

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 finding 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.

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 generates 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 generates 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.

Hydrodynamic Effects of an Arch-shaped Fiber Optic Probe in a Dissolution Testing Apparatus 2

Yiran Zhang 2012 Dissolution testing is widely used in the pharmaceutical industry to evaluate newly developed drug formulations and as a quality control method to insure that solid dosage forms have consistent dissolution property. Typically, samples are manually drawn from the dissolution vessel prior to analysis. An approach to overcome the limitations of manual sampling consists in the use of sampling probes, such as fiber optic probes, permanently inserted in the dissolution medium and continually sampling the drug concentration in it as the solid dosage form dissolves. Despite their advantages, permanently inserted fiber optic probes can alter the normal fluid flow within the vessel and produce different dissolution testing results. In this study, the hydrodynamic effects introduced by an arch-shaped fiber optic probe in a USP Dissolution Testing Apparatus 2 are studied by: (1) conducting dissolution tests, with and without the probe, using Prednisone tablets fixed at nine different locations at the bottom of the vessel and comparing the dissolution profiles obtained using statistical tools; and (2) experimentally determining the velocity profiles in the vessel, with and without the probe, using Particle Image Velocimetry (PIV) and quantifying changes in the flow velocities on selected horizontal iso-surfaces. The results show that the arch shaped fiber optic probe does have a baffling effect on the hydrodynamics in the dissolution vessel. This effect results in changes in the velocities in the fluid flow, and therefore in changes in the dissolution rate of the tablets undergoing testing. The baffle effect is observed mainly in the region where the probe is inserted. However, this perturbation is also found to reach the region below the impeller and to change the velocity profile there, resulting in differences in dissolution profiles when the tablets are fixed at positions that are downstream of the probe and within the low velocity region below the impeller. On the other hand, the hydrodynamic effect generated by the probe does not appear to be

particularly strong. In most dissolution testing runs, the changes in dissolution profile are not large enough to fail the tests, according to the FDA criteria (f1 and f2 values). The PIV measurements additionally show that the baffle effect is not strong enough to break the overall flow pattern, or to affect the region around the impeller, which is dominated by the main flow generated by the impeller. It can be concluded that the hydrodynamic effects generated by the arch-shaped fiber optic probe are real and observable, resulting in slightly modification of the fluid flow in the dissolution vessel and therefore in detectable differences in the dissolution profiles. However, these effects are limited and do not typically lead to dissolution testing failures.

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 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.

Quaestio juris controversi an impubes negotiorum gestor esse possit

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.

Modern Pharmaceutics, Two Volume Set

Alexander T. Florence 2016-04-19 This new edition brings you up-to-date on the role of pharmaceutics and its future paradigms in the design of medicines. Contributions from over 30 international thought leaders cover the core disciplines of pharmaceutics and the impact of biotechnology, gene therapy, and cell therapy on current findings. Modern Pharmaceutics helps you stay current

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.

Handbook of Pharmaceutical Manufacturing 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.

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.

3D Printing of Pharmaceuticals and Drug Delivery Devices

Dimitrios A. Lamprou 2020-07-01 The 3D printing (3DP) process was patented in 1986; however, only in the last decade has it begun to be used for medical applications, as well as in the fields of prosthetics, bio-fabrication, and pharmaceutical printing. 3DP or additive manufacturing (AM) is a

family of technologies that implement layer-by-layer processes in order to fabricate physical models based on a computer aided design (CAD) model. 3D printing permits the fabrication of high degrees of complexity with great reproducibility in a fast and cost-effective fashion. 3DP technology offers a new paradigm for the direct manufacture of individual dosage forms and has the potential to allow for variations in size and geometry as well as control dose and release behavior. Furthermore, the low cost and ease of use of 3DP systems means that the possibility of manufacturing medicines and medical devices at the point of dispensing or at the point of use could become a reality. 3DP thus offers the perfect innovative manufacturing route to address the critical capability gap that hinders the widespread exploitation of personalized medicines for molecules that are currently not easy to deliver. This Special Issue will address new developments in the area of 3D printing and bioprinting for drug delivery applications, covering the recent advantages and future directions of additive manufacturing for pharmaceutical products.

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.

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 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.

Aulton's Pharmaceutics E-Book Kevin M.G. Taylor 2021-04-23 The essential pharmaceutics textbook One of the world's best-known texts on pharmaceutics, Aulton's Pharmaceutics offers a complete course in one book for students in all years of undergraduate pharmacy and pharmaceutical sciences degrees. Thoroughly revised, updated and extended by experts in their fields and edited by Professors Kevin Taylor and Michael Aulton, this new edition includes the science of formulation, pharmaceutical manufacturing and drug delivery. All aspects of pharmaceutics are covered in a clear and readily accessible way and extensively illustrated throughout, providing an essential companion to the entire pharmaceutics curriculum from day one until the end of the course. Fully updated throughout, with the addition of new chapters, to reflect advances in formulation and drug delivery science, pharmaceutical manufacturing and medicines regulation Designed and written for newcomers to the design and manufacture of dosage forms Relevant pharmaceutical science

covered throughout Includes the science of formulation and drug delivery Reflects current practices and future applications of formulation and drug delivery science to small drug molecules, biotechnology products and nanomedicines Key points boxes throughout Over 400 online multiple choice questions

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 State 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 increasing 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 – 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 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.

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.

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.

Handbook of Bioequivalence Testing

Sarfaraz K. Niazi 2014-10-29 As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct adequate, efficient bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence. In addition, advances in the analytical technology used to detect drug and metabolite levels have

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 - Bibliography - Index

Pharmaceutical Dosage Forms - Tablets Larry L. Augsburger 2016-04-19 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

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 reference tool and constant companion for years to com

Handbook of Stability Testing in Pharmaceutical Development

Kim Huynh-Ba 2008-11-16 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.

The Pharmacist 2007

FASTtrack Pharmaceutics Dosage Form and Design, 2nd edition David S. Jones 2016-06-13

FASTtrack Pharmaceutics - 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.

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 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.

Modern Pharmaceutics Volume 1 Alexander T. Florence 2009-05-28 With over 100 illustrations, Volume 1 addresses the core disciplines of pharmaceutics (absorption, PK, excipients, tablet dosage forms, and packaging), and explores the challenges and paradigms of pharmaceutics. 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

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 nonparenteral liquids and semi-solids, products derived from biotechnology, dry blending and powder handling,

"Fast dissolving tablets " Dr.G.SANDHYARANI Guggilla

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.

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

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

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 **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 Practical Pharmaceutical Engineering is an indispensable "tool of the trade" for chemical engineers, mechanical engineers, and pharmaceutical engineers employed by pharmaceutical and biotech companies, engineering firms, and consulting firms. It also is a must-read for engineering students, pharmacy students, chemistry students, and others considering a career in pharmaceuticals.

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 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.

The Drugs and Cosmetics Act, 1940 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.

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.

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, Po , was less dependent on Reynolds number than Po 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.

Regulatory Affairs in the Pharmaceutical Industry Javed Ali 2021-11-14 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

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.