

# Dissolution Apparatus Types

This volume presents the proceedings of the Fifth International Conference on the Development of Biomedical Engineering in Vietnam which was held from June 16-18, 2014 in Ho Chi Minh City. The volume reflects the progress of Biomedical Engineering and discusses problems and solutions. It aims at identifying new challenges, and shaping future directions for research in biomedical engineering fields including medical instrumentation, bioinformatics, biomechanics, medical imaging, drug delivery therapy, regenerative medicine and entrepreneurship in medical devices.

Teaches future and current drug developers the latest innovations in drug formulation design and optimization  
This highly accessible, practice-oriented book examines current approaches in the development of drug formulations for preclinical and clinical studies, including the use of functional excipients to enhance solubility and stability. It covers oral, intravenous, topical, and parenteral administration routes. The book also discusses safety aspects of drugs and excipients, as well as regulatory issues relevant to formulation. Innovative Dosage Forms: Design and Development at Early Stage starts with a look at the impact of the polymorphic form of drugs on the preformulation and formulation development. It then offers readers reliable strategies for the formulation development of poorly soluble drugs. The book also studies the role of reactive impurities from the excipients on the formulation shelf life; preclinical formulation assessment of new chemical entities; and

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regulatory aspects for formulation design. Other chapters cover innovative formulations for special indications, including oncology injectables, delayed release and depot formulations; accessing pharmacokinetics of various dosage forms; physical characterization techniques to assess amorphous nature; novel formulations for protein oral dosage; and more. -Provides information that is essential for the drug development effort -Presents the latest advances in the field and describes in detail innovative formulations, such as nanosuspensions, micelles, and cocrystals -Describes current approaches in early pre-formulation to achieve the best in vivo results -Addresses regulatory and safety aspects, which are key considerations for pharmaceutical companies -Includes case studies from recent drug development programs to illustrate the practical challenges of preformulation design Innovative Dosage Forms: Design and Development at Early Stage provides valuable benefits to interdisciplinary drug discovery teams working in industry and academia and will appeal to medicinal chemists, pharmaceutical chemists, and pharmacologists.

Remington: The Science and Practice of Pharmacy, Twenty Third Edition, offers a trusted, completely updated source of information for education, training, and development of pharmacists. Published for the first time with Elsevier, this edition includes coverage of biologics and biosimilars as uses of those therapeutics have increased substantially since the previous edition. Also discussed are formulations, drug delivery (including prodrugs, salts, polymorphism. With clear, detailed color

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illustrations, fundamental information on a range of pharmaceutical science areas, and information on new developments in industry, pharmaceutical industry scientists, especially those involved in drug discovery and development will find this edition of Remington an essential reference. Intellectual property professionals will also find this reference helpful to cite in patents and resulting litigations. Additional graduate and postgraduate students in Pharmacy and Pharmaceutical Sciences will refer to this book in courses dealing with medicinal chemistry and pharmaceuticals. Contains a comprehensive source of principles of drug discovery and development topics, especially for scientists that are new in the pharmaceutical industry such as those with trainings/degrees in chemistry and engineering Provides a detailed source for formulation scientists and compounding pharmacists, from produg to excipient issues Updates this excellent source with the latest information to verify facts and refresh on basics for professionals in the broadly defined pharmaceutical industry

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

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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.

**Pharmaceutical Dosage Forms: Capsules** covers the development, composition, and manufacture of capsules. Despite the important role that capsules play in drug delivery and product development, few comprehensive texts on the science and technology of capsules have been available for the research and academic environments. This text addresses this gap, discussing how capsules provide unique capabilities and options for dosage form design and formulation.

