In Vitro Dissolution Testing For Solid Oral Dosage Forms

Pharmaceutical Product Development
Biopharmaceutics Applications in Drug Development
Toward Biopredictive Dissolution Testing of BCS Class II Acids
Handbook of Bioequivalence Testing
clozapine tables, in vivo bioequivalence and in vitro dissolution testing
Media for in Vitro Dissolution Testing of Polysaccharide Based CDDS
Isolation, Biological and Biomedical Applications
In Vitro-In Vivo Correlation
In-vitro In-vivo Correlation Developed Using a Biorelevant In-vitro Dissolution Test in the Prediction of In-vivo Pharmacokinetic Parameters for the Treatment of Multiple Sclerosis
Pharmacokinetic and Pharmacodynamic Data Analysis: Concepts and Applications, Third Edition
Development and Validation of Analytical Methods
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Guidance for Conducting In-vivo Bioequivalence Study and In-vitro Dissolution Testing on Clonidine Hydrochloride Drug Products
Nonclinical Statistics for Pharmaceutical and Biotechnology Industries
Activities of the AAPS In Vitro Release and Dissolution Testing Focus Group
SUPAC-MR : modified release solid oral dosage forms : scale-up and postapproval changes, chemistry, manufacturing and controls, in vitro dissolution testing and in vivo bioequivalence documentation
Guidance for Industry
Drug Delivery Systems

Generic Drug Product Development
In Vitro Drug Release Testing of Special Dosage Forms
Guidance for industry
Prediction and Assessment, Second Edition
Poorly Soluble Drugs
Guidance for industry
Dissolution of Disintegrating Solid Dosage Forms in a Modified Dissolution Testing Apparatus 2
Pharmaceutical Theory and Practice
Pharmaceutical Dissolution Testing
In Vitro Drug Release Testing of Special Dosage Forms
Development of in Vitro Dissolution Test for Dihydroartemisinin Capsules
Guidance for in Vivo Bioequivalence Study and in Vitro Dissolution Testing on Metaproterenol Sulfate Tablets
Seaweed Polysaccharides
A TOOL TO EVALUATE AMORPHOUS SOLID DISPERSION PERFORMANCE
Science, Applications, and Beyond
Dissolution, Bioavailability & Bioequivalence

MAURICE WALKER

Pharmaceutical Product Development John Wiley & Sons
The pharmaceutical industry is at a critical juncture. With little remnants of the "Golden Age of the Pharmaceuticals" and applied pressure from large companies experiencing a dissipation of proprietary compounds, trends indicate a transition from a decade of stagnant productivity to one in which high throughput screening technologies and computational chemistry have diversified the discovery of new chemical entities (NCE). Despite these advances, drug discovery has been challenged by chemical entities that present delivery limitations due to the properties of their molecular structure. A recent evaluation of development pipelines indicated that approximately 70% of drug candidates exhibit poor aqueous solubility; thereby, resulting in erratic dissolution and insufficient bioavailability. Due to intrinsic physical properties, these compounds are known by the biopharmaceutics classification system (BCS) as class II compounds and are amendable to solubility and bioavailability enhancement platforms. Approaches such as pH adjustment, micronization, nanosuspensions, co-solvent solubilization, cyclodextrin

