

Tablet Dissolution Test Apparatus

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Dissolution Testing of Prednisone and Salicylic Acid Calibrator Tablets at Different Tablet Locations Anandhavalavan Arulmozhi 2011

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.

Modern Pharmaceutics, Two Volume Set Alexander T. Florence 2016-04-19
This new edition brings you up-to-date on the role of pharmaceuticals and its future paradigms in the design of medicines. Contributions

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from over 30 international thought leaders cover the core disciplines of pharmaceuticals and the impact of biotechnology, gene therapy, and cell therapy on current findings. Modern Pharmaceuticals helps you stay current

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

Shrutiben Rameshbhai Parekh 2011 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.

Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems Loyd V. Allen 2021-08-16 The most trusted source on the subject available today, Ansel's *Pharmaceutical Dosage Forms and Drug Delivery Systems*, 12th Edition equips pharmacy students with everything they need to master the intricacies of pharmaceutical dosage form design and production and achieve successful outcomes in their courses and beyond. Reflecting the latest CAPE, APhA, and NAPLEX® competencies, this trusted, extensively updated resource clarifies the interrelationships

between pharmaceutical and biopharmaceutical principles, product design, formulation, manufacture, compounding, and the clinical application of the various dosage forms in patient care, as well as regulations and standards governing the manufacturing and compounding of pharmaceuticals. New and revised content throughout keeps students up to date with current approaches to key coverage areas, and additional case studies demonstrate concepts in action to reinforce understanding and prepare students for the clinical challenges ahead.

Bentley's Textbook of Pharmaceutics - E-Book

Sanjay Kumar Jain 2012-05-14 This adaptation of Bentley's *Textbook of Pharmaceutics* follows the same goals as those

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of the previous edition, albeit in a new look. The content of the old edition has been updated and expanded and several new chapters, viz. Complexations, Stability Testing as per ICH Guidelines, Parenteral Formulations, New Drug Delivery Systems and Pilot Plant Manufacturing, have been included, with an intention to make the book more informative for the modern pharmacists. The book has six sections: Section I deals with the physicochemical principles. Two new chapters: Complexations and ICH Guidelines for Stability Testing, have been added to make it more informative. Section II conveys the information regarding pharmaceutical unit operations and processes. Section III describes the area of pharmaceutical practice.

Extensive recent updates have been included in many chapters of this section. Two new chapters: Parenteral Formulations and New Drug Delivery Systems, have been added. Section IV contains radioactivity principles and applications. Section V deals with microbiology and animal products. Section VI contains the formulation and packaging aspects of pharmaceuticals. Pilot Plant Manufacturing concepts are added as a new chapter, which may be beneficial to readers to understand the art of designing of a plant from the pilot plant model.

Molecular Pharmacology
Angel Catala 2020-12-16
This book concentrates on recent developments related to the application of original structural biology, biochemistry, biophysics, physiology,

genetics, and molecular biology as well as basic pharmacological problems that offer mechanistic insights that are generally significant for the field of pharmacology. Written by experts, chapters cover such topics as drug transport mechanisms and drug-receptor complexes. This volume offers up-to-date, expert reviews of the fast-moving field of molecular pharmacology.

In Vitro-In Vivo

Correlations David B. Young 2013-03-08 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 September, 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 company 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 Nottingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. Iain 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 development of in vitro-in vivo relationships for ER products. The original idea went back approximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development. *Biopharmaceutics Applications in Drug Development* Rajesh Krishna 2007-09-20 The highly experienced authors here present readers with step-wise, detail-conscious information to develop quality pharmaceuticals.

The book is made up of carefully crafted sections introducing key concepts and advances in the areas of dissolution, BA/BE, BCS, IVIC, and product quality. It provides a specific focus on the integration of regulatory considerations and includes case histories highlighting the biopharmaceutics strategies adopted in development of successful drugs.