This book represents the invited presentations and some of the posters presented at the conference entitled "In Vitro-In Vivo Relationship (IVIVR) Workshop" held in September, 1996. The workshop was organized by the IVIVR Cooperative Working Group which has drawn together scientists from a number of organizations and institutions, both academic and industrial. In addition to Elan Corporation, which is a drug delivery company specializing in the development of ER (Extended Release) dosage forms, the IVIVR Cooperative Working Group consists of collaborators from the University of Maryland at Baltimore, University College Dublin, Trinity College Dublin, and the University of Nottingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. Iain Cumming, Elan Corporation Dr. John

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Devane, Elan Corporation Dr. Adrian Dunne, University College Dublin Dr. Stuart Madden, Elan Corporation Dr. Colin Melia, University of Nottingham Mr. Tom O'Hara, Elan Corporation Dr. Deborah Piscitelli, University of Maryland at Baltimore Dr. Araz Raoof, Elan Corporation Mr. Paul Stark, Elan Corporation Dr. David Young, University of Maryland at Baltimore The purpose of the workshop was to discuss new concepts and methods in the development of in vitro-in vivo relationships for ER products. The original idea went back approximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development.

The worldwide impact of HIV/AIDS is well recognized. This book provides for the first time a thorough and critical overview of current aspects, recent developments, and trends in the formulation and drug delivery concerning anti-HIV microbicides by leading scientists in the field. Additionally, pertinent regulatory aspects and socioeconomical issues related to the subject are discussed. In the absence of a cure, prophylaxis represents a cornerstone in the battle against infection. One promising strategy comprises the use around the time of sexual intercourse of vaginal/rectal products containing antiviral compounds, termed microbicides. It is now recognized that specific development of drug dosage forms and/or drug delivery systems is an indispensable aspect for the success of microbicides. Different groups strived over the last decade to optimize the biophysical and technological performance of traditional dosage forms (gels, tablets,

and suppositories) to fulfill the specificities of microbicides use, without neglecting users' preferences and affordability issues. Moreover, new formulation approaches, such as vaginal rings and films, nanotechnology-based systems, stimuli-sensitive formulations, targeted drug delivery systems, among others have been proposed and are currently undergoing pre-clinical or even clinical testing.

Ibuprofen has become one of the foremost pain-relieving medications world-wide with its proven safety and efficacy in a wide variety of painful and inflammatory conditions. It has also been widely investigated for application in a variety of painful and non-pain inflammatory states including cancer and neurodegenerative conditions, reflecting the unique and novel properties of the drug that would never have been foreseen from knowledge of the properties when it was initially discovered. Edited by leading world expert with over 40 years record in research, teaching and as a scientific advisor in the field of anti-inflammatory/analgesic agents. Professor Kim Rainsford is also the founding Editor-in-Chief of the journal, *Inflammopharmacology*, as well as being an Associate Editor of *The Journal of Pharmacy & Pharmacology*. Provides a thorough coverage of the medicinal chemistry and pharmaceuticals of ibuprofen, and its pharmacokinetics in both humans and animals. Includes molecular, pharmacological and toxicological studies, and discusses the safety and efficacy of non-prescription ibuprofen, including its side effects. *Ibuprofen: Discovery, Development & Therapeutics* provides a definitive

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reference on all the main aspects of the chemical and pharmaceutical properties, mechanisms of action and therapeutic uses of ibuprofen including its role in the prevention and treatment of rheumatic conditions, cancer and neurodegenerative conditions such as Alzheimer's and Parkinson's diseases. The book has its origins in a volume first published in 1999, since when there have been considerable advances in research and clinical studies on ibuprofen in the treatment of many inflammatory and even non-inflammatory states. This book will prove invaluable to scientists, clinicians, pharmacists and all those who need to know about the actions and uses of anti-inflammatory and analgesic drugs.

A comprehensive yet concise guide to Modern HPLC  
Written for practitioners by a practitioner, Modern HPLC for Practicing Scientists is a concise text which presents the most important High-Performance Liquid Chromatography (HPLC) fundamentals, applications, and developments. It describes basic theory and terminology for the novice, and reviews relevant concepts, best practices, and modern trends for the experienced practitioner. Moreover, the book serves well as an updated reference guide for busy laboratory analysts and researchers. Topics covered include: HPLC operation Method development Maintenance and troubleshooting Modern trends in HPLC such as quick-turnaround and "greener" methods Regulatory aspects While broad in scope, this book focuses particularly on reversed-phase HPLC, the most common separation mode, and on applications for the pharmaceutical

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industry, the largest user segment. Accessible to both novice and intermediate HPLC users, information is delivered in a straightforward manner illustrated with an abundance of diagrams, chromatograms, tables, and case studies, and supported with selected key references and Web resources. With intuitive explanations and clear figures, *Modern HPLC for Practicing Scientists* is an essential resource for practitioners of all levels who need to understand and utilize this versatile analytical technology.

