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## An Evaluation of the Usp Dissolution Apparatus

## Dissolution Kinetics of Calibrator and Matrix Tablets in the U.S.P. Dissolution Apparatus

## Numerical Simulation of Capsule Dissolution in the Usp Apparatus Ii

The capsule is the second most common type of drug dosage form, yet detailed research of capsule dissolution in the USP Apparatus II (a paddle dissolution apparatus that mimics the drug dissolution process in an in vivo environment) is not well reported. In this work, a mathematical model was developed that incorporates both the dissolution of the capsule shell and the slug within the capsule shell. Capsule shell dissolution was modeled with the assumption that the shell undergoes an erosion process only. The capsule slug dissolution model incorporated mass transfer principles, Markov chain theory, and the influence of hydrodynamics on capsules dissolution using computational fluid dynamics (CFD)-predicted velocity profiles. To complete the model, the mass transfer coefficients (determined experimentally and theoretically) were incorporated. The model was validated by statistically comparing the simulated profiles to the experimental data using the similarity factor. In addition, this model can provide insights into the dissolution mechanism where a drug product may either disintegrate or erode during dissolution testing. This capsule slug dissolution model has the potential to reduce substantially the number of time-consuming physical dissolution experiments and maximize the efficiency of process development.

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

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.

# Hydrodynamic Effects of a Cannula in a USP Dissolution Testing Apparatus 2

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 (f1 and f2 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 mod fications 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.

# Pharmaceutical Dissolution Testing

CRC Press Introduction, Historical Highlights, and the Need for Dissolution Testing Theories of Dissolution Dissolution Testing Devices Automation in Dissolution Testing, by William A. Hanson and Albertha M. Paul Factors That Influence Dissolution Testing Interpretation of Dissolution Rate Data Techniques and of In Vivo Dissolution, by Umesh V. Banakar, Chetan D. Lathia, and John H. Wood Dissolution of Dosage Forms Dissolution of Modified-Release Dosage Forms Dissolution and Bioavailability Dissolution Testing and the Assessment of Bioavailability/Bioequivalence, by Santosh J. Vetticaden Dissolution Rediscovered, by John H. Wood Appendix: USP/NF Dissolution Test.

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

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 an 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.

# Design and Evaluation of a Modified USP/NF Dissolution Apparatus

# Dissolution Testing of Prednisone and Salicylic Acid Calibrator Tablets at Different Tablet Locations

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 f1 and the Difference Factor f2. 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.

# Hydrodynamic Characterization of the USP Apparatus 2 Dissolution Test

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

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, Njs, at which the just suspended state by dispersed particles is achieved in a mini paddle system (thus removing "coning" effects). In the past, Njs, 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 Njs. 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 (Njs-Ds method). The results of this method agree well the visually observable values of Njs(Njs-visual).Once new method was validated in mini vessels, Njs 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 (dp), and paddle clearance-to-vessel diameter ratio Cb/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.

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

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.

# Media for in Vitro Dissolution Testing of Polysaccharide Based CDDS

# Dissolution Media with Colonic Probiotics

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

# Handbook of Dissolution Testing

Pharmaceutical Technology

# Pharmaceutical Dissolution Testing

CRC Press An expertly written source on the devices, systems, and technologies used in the dissolution testing of oral pharmaceutical dosage forms, this reference provides reader-friendly chapters on currently utilized equipment, equipment qualification, consideration of the gastrointestinal physiology in test design, the analysis and interpretation of data and procedure automation -laying the foundation for the creation of appropriate and useful dissolution tests according to the anticipated location and duration of drug release from the dosage form within the gastrointestinal tract.