Quaestio juris controversi an impubes negotiorum gestor esse possit

Hydrophilic Matrix Tablets for Oral

Controlled Release Peter Timmins 2014-10-11 This detailed volume addresses key issues and subtle nuances involved in developing hydrophilic matrix tablets as an approach to oral controlled release. It brings

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together information from more than five decades of research and development on hydrophilic matrix tablets and provides perspective on contemporary issues. Twelve comprehensive chapters explore a variety of topics including polymers (hypromellose, natural polysaccharides and polyethylene oxide) and their utilization in hydrophilic matrices, critical interactions impacting tablet performance, in vitro physical and imaging techniques, and microenvironmental pH control and mixed polymer approaches, among others. In one collective volume, *Hydrophilic Matrix Tablets for Oral Controlled Release* provides a single source of current knowledge, including sections of previously unpublished

data. It is an important resource for industrial and academic scientists investigating and developing these oral controlled release formulations.

Hydrodynamic Effects of a Cannula in a USP Dissolution Testing Apparatus 2 Qianqian Liu 2013 Dissolution testing is routinely used in the pharmaceutical industry to provide in vitro drug release information for drug development and quality control purposes. The USP Testing Apparatus 2 is the most common dissolution testing system for solid dosage forms. Usually, sampling cannulas are used to take samples manually from the dissolution medium. However, the inserted cannula can alter the normal fluid flow within the vessel and produce different dissolution testing results. The

hydrodynamic effects introduced by a permanently inserted cannula in a USP Dissolution Testing Apparatus 2 were evaluated by two approaches. Firstly, the dissolution tests were conducted with two dissolution systems, the testing system (with cannula) and the standard system (without cannula), for nine different tablet positions using non-disintegrating salicylic acid calibrator tablets. The dissolution profiles at each tablet location in the two systems were compared using statistical tools. Secondly, Particle Image Velocimetry (PIV) was used to obtain experimentally velocity vector maps and velocity profiles in the vessel for the two systems and to quantify changes in the velocities on selected horizontal so-

surfaces. The results show that the system with the cannula produced higher dissolution profiles than that without the cannula and that the magnitude of the difference between dissolution profiles in the two systems depended on tablet location. However, in most dissolution tests, the changes in dissolution profile due to the cannula were small enough to satisfy the FDA criteria for similarity between dissolution profiles (f_1 and f_2 values). PIV measurements showed slightly changes in the velocities of the fluid flow in the vessel where the cannula was inserted. The most significant velocity changes were observed closest to the cannula. However, generally the hydrodynamic effect generated by the cannula

did not appear to be particularly strong, which was consistent to dissolution test results. It can be concluded that the hydrodynamic effects generated by the inserted cannula are real and observable. Such effects result in slightly modifications of the fluid flow in the dissolution vessel and in detectable differences in the dissolution profiles, which, although limited, can introduce variations in test results possibly leading to failure of routine dissolution tests.

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

Yimin Wang 2011

Dissolution testing is routinely conducted in the pharmaceutical industry to provide

critical in vitro drug release information for quality control purposes, and especially to assess batch-to-batch consistency of solid oral dosage forms such as tablets. Among the different types of apparatuses listed in the United States Pharmacopoeia (USP), the most commonly used dissolution system for solid dosage forms is the USP Dissolution Testing Apparatus 2, consisting of an unbaffled, hemispherical-bottomed vessel equipped with a 2-blade radial impeller. Despite its extensive use in industry and a large body of work, some key aspects of the hydrodynamics of Apparatus 2 have received very little attention, such as the determination of its power dissipation requirements (which controls solid-liquid

mass transfer processes) and the velocity distribution under the different agitation conditions at which this system is routinely operated. In addition, the tablet dissolution performance of Apparatus 2 has been shown to be highly sensitive to a number of small geometric factors, such as the exact locations of the impeller and the dissolving tablet. Therefore, in this study, computation and experimental work was conducted to (a) quantify the roles of some key hydrodynamic variables of importance for the standard Apparatus 2 system and determine their impact on the dissolution profiles of solid dosage forms, and (b) design and test a modified Apparatus 2 that can overcome the major limitations of the standard system, and