inclusion complexation, salt formation, emulsified drug formulations and amorphous solid dispersions (ASD) are commonly utilized to maximize bioavailability and enrich in vivo absorption by prolonging exposure to high concentrations of dissolved drug in the gastrointestinal tract (GIT). Single-phase amorphous systems, such as solid dispersions, have been the focal point of the aforementioned practices as a result of their ability to promote a state of drug supersaturation over an extended duration of time. Within the structure of this dissertation, the application of concentration enhancing polymers for bioavailability enhancement of low solubility compounds was evaluated using solvent and fusion-based solid dispersion technologies. Exploiting a variety of analytical methodologies and tools, formulations produced by spray drying and hot melt extrusion (HME) techniques were investigated for sufficient dissolution enhancement. Studies revealed the selected formulation approaches provided a viable platform for manufacturing solid dispersions by illustrating systems that offered rapid and prolonged periods of supersaturation. While of the applications of single-phase amorphous solid dispersions are continuously expanding, their dissolution behavior is not as well understood. The overarching objective of dissolution testing during formulation development is to achieve biological relevance and predict in vivo performance. Proper in vitro dissolution testing can convey the influence of key in vivo performance parameters and be implemented for assessment and comparison of ASD formulations. Studies suggest that existing research fails to accurately address the intricacies associated with the supersaturated state. Upon solvation and during transit in the GIT, several high-energy drug-containing species are present in addition to free drug. Although these species are not absorbed in vivo, they play a pivotal role in generating and maintaining the supersaturation of a drug substance and function to replenish the supply of free drug as it permeates across the gastrointestinal membrane. Established dissolution apparatuses and methodologies in the United States Pharmacopeia (USP) focus on evaluation of total dissolved drug and may not be physiologically relevant for determining the amount of drug absorbed in vivo. Within the framework of this dissertation, a dissolution methodology was designed to reflect the physiochemical, physiological and hydrodynamic conditions that transpire throughout dissolution and absorption of an ASD during transit in the GIT. The apparatus and model present the ability to understand the kinetics and mechanisms of dissolution, supersaturation and nucleation. To support this hypothesis, analytical methods including high pressure liquid chromatography (HPLC) with ultraviolet (UV) detection were developed and fully validated. In parallel, a novel plasma membrane treatment was established to fabricate biomimetic membranes that possessed a hydrophilic and hydrophobic surface. The treated membranes are comprised of applied surface chemistries that emulate the unstirred aqueous layer created by microvilli protruding from the intestinal epithelial membrane as well as lipophilic constituents corresponding to the epithelial lipid membrane. Calculated in vitro similarity (f2) and difference (f1)

factors support the hypotheses that plasma treated microporous polymer membranes exhibit biorelevant properties and demonstrate adequate biorelevance for in vitro dissolution studies. The described dissolution methodology has been applied as a tool for selection of candidates to move forward to pharmacokinetic studies. In a culminating study, in vitro - in vivo correlations (IVIVC) were performed employing the universal membrane-permeation non-sink dissolution method for formulations of Carbamazepine. To demonstrate the utility of the methodology, multiple level C correlations were established. The membrane-permeation model enables quantitative assessment of drug dissolution and absorption and offers a means to predict the relative in vivo performance of amorphous solid dispersions for BCS class II drug substances.

Biopharmaceutics Applications in Drug Development Academic Press
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 Sep tember, 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 com pany 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 Not tingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. lain Cumming, Elan Corporation Dr. John Devane, Elan Corporation Dr. Adrian Dunne, University College Dublin Dr. Stuart Madden, Elan Corporation Dr. Colin Melia, University of Nottingham Mr. Tom O'Hara, Elan Corporation Dr. Deborah Piscitelli, University of Maryland at Baltimore Dr. Araz Raoof, Elan Corporation Mr. Paul Stark, Elan Corporation Dr. David Young, University of Maryland at Baltimore The purpose of the workshop was to discuss new concepts and methods in the devel opment of in vitro-in vivo relationships for ER products. The original idea went back ap proximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development.

Toward Biopredictive Dissolution Testing of BCS Class II Acids CRC Press
Guides readers on the proper use of in vitro drug release methodologies in order to evaluate the performance of special dosage forms In the last decade, the application of drug release testing has widened to a variety of novel/special dosage forms. In order to predict the in vivo behavior of such dosage forms, the design and development of the in vitro test methods need to take into account various aspects, including the dosage form design and the conditions at the site of application and the site of drug release. This unique book is the first to cover the field of in vitro release testing of special dosage forms in one volume. Featuring contributions from an international team of experts, it presents the state of the art of the use of in vitro drug release methodologies for assessing special

dosage forms' performances and describes the different techniques required for each one. In Vitro Drug Release Testing of Special Dosage Forms covers the in vitro release testing of: lipid based oral formulations; chewable oral drug products; injectables; drug eluting stents; inhalation products; transdermal formulations; topical formulations; vaginal and rectal delivery systems and ophthalmics. The book concludes with a look at regulatory aspects. Covers both oral and non-oral dosage forms Describes current regulatory conditions for in vitro drug release testing Features contributions from well respected global experts in dissolution testing In Vitro Drug Release Testing of Special Dosage Forms will find a place on the bookshelves of anyone working with special dosage forms, dissolution testing, drug formulation and delivery, pharmaceutics, and regulatory affairs.