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

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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.

Dosage Form Design Parameters, Volume I, examines the history and current state of the field within the pharmaceutical sciences, presenting key developments. Content includes drug development issues, the scale up of formulations, regulatory issues, intellectual property, solid state properties and polymorphism. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters. Chapters delve into a particular aspect of this fundamental field, covering principles, methodologies and the technologies employed by pharmaceutical scientists. In addition, the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnology and related industries.

Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects, preformulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates, graduate students and those interested in drug dosage design  
Physical Pharmacy Nirali Prakashan Drug Delivery Systems Academic Press

Introduction, Historical Highlights, and the Need for

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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.

With its expansion into the global marketplace, the pharmaceutical industry of today is uniquely positioned to improve the global health standards of society by saving lives and improving the quality of lives around the world. *Modern Pharmaceutical Industry: A Primer* comprehensively explains the broad range of divisions in this complex industry. Experts actively involved in each division discuss their own contribution to a pharmaceutical company's work and success. Divisions include regulatory affairs, research and development, intellectual property, pricing, marketing, generics, OTC, and more

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

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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.

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

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 solid dispersion approach • Addresses global regulatory issues including US regulations, ICH guidelines, and

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patent concerns around the world

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.

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

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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

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.

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

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This test guideline describes a test procedure to gain information on dispersion stability of manufactured nanomaterials in simulated environmental media. The main purpose of this guideline is to assess the ability of a nanomaterial to attain a colloidal dispersion and to conserve this ...

The highly experienced authors here present readers with step-wise, detail-conscious information to develop quality pharmaceuticals. The book is made up of carefully crafted sections introducing key concepts and advances in the areas of dissolution, BA/BE, BCS, IVIC, and product quality. It provides a specific focus on the integration of regulatory considerations and includes case histories highlighting the biopharmaceutics strategies adopted in development of successful drugs.

Written for practitioners in both the drug and biotechnology industries, the Handbook of Analytical Validation carefully compiles current regulatory requirements on the validation of new or modified analytical methods. Shedding light on method validation from a practical standpoint, the handbook: Contains practical, up-to-date guidelines for analytical method validation Summarizes the latest regulatory requirements for all aspects of method validation, even those coming from the USP, but undergoing modifications Covers development, optimization, validation, and transfer of many different types of methods used in the regulatory

environment Simplifying the overall process of method development, optimization and validation, the guidelines in the Handbook apply to both small molecules in the conventional pharmaceutical industry, as well as well as the biotech industry. The application of drug delivery is a valuable, cost-effective lifecycle management resource. By endowing drugs with new and innovative therapeutic benefits, drug delivery systems extend products' profitable lifecycle, giving pharmaceutical companies competitive and financial advantages, and providing patients with improved medications. Formulation development is now being used to create new dosage forms for existing products, which not only reduces the time and expense involved in new drug development, but also helps with regard to patent protection and bypassing existing patents. Today's culture demands convenience, a major factor determining adherence to drug therapy. Over the past few years, patient convenience-oriented research in the field of drug delivery has yielded a range of innovative drug-delivery options. As a result, various drug-delivery systems, including medicated chewing gums, oral dispersible tablets, medicated lozenges and lollipops, have now hit the market and are very popular. These dosage forms offer a highly convenient way to dose medications, not only for special population groups with swallowing difficulties, such as children and the

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elderly, but for the general populace as well. This book provides valuable insights into a number of formulation design approaches that are currently being used, or could be used, to provide new benefits from existing drug molecules.