especially those related to the sensitivity of the current apparatus to tablet location. Accordingly, the hydrodynamics in the standard USP Apparatus 2 vessel was experimentally quantified using Laser-Doppler Velocimetry (LDV) and Particle Image Velocimetry (PIV). Complete experimental mapping of the velocity distribution inside the standard Apparatus 2 was obtained at three agitation intensities, i.e., 50 rpm ($NRe=4939$), 75 rpm ($NRe=7409$) and 100 rpm ($NRe=9878$). The velocity distributions from both LDV and PIV were typically found to be very similar. It was found that the overall flow pattern throughout the whole vessel was dominated by the tangential component of the velocity at all agitation speeds, whereas the magnitudes

of the axial and radial velocity components were typically much smaller. In the bottom zone of the vessel, two regions were observed, i.e., a central, low-velocity inner core region, and an outer recirculation loop below the impeller, rotating around the central inner core region. This core region typically persisted, irrespective of the impeller agitation speed. Computation Fluid Dynamics (CFD) was additionally used to predict velocity profiles. Typically, the CFD predictions matched well the experimental results. The power dissipated by the impeller in Apparatus 2 was experimentally measured using a frictionless system coupled with torque measurement. CFD was additionally used to predict the power consumption, using two

different approaches, one based on the integration of the local value of the energy dissipation rate, and the other based on the prediction of the pressure distribution on the impeller blade, from which the torque and the power required to rotate the impeller were predicted. The agreement between the experimental data and both types of numerical predictions was found to be quite satisfactory in most cases. The results were expressed in terms of the non-dimensional Power number, Po , which was typically found to be on the order of ~ 0.3 . The power number was observed to decrease very gradually with increasing agitation speeds. The results of this work and of previous work with the standard USP Apparatus 2 confirm that this apparatus is very

sensitive to the location of the tablet, which is typically not controlled in a typical test since the tablet is dropped into the vessel at the beginning of the test and it may rest at random locations on the vessel bottom.

Therefore, in this work a modified USP Dissolution Testing Apparatus 2, in which the impeller was placed 8-mm off-center in the vessel, was designed and tested. This design eliminates the poorly mixed inner core region below the impeller observed in the standard Apparatus 2 vessel. Dissolution tests were conducted with the Modified Apparatus for different tablet locations using both disintegrating calibrator tablets (Prednisone) and non-disintegrating calibrator tablets (Salicylic Acid). The

experimental data clearly showed that all dissolution profiles in the Modified Apparatus were not affected by the tablet location at the bottom of the vessel. This design can effectively eliminate artifacts generated by having the tablet settle randomly at different locations on the vessel bottom after dropping it at the beginning of a dissolution testing experiment. The hydrodynamic and mixing characteristics of the modified Apparatus 2 were studied in some detail by experimentally measuring and computationally predicting the velocity distribution, power dissipation, and mixing time in the modified system. The velocity profiles near the bottom of the vessel were found to be significantly more uniform than in the standard Apparatus 2,

because of the elimination of the poorly mixed zone below the impeller. The power dissipation in the modified Apparatus 2 was typically higher than in the standard system, as expected for a non-symmetrical system, and the corresponding Power number, P_o , was less dependent on Reynolds number than P_o in the standard system. Finally, the mixing time in the modified system, as experimentally measured by using a decolorization method and computationally predicted through CFD simulation, was found to be shorter in the modified Apparatus 2 by 7.7 %-12.9 % as compared to Apparatus 2. It can be concluded that the modified Apparatus 2 is a more robust testing apparatus, which is capable of producing dissolution profiles that are less sensitive

to small geometric factors that play a major role in the standard USP Apparatus 2.

The Drugs and Cosmetics Act, 1940

Handbook of Pharmaceutical Formulations, Third Edition Sarfaraz K.

Niazi 2019-12-06 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.