# In Vitro Drug Release Testing of Special Dosage Forms

Wiley-Blackwell Guides readers on the proper use of in vitro drug release methodologies in order to evaluate the performance of special dosage forms In the last decade, the application of drug release testing has widened to a variety of novel/special dosage forms. In order to predict the in vivo behavior of such dosage forms, the design and development of the in vitro test methods need to take into account various aspects, including the dosage form design and the conditions at the site of application and the site of drug release. This unique book is the first to cover the field of in vitro release testing of special dosage forms in one volume. Featuring contributions from an international team of experts, it presents the state of the art of the use of in vitro drug release methodologies for assessing special dosage forms' performances and describes the different techniques required for each one. In Vitro Drug Release Testing of Special Dosage Forms covers the in vitro release testing of: lipid based oral formulations; chewable oral drug products; injectables; drug eluting stents; inhalation products; transdermal formulations; topical formulations; vaginal and rectal delivery systems and ophthalmics. The book concludes with a look at regulatory aspects. Covers both oral and non-oral dosage forms Describes current regulatory conditions for in vitro drug release testing Features contributions from well respected global experts in dissolution testing In Vitro Drug Release Testing of Special Dosage Forms will find a place on the bookshelves of anyone working with special dosage forms, dissolution testing, drug formulation and delivery, pharmaceutics, and regulatory affairs.

# Quæstio juris controversi an impubes negotiorum gestor esse possit

# Dissolution of Different Commercial Aspirin Tablets Using a Novel Off-center Paddle Impeller (OPI) Dissolution Testing System

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.

# Dissolution Shelf Life of Prednisone

# Therapeutic Dosage Form Tablet

# Quality Control of Antacid Preparations

# Up-dating the RIGO Method Using Standard USP Dissolution Test Apparatus

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

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.

# Pharmaceutical Process Scale-Up

CRC Press 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, granulation and drying, fluid bed applications, compaction and tableting, and film coating and regulatory requirements for scale-up and postapproval changes. Drawing on the experience of twenty contributing researchers, the book employs dimensional analysis as a unified scientific approach to quantify similar processes on different scales.

# Comparative Analysis of the Dissolution Performance of Aspirin Tablets in the Usp Apparatus 2 and in a Minivessel Dissolution System

The dissolution curves in the Minivessel and in the USP 2 were compared and it was found that operating the Minivessel as predicted to achieve similar mass transfer coefficients in the USP 2 produced similar dissolution curves in both systems. The comparison was additionally quantified by using the difference factor f1 and the similarity factor f2 recommended by the Food and Drug Administration (FDA).

# Handbook of Stability Testing in Pharmaceutical Development

# Regulations, Methodologies, and Best Practices

Springer Science & Business Media 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 Japanese Pharmacopoeia

# Developing Solid Oral Dosage Forms

# Pharmaceutical Theory and Practice

Academic Press Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with: Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design, characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges,

trends, opportunities, intellectual property issues and regulations in solid product development The first book (ever) that provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice, applications, regulation, intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies

# Pharmaceutical Capsules

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

# Formulation and Analytical Development for Low-Dose Oral Drug Products

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

# In Vitro Drug Release Testing of Special Dosage Forms

John Wiley & Sons Guides readers on the proper use of in vitro drug release methodologies in order to evaluate the performance of special dosage forms In the last decade, the application of drug release testing has widened to a variety of novel/special dosage forms. In order to predict the in vivo behavior of such dosage forms, the design and development of the in vitro test methods need to take into account various aspects, including the dosage form design and the conditions at the site of application and the site of drug release. This unique book is the first to cover the field of in vitro release testing of special dosage forms in one volume. Featuring contributions from an international team of experts, it presents the state of the art of the use of in vitro drug release methodologies for assessing special dosage forms' performances and describes the different techniques required for each one. In Vitro Drug Release Testing of Special Dosage Forms covers the in vitro release testing of: lipid based oral formulations; chewable oral drug products; injectables; drug eluting stents; inhalation products; transdermal formulations; topical formulations; vaginal and rectal delivery systems and ophthalmics. The book concludes with a look at regulatory aspects. Covers both oral and non-oral dosage forms Describes current regulatory conditions for in vitro drug release testing Features contributions from well respected global experts in dissolution testing In Vitro Drug Release Testing of Special Dosage Forms will find a place on the bookshelves of anyone working with special dosage forms, dissolution testing, drug formulation and delivery, pharmaceutics, and regulatory affairs.