Handbook of Bioequivalence Testing Pharmaceutical Dissolution Testing Seaweed Polysaccharides: Isolation, Biological, and Biomedical Applications examines the isolation and characterization of algal biopolymers, including a range of new biological and biomedical applications. In recent years, significant developments have been made in algae-based polymers (commonly called polysaccharides), and in biomedical applications such as drug delivery, wound dressings, and tissue engineering. Demand for algae-based polymers is increasing and represent a potential—very inexpensive—resource for these applications. The structure and chemical modification of algal polymers are covered, as well as the biological properties of these materials – including antithrombic, anti-inflammatory, anticoagulant, and antiviral aspects. Toxicity of algal biopolymers is also covered. Finally, the book introduces and explains real world applications of algal-based biopolymers in biomedical applications, including tissue engineering, drug delivery, and biosensors. This is the first book to cover the extraction techniques, biomedical applications, and the economic perspective of seaweed polysaccharides. It is an essential text for researchers and industry professionals looking to work with this renewable resource. Provides comprehensive coverage of the research currently taking place in biomedical applications of algae biopolymers Includes practical guidance on the isolation, extraction, and characterization of polysaccharides from sustainable marine sources Covers the extraction techniques, biomedical applications, and economic outlook of seaweed polysaccharides

clozapine tables, in vivo bioequivalence and in vitro dissolution testing 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.

Media for in Vitro Dissolution Testing of Polysaccharide Based CDDS Springer Science & Business Media

1. Evolution of dissolution testing 5; 2. Theory of dissolution 11; 3. Theoretical concepts for the release of a drug from dosage forms 37; 4. Effect of the physicochemical properties of the drug on dissolution rate 53; 5. Factors affecting the rate of dissolution of solid dosage forms 73; 6. Effects of storage and packaging on the dissolution of drug formulations 107; 7. Factors relating to the dissolution apparatus 115; 8. Effect of the test parameters on dissolution rate 145; 9. Dissolution of suspensions 173; 10. Dissolution of topical dosage forms (creams, gels, and ointments) 189; 11. Dissolutions of suppositories 205; 12. Dissolution characteristics of controlled-release systems 215; 13. Methods for enhancement of the drug-dissolution characteristics 265; 14. Developing a new dissolution method 285; 15. Bioavailability, definitions and historical perspective 297; 17. In vitro modeling for drug absorption 315; 18. Pharmacokinetic considerations in bioavailability studies 335; 19. Bioavailability and variations in drug blood levels 367; 20. Bioavailability and the biologic response 385; 21. Measurements of bioavailability 399; 22. General issues to be considered in conducting bioavailability studies 415; 23. Bioavailability of controlled-release dosage forms 425; 24. In vivo release and bioavailability of topical preparations 437; 25. Methods for enhancement of bioavailability 455; 26. Bioequivalence: general definitions 477; 27. Bioequivalence: case histories 481; 28. Correlation of in vitro rate of dissolution with in vivo bioavailability 491; 29. Determination of bioequivalence and its regulatory aspects 517; 30. The official bioequivalence protocols and therapeutic equivalence 533.

Isolation, Biological and Biomedical Applications Elsevier

For inhalation drug products, the site of deposition in the lungs is assumed to be the most essential factor to control the clinical performance. Therefore, delivering the active pharmaceutical ingredient from the inhalation device to the targeted site is the only concern of the regulatory affairs. -- However, inhaled particles have to undergo dissolution in the lung fluid before being available for absorption. This implies that the dissolution kinetics of the inhaled particles might have an effect on the therapeutic action. -- The lung fluid where dissolution occurs is one of critical factors that govern the dissolution process of the inhaled particles. Therefore, identifying the lung fluid composition is very essential during the in-vitro dissolution testing. -- The in-vitro dissolution testing can be used for different quality measures. However, it can also be employed to predict the in-vivo dissolution rate of various inhaled

products, therefore, determine if the dissolution in the lung fluid is the rate limiting step for absorption or not. -- Hence, this thesis will be focusing on defining the various lung fluids and their importance regarding the dissolution process. Also, factors affecting dissolution in the lung fluid will be discussed and finally, developing an in-vitro dissolution system based upon what will be explained throughout the research.

In Vitro-In Vivo Correlation Frontiers Media SA

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.