Basic Pharmacokinetics, Second Edition Mohsen A. Hedaya

2012-02-09

Knowledge of pharmacokinetics is critical to understanding the absorption, distribution, metabolism, and excretion of drugs. It is therefore vital to those engaged in the discovery, development,

and preclinical and clinical evaluation of drugs, as well as practitioners involved in the clinical use of drugs. Using different approaches accessible to a wide variety of readers, *Basic Pharmacokinetics: Second Edition* demonstrates the quantitative pharmacokinetic relations and the interplay between pharmacokinetic parameters. After a basic introduction to pharmacokinetics and its related fields, the book examines: Mathematical operations commonly used in pharmacokinetics Drug distribution and clearance and how they affect the rate of drug elimination after a single dose Factors affecting drug absorption following extravascular drug administration, the rate and extent of drug absorption, and drug

bioequivalence The steady-state concept during constant rate intravenous infusion and during multiple drug administration Renal drug elimination, drug metabolism, multicompartment models, nonlinear pharmacokinetics, and drug administration by intermittent intravenous infusion Pharmacokinetic-pharmacodynamic modeling, noncompartmental pharmacokinetic data analysis, clearance concept from the physiological point of view, and physiological modeling Clinical applications of pharmacokinetics, including therapeutic drug monitoring, drug pharmacokinetics in special populations, pharmacokinetic drug-drug interactions, pharmacogenomics, and applications of

computers in pharmacokinetics Accompanying the book is a CD-ROM with self-instructional tutorials and pharmacokinetic and pharmacokinetic-pharmacodynamic simulations, allowing visualization of concepts for enhanced comprehension. This learning tool received an award from the American Association of Colleges of Pharmacy for innovation in teaching, making it a valuable supplement to this essential text.

Controlled Release in Oral Drug Delivery Clive G. Wilson 2011-09-22
Controlled Release in Oral Drug Delivery provides focus on specific topics, complementing other books in the initial CRS series. Each chapter sets the context for the inventions described and describe the latitude that the inventions

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allow. In order to provide some similar look to each chapter, the coverage includes the historical overview, candidate drugs, factors influencing design and development, formulation and manufacturing and delivery system design. This volume was written along three main sections: the relevant anatomy and physiology, a discussion on candidates for oral drug delivery and the major three groups of controlled release systems: diffusion control (swelling and inert matrices); environmental control (pH sensitive coatings, time control, enzymatic control, pressure control) and finally lipidic systems.

Dissolution Theory, Methodology, and Testing

Arthur H. Kibbe

2007-01-01

In Vitro Drug Release Testing of Special

Dosage Forms Nikoletta Fotaki 2019-10-10 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

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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.
Pharmaceutics – Practical Manual (According to the PCI new Syllabus as per ER-2020) D. Pharm- First year Mr. Dhaneshwar Kumar Vishwakarma, Dr. Jai Narayan Mishra
2022-05-21 The book has been designed for pharmacy students as per the new syllabus (ER-2020) prescribed by Pharmacy Council of India (PCI). This book contains essential information that students gathered knowledge for formulation various dosage forms and prepare for competitive as well as annual or semester

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examination. Its primary objective is to provide knowledge about various formulation aspect which helpful for formulating a dosage form. This textbook has been written in easy language to ensure a lower reading level and understandable contents than ever. This book covers all major pharmaceuticals dosage forms formulation. This book contains many chapters, each providing a description of various dosage forms formulation and their evaluation like syrup, suspension, emulsion, cream, ointment, lotion, lineaments, gel, tablets capsule, dusting powder, effervescent powder, injection, cosmetic preparation, evaluation of tablets, capsule, emulsion, parenteral products, and use of insulin pen, inhalers and spacer.

Pharmaceutical Process

Scale-Up Michael Levin
2001-12-12 Focusing on scientific and practical aspects of process scale-up, this resource details the theory and practice of transferring pharmaceutical processes from laboratory scale to the pilot plant and production scale. It covers parenteral and nonparenterel liquids and semi-solids, products derived from biotechnology, dry blending and powder handling,
Generic Drug Product Development Leon Shargel
2013-10-24 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

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concerns. Generic Drug Product Development: Solid Oral
The International Pharmacopoeia World Health Organization 1979
The International Pharmacopoeia contains a collection of recommended methods for analysis and quality specifications for pharmaceutical substances, excipients and products. Volume five of this publications describes methods and procedures for the quality control of pharmaceutical substances and tablets, tests for dosage forms for suppositories and ophthalmic preparations, and a new section on quality control of anti-malarials. Supplementary information on International Chemical Reference Substances and International Reference Spectra, and on the establishment, maintenance and

distribution of chemical reference substances are also included.