# Oral Drug Absorption

# Prediction and Assessment, Second Edition

CRC Press 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

# Generic Drug Product Development

# Solid Oral Dosage Forms, Second Edition

CRC Press In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns.Generic Drug Product Development: Solid Oral

# Oral Drug Delivery for Modified Release Formulations

John Wiley & Sons ORAL DRUG DELIVERY FOR MODIFIED RELEASE FORMULATIONS Provides pharmaceutical development scientists with a detailed reference guide for the development of MR formulations Oral Drug Delivery for Modified Release Formulations is an up-to-date review of the key aspects of oral absorption from modified-release (MR) dosage forms. This edited volume provides in-depth coverage of the physiological factors that influence drug release and of the design and evaluation of MR formulations. Divided into three sections, the book begins by describing the gastrointestinal tract (GIT) and detailing the conditions and absorption processes occurring in the GIT that determine a formulation’s oral bioavailability. The second section explores the design of modified release formulations, covering early drug substance testing, the biopharmaceutics classification system, an array of formulation technologies that can be used for MR dosage forms, and more. The final section focuses on in vitro, in silico, and in vivo evaluation and regulatory considerations for MR formulations. Topics include biorelevant dissolution testing, preclinical evaluation, and physiologically-based pharmacokinetic modelling (PBPK) of in vivo behaviour. Featuring contributions from leading researchers with expertise in the different aspects of MR formulations, this volume: Provides authoritative coverage of physiology, physicochemical determinants, and in-vitro in-vivo correlation (IVIVC) Explains the different types of MR formulations and defines the key terms used in the field Discusses the present status of MR technologies and identifies current gaps in research Includes a summary of regulatory guidelines from both the US and the EU Shares industrial experiences and perspectives on the evaluation of MR dosage formulations Oral Drug Delivery for Modified Release Formulations is an invaluable reference and guide for researchers, industrial scientists, and graduate students in general areas of drug delivery including pharmaceutics, pharmaceutical sciences, biomedical engineering, polymer and materials science, and chemical and biochemical engineering.

# Dissolution Theory, Methodology, and Testing

# Theory and Practice of Physical Pharmacy - E-Book

Elsevier Health Sciences A core subject in pharmaceutics, physical pharmacy is taught in the initial semesters of B. Pharm. The methodical knowledge of the subject is required, and is essential, to understand the principles pertaining to design and development of drug and drug products. Theory and Practice of Physical Pharmacy is unique as it fulfils the twin requirements of physical pharmacy students: the authentic text on theoretical concepts and its application including illustrative exercises in the form of practicals. Covers all the topics included in various existing syllabi of physical pharmacy Provides an integrated understanding of theory and practical applications associated with physicochemical concepts Explore the latest developments in the field of pharmaceutics Reviews the relevance of physicochemical principles in the design of dosage form Ensures proper recapitulation through sufficient end-of-chapter questions Provides valuable learning tool in the form of multiple choice questions Multiple choice questions section especially useful for GPAT aspirants

# Specification of Drug Substances and Products

# Development and Validation of Analytical Methods

Newnes Specification of Drug Substances and Products: Development and Validation of Analytical Methods is a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development and validation of analytical methods. This book is intended as more than a review of new regional guidelines, existing regulatory guidance, and industry practices. It provides a hands-on guide to understanding and applying these in practice. The authors discuss critical issues, novel approaches, and future directions while also providing insight into how International Guidelines were developed and the rationale behind them. Guide to industry best practices of analytical methodologies used in the specification of new drug substances and products (e.g. DOE, QbD) Critical assessment of the application of ICH guidelines on method validation and specification setting, written by experts involved in the

development and application of the guidelines to aid understanding of requirements and what is expected by regulatory authorities Direct applicability to the day-to-day activities in drug development and the potential to increase productivity

# Poorly Soluble Drugs

# Dissolution and Drug Release

CRC Press This book is the first text to provide a comprehensive assessment of the application of fundamental principles of dissolution and drug release testing to poorly soluble compounds and formulations. Such drug products are, vis-à-vis their physical and chemical properties, inherently incompatible with aqueous dissolution. However, dissolution methods are required for product development and selection, as well as for the fulfillment of regulatory obligations with respect to biopharmaceutical assessment and product quality understanding. The percentage of poorly soluble drugs, defined in classes 2 and 4 of the Biopharmaceutics Classification System (BCS), has significantly increased in the modern pharmaceutical development pipeline. This book provides a thorough exposition of general method development strategies for such drugs, including instrumentation and media selection, the use of compendial and non-compendial techniques in product development, and phase-appropriate approaches to dissolution development. Emerging topics in the field of dissolution are also discussed, including biorelevant and biphasic dissolution, the use on enzymes in dissolution testing, dissolution of suspensions, and drug release of non-oral products. Of particular interest to the industrial pharmaceutical professional, a brief overview of the formulation and solubilization techniques employed in the development of BCS class 2 and 4 drugs to overcome solubility challenges is provided and is complemented by a collection of chapters that survey the approaches and considerations in developing dissolution methodologies for enabling drug delivery technologies, including nanosuspensions, lipid-based formulations, and stabilized amorphous drug formulations.