In-vitro In-vivo Correlation Developed Using a Biorelevant In-vitro Dissolution Test in the Prediction of In-vivo Pharmacokinetic Parameters for the Treatment of Multiple Sclerosis Wiley-Blackwell

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

Pharmacokinetic and Pharmacodynamic Data Analysis: Concepts and Applications, Third 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

Development and Validation of Analytical Methods Academic Press

This is a revised and very expanded version of the previous second edition of the book. "Pharmacokinetic and Pharmacodynamic Data Analysis" provides an introduction into pharmacokinetic and pharmacodynamic concepts using simple illustrations and reasoning. It describes ways in which pharmacodynamic and pharmacodynamic theory may be used to give insight into modeling questions and how these questions can in turn lead to new knowledge. This book differentiates itself from other texts in this area in that it bridges the gap between relevant theory and the actual application of the theory to real life situations. The book is divided into two parts; the first introduces fundamental principles of PK and PD concepts, and principles of mathematical modeling, while the second provides case studies obtained from drug industry and academia. Topics included in the first part include a discussion of the statistical principles of model fitting, including how to assess the adequacy of the fit of a model, as well as strategies for selection of time points to be included in the design of a study. The first part also introduces basic pharmacokinetic and pharmacodynamic concepts, including an excellent discussion of effect compartment (link) models as well as indirect response models. The second part of the text includes over 70 modeling case studies. These include a discussion of the selection of the model, derivation of initial parameter estimates and interpretation of the corresponding output. Finally, the authors discuss a number of pharmacodynamic modeling situations including receptor binding models, synergy, and tolerance models (feedback and precursor models). This book will be of interest to researchers, to graduate students and advanced undergraduate students in the PK/PD area who wish to learn how to analyze biological data and build models and to become familiar with new areas of application. In addition, the text will be of interest to toxicologists interested in learning about determinants of exposure and performing toxicokinetic modeling. The inclusion of the numerous exercises and models makes it an excellent primary or adjutant text for traditional PK courses taught in pharmacy and medical schools. A diskette is included with the text that includes all of the exercises and solutions using WinNonlin.

Clinically Relevant in Vitro Dissolution/release Testing for Parenteral Formulations CRC Press

As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct efficient and successful bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence, and advances in the analytical technology used to detect drug and metabolite levels have made

Dosage Form Design Considerations CRC Press

Explore the cutting-edge of dissolution testing in an authoritative, one-stop resource In Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence: Science, Applications, and Beyond, distinguished pharmaceutical

advisor and consultant Dr. Umesh Banakar delivers a comprehensive and up-to-date reference covering the established and emerging roles of dissolution testing in pharmaceutical drug development. After discussing the fundamentals of the subject, the included resources go on to explore common testing practices and methods, along with their associated challenges and issues, in the drug development life cycle. Over 19 chapters and 1100 references allow practicing scientists to fully understand the role of dissolution, apart from mere quality control. Readers will discover a wide range of topics, including automation, generic and biosimilar drug development, patents, and clinical safety. This volume offers a one-stop resource for information otherwise scattered amongst several different regulatory regimes. It also includes: A thorough introduction to the fundamentals and essential applications of pharmaceutical dissolution testing Comprehensive explorations of the foundations and drug development applications of bioavailability and bioequivalence Practical discussions about solubility, dissolution, permeability, and classification systems in drug development In-depth examinations of the mechanics of dissolution, including mathematical models and simulations An elaborate assessment of biophysiologically relevant dissolution testing and IVIVCs, and their unique applications A complete understanding of the methods, requirements, and global regulatory expectations pertaining to dissolution testing of generic drug products Ideal for drug product development and formulation scientists, quality control and assurance professionals, and regulators, Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence is also the perfect resource for intellectual property assessors.

Improvements to biorelevant dissolution testing: lyophilized media, buffer alternatives and miniaturized apparatus Springer Science & Business Media

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

Immediate Release Solid Oral Dosage Forms : Scale-up and Postapproval Changes, Chemistry, Manufacturing and Controls, in Vitro Dissolution Testing, and in Vivo Bioequivalence Documentation CRC Press

During the last two decades, the pharmaceutical industry has been under pressure to reduce development costs and the time needed to bring drugs to market in order to maximize return on investment and bring treatments to patients sooner. To meet these ends, pharmaceutical scientists working in the differing areas of pharmacy, pharmaceutics, and phar

US-FDA Bioequivalence Guidance CRC Press

Dissolution tests are routinely carried out in the pharmaceutical industry to determine the dissolution rate of solid dosage forms. Dissolution testing serves as a surrogate for drug bioavailability through in vitro–in vivo correlation (IVIVR), and it additionally helps in guiding the development of new formulations and in assessing lot-to-lot consistency, thus

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

Solid Oral Dosage Forms, Second Edition Springer

Pharmaceutical Dissolution TestingCRC Press

Guidance for Conducting In-vivo Bioequivalence Study and In-vitro Dissolution Testing on Clonidine Hydrochloride Drug Products 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.
Nonclinical Statistics for Pharmaceutical and Biotechnology Industries Cuvillier Verlag
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.

John Wiley & Sons

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.