Applied Pharmaceutics in Contemporary Compounding

Robert P. Shrewsbury
2015-01-01 Applied Pharmaceutics in Contemporary Compounding, Third Edition is designed to convey a fundamental understanding of the principles and practices involved in both the development and the production of compounded dosage forms by applying pharmaceutical principles.

Developing Solid Oral Dosage Forms Yihong Qiu
2009-03-10 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

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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

The Japanese

Pharmacopoeia 1996

FASTtrack Pharmaceuticals

Dosage Form and Design, 2nd edition David S.

Jones 2016-06-13

FASTtrack Pharmaceuticals

– Dosage Form and Design

focuses on what you really need to know in order to pass your pharmacy exams. It provides concise, bulleted information, key points, tips and an all-important self-assessment section, including MCQs.

The Modification of an Automated Dissolution Test Apparatus for the Rotating Disk Method of Intrinsic Dissolution Rate Measurement, Its Validation and Use in Evaluating Tablet Diluents Arun Dattatreya Koparkar 1983

Effect of Tablet Compression on the

Dissolution of Aspirin Tablets Using a Novel Off-center Paddle Impeller (opi)

Dissolution Testing

System Chuan Sun 2013

In the pharmaceutical industry, dissolution testing is routinely carried out to determine the dissolution rate of oral solid dosage forms. Among several testing devices, the USP Dissolution Apparatus 2 is the device most commonly used. However, despite its widespread use, this apparatus has been shown to produce test failures and to be very sensitive to a number of small geometry changes. The objective of this study was to determine whether a novel dissolution system termed "OPI" for "off-center paddle impeller" was sensitive enough to determine differences in tablet dissolution profiles caused by different compression

pressure during the tablet manufacturing process. The OPI Dissolution System simply consists of a modified Apparatus 2 in which the impeller is placed 8mm off center in the vessel. In this work, aspirin tablets were manufactured from powder with a manual tablet press using three different compression pressures. The dissolution profiles of these tablets were then obtained in both the OPI system and the standard USP Apparatus 2 system. Tests were conducted by dropping the tablets in the vessels at the beginning of an experiment, and, in separate experiments, by initially immobilizing the tablets on the vessel bottom at nine different locations. This approach has been used in the past by our group to determine the sensitivity of the

dissolution apparatus to minor changes in the geometry of the dissolution system. All dissolution profiles were found to be affected by the compression pressure. Faster dissolution profiles were obtained at lower compression pressures. When tablets were dropped in the vessel, a comparison of the dissolution profiles obtained in the standard Apparatus 2 system and in the OPI system showed that similarly manufactured tablets produced statistically similar dissolution profiles in both systems, i.e., that the OPI system was just as sensitive as the standard system to variations in the tablet manufacturing process. However, when the tablets were immobilized during the dissolution process, the standard system generated very

different dissolution profiles even for tablets manufactured at the same compression pressure. By contrast, the dissolution profiles in the OPI system for tablets manufactured at different pressure but located at different positions were very similar. It can be concluded that the OPI system is sensitive enough to detect differences in intrinsic tablet dissolution rates (such as those caused, as in this case, by changes in the manufacturing process), while being unaffected by small changes in the system geometry that instead caused the standard system to fail. Therefore, the OPI system appears to be a more reliable dissolution testing apparatus than the current apparatus. Modern Pharmaceutics Volume 1 Alexander T.

Florence 2009-05-28 With over 100 illustrations, Volume 1 addresses the core disciplines of pharmaceuticals (absorption, PK, excipients, tablet dosage forms, and packaging), and explores the challenges and paradigms of pharmaceuticals. Key topics in Volume 1 include: • principles of drug absorption, chemical kinetics, and drug stability • pharmacokinetics • the effect of route of administration and distribution on drug action • in vivo imaging of dose forms: gamma scintigraphy, PET imaging NMR, MRI, etc. • powder technology • excipient design and characterization • preformulation • optimization techniques in pharmaceutical formulation and processing • disperse and surfactant systems •

the solid state, tablet dosage forms, coating processes, and hard and soft shell capsules • parenteral products

Formulation and Analytical Development for Low-Dose Oral Drug Products Jack Zheng
2009-03-04 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.

