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KEY=DISSOLUTION - MELISSA OROZCO

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.

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.

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.

The Japanese Pharmacopoeia

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

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.

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

Dissolution, Bioavailability & Bioequivalence

Mack Publishing Company 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.

Aulton's Pharmaceutics

The Design and Manufacture of Medicines

Elsevier Health Sciences 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 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.

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.

Dissolution Theory, Methodology, and Testing

A Microwave System for the Acid Dissolution of Metal and Mineral Samples

In Vitro-In Vivo Correlations

Springer Science & Business Media 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.

Pulmonary Drug Delivery

Advances and Challenges

John Wiley & Sons Drug therapy via inhalation route is at the cutting edge of modern drug delivery research. There has been significant progress on the understanding of drug therapy via inhalation products. However, there are still problems associated with their formulation design, including the interaction between the active pharmaceutical ingredient(s) (APIs), excipients and devices. This book seeks to cover some of the most pertinent issues and challenges of such formulation design associated with industrial production

and desirable clinical outcome. The chapter topics have been selected with a view to integrating the factors that require consideration in the selection and design of device and formulation components which impact upon patient usability and clinical effectiveness. The challenges involved with the delivery of macromolecules by inhalation to both adult and pediatric patients are also covered. Written by leading international experts from both academia and industry, the book will help readers (formulation design scientists, researchers and post-graduate and specialized undergraduate students) develop a deep understanding of key aspects of inhalation formulations as well as detail ongoing challenges and advances associated with their development.

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

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.

Applied Physical Pharmacy

McGraw Hill Professional Designed as the core textbook for the required physical pharmacy or pharmaceutics course within the pharmacy school curriculum. With a focus on examples from pharmacy practice, this book presents the chemical and physical chemical principles fundamental to the development of medication dosage forms. Numerous case studies present relevant examples of physical chemical principles in current pharmacy practice.

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.

Handbook of Bioequivalence Testing

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

Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence

Science, Applications, and Beyond

John Wiley & Sons 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.

Comprehensive Medicinal Chemistry II, Vol 8

CASE HISTORIES AND CUMULATIVE SUBJECT INDEX

Elsevier Science Limited This e-book comprises 8 volumes, with all chapter sections available as PDF or HTML, and includes bibliographical references and index.

Biopharmaceutics

From Fundamentals to Industrial Practice

John Wiley & Sons Explore the latest research in biopharmaceutics from leading contributors in the field In Biopharmaceutics - From Fundamentals to Industrial Practice, distinguished Scientists from the UK's Academy of Pharmaceutical Sciences Biopharmaceutica Focus Group deliver a comprehensive examination of the tools used within the field of biopharmaceutics and their applications to drug development. This edited volume is an indispensable tool for anyone seeking to better understand the field of biopharmaceutics as it rapidly develops and evolves. Beginning with an expansive introduction to the basics of biopharmaceutics and the context that underpins the field, the included resources go on to discuss how biopharmaceutics are integrated into product development within the pharmaceutical industry. Explorations of how the regulatory aspects of biopharmaceutics function, as well as the impact of physiology and anatomy on the rate and extent of drug absorption, follow. Readers will find insightful discussions of physiologically based modeling as a valuable asset in the biopharmaceutics toolkit and how to apply the principles of the field to special populations. The book goes on to discuss: Thorough introductions to biopharmaceutics, basic pharmacokinetics, and biopharmaceutics measures Comprehensive explorations of solubility, permeability, and dissolution Practical discussions of the use of biopharmaceutics to inform candidate drug selection and optimization, as well as biopharmaceutics tools for rational formulation design In-depth examinations of biopharmaceutics classification systems and regulatory biopharmaceutics, as well as regulatory biopharmaceutics and the impact of anatomy and physiology Perfect for professionals working in the pharmaceutical and biopharmaceutical industries, Biopharmaceutics - From Fundamentals to Industrial Practice is an incisive and up-to-date resource on the practical, pharmaceutical applications of the field.