# Pharmaceutical Dosage Forms - Tablets

CRC Press The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form, an

# Handbook of Pharmaceutical Analysis by HPLC

Elsevier High pressure liquid chromatography–frequently called high performance liquid chromatography (HPLC or, LC) is the premier analytical technique in pharmaceutical analysis and is predominantly used in the pharmaceutical industry. Written by selected experts in their respective fields, the Handbook of Pharmaceutical Analysis by HPLC Volume 6, provides a complete yet concise reference guide for utilizing the versatility of HPLC in drug development and quality control. Highlighting novel approaches in HPLC and the latest developments in hyphenated techniques, the book captures the essence of major pharmaceutical applications (assays, stability testing, impurity testing, dissolution testing, cleaning validation, high-throughput screening). A complete reference guide to HPLC Describes best practices in HPLC and offers 'tricks of the trade' in HPLC operation and method development Reviews key HPLC pharmaceutical applications and highlights currents trends in HPLC ancillary techniques, sample preparations, and data handling

# Analytical Testing for the Pharmaceutical GMP Laboratory

John Wiley & Sons Provides practical guidance on pharmaceutical analysis, written by leading experts with extensive industry experience Analytical Testing for the Pharmaceutical GMP Laboratory presents a thorough overview of the pharmaceutical regulations, working processes, and drug development best practices used to maintain the quality and integrity of medicines. With a focus on smaller molecular weight drug substances and products, the book provides the knowledge necessary for establishing the pharmaceutical laboratory to support Quality Systems while maintaining compliance with Good Manufacturing Practices (GMP) regulations. Concise yet comprehensive chapters contain up-to-date coverage of drug regulations, pharmaceutical analysis methodologies, control strategies, testing development and validation, method transfer, electronic data documentation, and more. Each chapter includes a table of contents, definitions of acronyms, a reference list, and ample tables and figures. Addressing the principal activities and regulatory challenges of analytical testing in the development and manufacturing of pharmaceutical drug products, this authoritative resource: Describes the structure, roles, core guidelines, and GMP regulations of the FDA and ICH. Covers the common analytical technologies used in pharmaceutical laboratories, including examples of analytical techniques used for the release and stability testing of drugs. Examines control strategies established from quality systems supported by real-world case studies. Explains the use of dissolution testing for products such as

extended-release capsules, aerosols, and inhalers. Discusses good documentation and data reporting practices, stability programs, and the Laboratory Information Management System (LIMS) to maintain compliance. Includes calculations, application examples, and illustrations to assist readers in day-to-day laboratory operations. Contains practical information and templates to structure internal processes or common Standard Operating Procedures (SOPs). Analytical Testing for the Pharmaceutical GMP Laboratory is a must-have reference for both early-career and experienced pharmaceutical scientists, analytical chemists, pharmacists, and quality control professionals. It is also both a resource for GMP laboratory training programs and an excellent textbook for undergraduate and graduate courses of analytical chemistry in pharmaceutical sciences or regulatory compliance programs.

# Pharmaceutical Amorphous Solid Dispersions

John Wiley & Sons Providing a roadmap from early to late stages of drug development, this book overviews amorphous solid dispersion technology – a leading platform to deliver poorly water soluble drugs, a major hurdle in today’s pharmaceutical industry. • Helps readers understand amorphous solid dispersions and apply techniques to particular pharmaceutical systems • Covers physical and chemical properties, screening, scale-up, formulation, drug product manufacture, intellectual property, and regulatory considerations • Has an appendix with structure and property information for polymers commonly used in drug development and with marketed drugs developed using the amorphous sold dispersion approach • Addresses global regulatory issues including USA regulations, ICH guidelines, and patent concerns around the world