Oral Drug Absorption Jennifer B. Dressman
2016-04-19 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

Basic Pharmacokinetics Mohsen A. Hedaya
2007-04-23 This volume is a self-instructional computer-assisted medium for active learning. Indeed, the tutorial

materials included in the accompanying compact disk have received an award from the American Association of Colleges of Pharmacy for innovation in teaching. This volume and its companion CD are intended for students and practitioners in the health professions who need to comprehend the concepts and principles related to how the body absorbs, distributes, metabolizes, and excretes drugs. "...The author's reliance on active learning, his use of examples illustrating important pharmacokinetic principles, and particularly the thoughtful simulation tools he has developed make this text and its companion CD an extremely effective and enjoyable introduction to the field of pharmacokinetics." From the Foreword, Ronald J.

Sawchuk Minneapolis, Minnesota Pharmacokinetics has become an essential component of all the processes involved in drug development, discovery, and preclinical evaluation, as well as with the clinical use of drugs. While this has led to the development of many highly complex techniques, basic pharmacokinetic concepts remain the backbone of all these new developments. Consequently, a thorough understanding of the basic concepts is essential before one can tackle the more involved and applied areas of pharmacokinetics. Basic Pharmacokinetics consists of two parts: textual printed materials and highly interactive computer-based presentations. Together, these provide a useful combination

that makes it easy to grasp basic principles. The computer-based information is presented in a self-instructional format, which introduces concepts, utilizing highly interactive graphical presentations and simulations. It visualizes the interplay between the different pharmacokinetic parameters, observing how the change in one or more of these parameters impacts the drug concentration-time profile in the body. Uniquely and carefully designed, the learning modules in the CD closely support and complement the text, providing the learner with an opportunity to reinforce his or her understanding of the principles presented.

The Pharmacist 2007
Drug Design and Development Chris Rostron 2020-05-15 Drug Design and Development

outlines the processes involved in the design and development of new drugs and emphasises the significance of these processes to the practice of pharmacy.

Practical Pharmaceutical Engineering Gary Prager

2018-11-28 A practical guide to all key the elements of pharmaceuticals and biotech manufacturing and design Engineers working in the pharmaceutical and biotech industries are routinely called upon to handle operational issues outside of their fields of expertise.

Traditionally the competencies required to fulfill those tasks were achieved piecemeal, through years of self-teaching and on-the-job experience—until now. Practical Pharmaceutical Engineering provides readers with the technical information and tools needed to deal

with most common engineering issues that can arise in the course of day-to-day operations of pharmaceutical/biotech research and manufacturing. Engineers working in pharma/biotech wear many hats. They are involved in the conception, design, construction, and operation of research facilities and manufacturing plants, as well as the scale-up, manufacturing, packaging, and labeling processes. They have to implement FDA regulations, validation assurance, quality control, and Good Manufacturing Practices (GMP) compliance measures, and to maintain a high level of personal and environmental safety. This book provides readers from a range of engineering specialties with a detailed

blueprint and the technical knowledge needed to tackle those critical responsibilities with confidence. At minimum, after reading this book, readers will have the knowledge needed to constructively participate in contractor/user briefings. Provides pharmaceutical industry professionals with an overview of how all the parts fit together and a level of expertise that can take years of on-the-job experience to acquire. Addresses topics not covered in university courses but which are crucial to working effectively in the pharma/biotech industry. Fills a gap in the literature, providing important information on pharmaceutical operation issues required for meeting regulatory guidelines, plant

support design, and project engineering
Covers the basics of HVAC systems, water systems, electric systems, reliability, maintainability, and quality assurance, relevant to pharmaceutical engineering
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Pharmaceutical Statistics Sanford Bolton 2009-12-23
Through the use of

practical examples and solutions,
Pharmaceutical Statistics: Practical and Clinical Applications, Fifth Edition provides the most complete and comprehensive guide to the various statistical applications and research issues in the pharmaceutical industry, particularly in clinical trials and bioequivalence studies.
Encyclopedia of Pharmaceutical Technology James Swarbrick 2013-07-01
Presenting authoritative and engaging articles on all aspects of drug development, dosage, manufacturing, and regulation, this Third Edition enables the pharmaceutical specialist and novice alike to keep abreast of developments in this rapidly evolving and highly competitive field. A dependable