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 come

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

Presents a detailed discussion of important solid-state properties, methods, and applications of solid-state analysis Illustrates the various phases or forms that solids can assume and discusses various issues related to the relative stability of solid forms and tendencies to undergo transformation Covers key methods of solid state analysis including X-ray powder diffraction, thermal analysis, microscopy, spectroscopy, and solid state NMR Reviews critical physical attributes of pharmaceutical materials,

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mainly related to drug substances, including particle size/surface area, hygroscopicity, mechanical properties, solubility, and physical and chemical stability Showcases the application of solid state material science in rational selection of drug solid forms, analysis of various solid forms within drug substance and the drug product, and pharmaceutical product development Introduces appropriate manufacturing and control procedures using Quality by Design, and other strategies that lead to safe and effective products with a minimum of resources and time

Due to a worldwide need for lower cost drug therapy, use of generic and multi-source drug products have been increasing. To meet international patent and trade agreements, the development and sale of these products must conform to national and international laws, and generic products must prove that they are of the same quality and are therapeutically equivalent to the brand name alternative. However, many countries have limited resources to inspect and verify the quality of all drug products for sale in their country. This title discusses the worldwide legislative and regulatory requirements for the registration of generic and multi-source drug products.

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.

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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

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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  $\sim 0.3$ . 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. This book covers the essentials of drug delivery research and provides a unique forum for scientific experimental methods that are exclusively focused by the in-vitro, ex-vivo, and in-vivo methodologies of drug delivery research and felicitates translational research. The book includes recent and novel approaches in evaluation methods of transdermal, nasal, ocular, oral and intraoral, gastro-retentive, colon-targeted, and brain-targeted drug delivery systems. Providing up to date and comprehensive information, this text is invaluable to students, teachers, scientists, and others employed in the field of drug delivery.

Pharmaceutics is one of the most diverse subject areas in all of pharmaceutical science. In brief, it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms or medicines. An understanding of pharmaceutics is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely, effectively and conveniently to the patient. Now in its fourth edition, this best-selling textbook in pharmaceutics has been brought completely up to date to reflect the rapid advances in delivery methodologies by eye and injection, advances in

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drug formulations and delivery methods for special groups (such as children and the elderly), nanomedicine, and pharmacognosy. At the same time the editors have striven to maintain the accessibility of the text for students of pharmacy, preserving the balance between being a suitably pitched introductory text and a clear reflection of the state of the art. provides a logical, comprehensive account of drug design and manufacture includes the science of formulation and drug delivery designed and written for newcomers to the design of dosage forms New to this edition New editor: Kevin Taylor, Professor of Clinical Pharmaceutics, School of Pharmacy, University of London. Twenty-two new contributors. Six new chapters covering parenteral and ocular delivery; design and administration of medicines for the children and elderly; the latest in plant medicines; nanotechnology and nanomedicines, and the delivery of biopharmaceuticals. Thoroughly revised and updated throughout.

A one-stop resource for researchers, developers, and post graduate students in pharmaceutical science. This handbook and ready reference provides detailed, but not overloaded information -- presenting the topic without unnecessarily complex formalism. As such, it gives a systematic and coherent overview of disordered materials for pharmaceutical applications, covering fundamental

aspects, as well as preparation and characterization techniques for the target-oriented development of drug delivery systems based on disordered crystals and amorphous solids. Special attention is paid to examine the different facets and levels of disorder in their structural and dynamic aspects as well as the effect of disorder on dissolution and stability.

Chapters on processing induced disorder and on patenting issues round off the book. As a result the book helps overcoming the challenges of using these materials in the pharmaceutical industry. For pharmaceutical and medicinal chemists, materials scientists, clinical physicists, and pharmaceutical laboratories looking to make better and more potent pharmaceuticals.

Drug Delivery Systems examines the current state of the field within pharmaceutical science and concisely explains the history of drug delivery systems, including key developments. The book translates the physicochemical properties of drugs into drug delivery systems administered via various routes, such as oral, parenteral, transdermal and inhalational. Regulatory and product development topics are also explored. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of drug delivery systems within the pharmaceutical sciences industry and research, as well as in chemical engineering. Each chapter

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delves into a particular aspect of this fundamental field to cover the principles, methodologies and technologies employed by pharmaceutical scientists. This book provides a comprehensive examination that is suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnologies, and related industries. Provides up-to-date information on how to translate the physicochemical properties of drugs into drug delivery systems Explores how drugs are administered via various routes, such as oral, parenteral, transdermal and inhalational Contains extensive references and further reading for course and self-study

The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation,

cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures

and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

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