discussed include: Active pharmaceutical ingredients Experimental formulation development, including a new section on Quality by Design (QbD) Scale-up Commercial product formulation Quality control and bioequivalence Drug product performance ANDA regulatory process Post-approval changes Post-marketing surveillance Legislative and patent challenges This second edition also contains a new chapter on the relationship between the FDA and the United States Pharmacopeia and in Chapter 4, using specific examples, the application of Quality by Design (QbD) during formulation development is examined. The book is a thorough guide to the development of solid oral generic dosage formulations. This textbook is ideal for the pharmaceutical industry, graduate programs in pharmaceutical sciences, and health professionals working in the area of generic drug development.

Quality Control of Antacid Preparations CRC Press

The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume One, Compressed 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 first volume of a six-volume set, compiles data from FDA new drug applications, patent applications, and other sources of generic and proprietary formulations to cover the broad spectrum of GMP 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.

Effects of Operating and Geometric Variables on Hydrodynamics and Tablet Dissolution in Standard and Modified Dissolution Testing Apparatuses 2 CRC Press

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Issues in National, Regional, and Environmental Health and Medicine: 2011 Edition CRC Press

The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. Pharmaceutical Dosage Forms:

Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form, an

Dissolution of Disintegrating Solid Dosage Forms in a Modified Dissolution Testing Apparatus 2 CRC Press 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

Pharmaceutical Capsules Academic Press

Dissolution tests are routinely carried out in the pharmaceutical industry to determine the dissolution rate of solid dosage forms. Dissolution testing serves as a surrogate for drug bioavailability through in vitro – in vivo correlation (IVIVR), and it additionally helps in guiding the development of new formulations and in assessing lot-to-lot consistency, thus ensuring product quality. The United States Pharmacopoeia (USP) Dissolution Testing Apparatus 2 is the device most commonly used for this purpose. Despite its widespread use, dissolution testing using this apparatus remains susceptible to significant error and test failures. There is documented evidence that this apparatus is sensitive to several geometric variables that can affect the release profile of oral dosage forms, including tablet location during the dissolution process. In this work, the dissolution profiles of disintegrating calibrator tablets containing Prednisone were experimentally determined using two systems, i.e., a Standard USP Dissolution Testing Apparatus 2 (Standard System) and a Modified Standard USP Dissolution Testing Apparatus 2 (Modified System) in which the impeller was located 8 mm off the vessel centerline. The dissolving tablets were located at different off-center positions on the vessel bottom to test the effect of tablet location in these two systems. Tablet dissolution in the Standard System was found to be strongly dependent on tablet location, as previously reported by this and other research groups. This apparatus appears to generate variable results that may not be associated with the tablets undergoing testing but with the hydrodynamic characteristics of the apparatus itself and the location of the tablet on the vessel bottom. However, when the same experiments were conducted in the Modified System, the dissolution profiles for the same tablets were found to be nearly completely insensitive to tablet location. The dissolution process in the Modified System was faster than that in the Standard System because of the improved mixing performance of the Modified System resulting from the non-symmetrical placement of the impeller. However, when the Modified System was operated at 35 rpm, the dissolution profiles for centrally located tablets were found to be very similar to those for the Standard System operating at 50 rpm. Unlike the Standard System however, the dissolution profiles obtained at 35 rpm in the Modified System were found to be insensitive to tablet location. It can be concluded that the newly proposed Modified System for dissolution testing is a simple and yet robust and valid alternative to the current dissolution testing practice using the Standard USP Dissolution Testing Apparatus.

Voigt's Pharmaceutical Technology Wiley-Blackwell

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

Generic Drug Product Development John Wiley & Sons

There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.