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Experimental Determination of the Agitation Requirements for Solids Suspension in Dissolution Systems Using a Mini Paddle Apparatus Yang Song 2015

Dissolution testing is a critical step in quality control of manufactured final products in the pharmaceutical industry. The United States Pharmacopeia (USP) Dissolution Testing Apparatus 2 (paddle) is the most widely used dissolution test devices in the pharmaceutical industry to formulate solid drug dosage forms and to develop quality control specifications for its manufacturing process. Mini vessels and mini paddle dissolution testing systems are smaller versions of the USP 2 Apparatus. The concept of the mini paddle

apparatus is similar to that of the USP 2 setup but it is scaled down about to 1/5 of the volume and 40% with respect to vessel and impeller sizes. Mini vessel systems, requiring a small volume (200 mL) and a mini paddle impeller, are becoming increasingly common in the pharmaceutical industry to overcome the limitations associated with the USP 2 dissolution testing method, especially for dissolution testing involving very small tablets. Mini apparatuses can be useful tools in characterizing drug release profiles since smaller sample sizes and smaller volumes of media are needed, thus offering several advantages in terms of substance, analytical, and material cost savings when evaluating

release properties of drug candidates. Despite their increasing importance in dissolution testing, little information is currently available on mini vessels, and especially on the agitation speed needed to prevent "coning" effects. Typically during dissolution testing, a disintegrating tablet becomes rapidly fragmented, and the resulting solid particles may or may not become suspended depending on the agitation speed of the paddle and other geometric and operating parameters "Coning" (the accumulation of particle fragments from a disintegrating tablet) often appears in dissolution testing but can be eliminated by increasing the agitation speed N . Therefore, it is important to be able

to predict the minimum rotation speed at which coning phenomena disappears in a dissolution testing system and especially in mini vessels systems. The focus of this work was the determination of the minimum agitation speed, N_{js} , at which the just suspended state by dispersed particles is achieved in a mini paddle system (thus removing "coning" effects). In the past, N_{js} has been experimentally obtained in mixing systems by determining the agitation speed at which no particles are visually observed to be at rest on the vessel bottom for more than one to two seconds. Therefore, the first objective of this work was to develop an observer-independent method to measure experimentally N_{js} . This was achieved by

extending to mini vessel a method that was recently developed in our laboratory and that is based on the determination of the fraction of unsuspended solids in the vessel at different agitation speed (N_{js} - D_s method). The results of this method agree well the visually observable values of N_{js} (N_{js} -visual). Once new method was validated in mini vessels, N_{js} was experimentally measured using well characterized solid particles under a number of operating conditions, such as liquid level-to-vessel diameter ratio (H/T), particle size (d_p), and paddle clearance-to-vessel diameter ratio (C_b/T). The results could be interpreted using the Zwietering Equation originally developed for solids suspension in baffled stirred tanks. The Zwietering "S"

parameter was obtained for the mini vessel system thus enabling the use of this equation to predict when "coning" effects can be eliminated in mini vessel systems during tablet dissolution testing.

Pharmaceutics Av Yadav
2016-06-16 Introduction to Pharmaceutics and its Scope - Development of a New Drug - Introduction to Dosage Forms of Drugs - History and Development of Profession of Pharmacy - Introduction to Pre-formulation - Biopharmaceutics - Good Manufacturing Practices - Introduction to Pre-formulation - Biopharmaceutics - Good Manufacturing Practices - Introduction to Alternative Systems of Medicines - Drug Delivery Systems - Biological Products - Packaging of Pharmaceuticals -

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Dissolution of Different Commercial Aspirin Tablets Using a Novel Off-center Paddle Impeller (OPI) Dissolution Testing System Yang Qu 2013
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.