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

Modern Pharmaceutics

CRC Press "Completely revised and expanded throughout. Presents a comprehensive integrated, sequenced approach to drug dosage formulation, design, and evaluation. Indentifies the pharmacodynamic and physicochemical factors influencing drug action through various routes of administration."

Research and Development Abstracts of the USAEC.

Technical Progress Report

EDRO research reports

Biopharmaceutics Applications in Drug Development

Springer Science & Business Media 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.

Novel Formulation Strategies with a Mechanistic Approach to Improving the Dissolution of a Poorly Water-soluble Drug

The intrinsic cohesive nature of micronized poorly water-soluble drug particles often promotes the formation of drug agglomerates with reduced surface areas for dissolution. The objective of this thesis was to investigate novel and innovative formulation strategies to improve the de-agglomeration behaviour and in vitro dissolution rate of a micronized model poorly water-soluble drug, indomethacin. In the first approach, various micronized poorly water-soluble excipients (including aluminium hydroxide, barium sulphate, calcium phosphate and calcium sulphate) were incorporated into lactose-based indomethacin interactive mixtures. In the second approach, the indomethacin powders were mechanically dry coated (by mechanofusion) with force control agents (such as magnesium and sodium stearate). Mathematical modelling approaches were explored using multi-exponential and mechanism-based models in order to gain an insight into the de-agglomeration and dissolution mechanisms.Dissolution of the various mixtures and coated powders of indomethacin was conducted with an automated dissolution apparatus (Erweka DT6, Germany) using the USP paddle method in buffered media at pH 5.0 under sink conditions. Dissolution data were modelled with multi-exponential equations via the standard-two-stage (STS) estimation method and mechanism-based models were developed by population estimation methods in S-ADAPT. Particle size distributions of the raw materials, interactive mixtures and coated powders were measured by laser diffraction using the Mastersizer S (Malvern Instruments Ltd., UK). The dispersion of indomethacin mixtures was measured by laser diffraction in dissolution media under non-sink conditions. The addition of cohesive aluminium hydroxide and calcium phosphate (10% each) to binary lactose-based interactive mixtures of 10% indomethacin was found to counter-intuitively and significantly increase the dissolution rate of indomethacin. The improvements in dissolution for these ternary mixtures were unrelated to pH effects but associated with the ability of the poorly water-soluble excipients to facilitate the de-agglomeration of indomethacin agglomerates. Multi-exponential modelling revealed increases in the estimated initial concentration (Cd) and dissolution rate constant (kd) of dispersed indomethacin particles upon addition of the cohesive additives to the binary mixtures. Dissolution of indomethacin was found to increase as a function of the concentration of aluminium hydroxide (5-20%) added to the binary mixtures. Where three particle size fractions of aluminium hydroxide (with significantly different D90 sizes) were used, increasing the proportion of larger particles of the aluminium hydroxide increased the dissolution rate of indomethacin. Modelling revealed increases in the kd for the ternary 5-20% aluminium hydroxide mixtures compared with the binary mixture, indicating larger exposed surface areas of dispersed indomethacin particles to the dissolution medium; Cd increased with both the concentration and particle size of the added aluminium hydroxide to the mixtures. Monitoring the extent of particle dispersion over time in dissolution media under non-sink conditions demonstrated an increasing trend in dispersion during the first 12 minutes for the ternary mixtures containing 5-15% aluminium hydroxide; however, no change in the degree of dispersion was observed for the mixture incorporating micronized aluminium hydroxide particles. The underlying mechanisms of dissolution were elucidated and quantified by development of a mechanism-based compartmental model. A series of 5 transit compartments included into the model successfully described the slow initial dissolution rate of the indomethacin mixtures. More importantly, this indicated that agglomerates had inter-converted to dispersed particles; the mean dissolution time of the dispersed particles decreased with the addition of aluminium hydroxide to the binary mixtures. For the ternary mixtures incorporating at least 10% aluminium hydroxide, the faster dissolution was attributed to lower mean de-agglomeration times and reduced initial concentrations of agglomerates compared with the binary mixture. This supported the

hypothesized phenomenon of the role of aluminium hydroxide in enhancing the de-agglomeration of cohesive indomethacin powders. Dry coating micronized powders of indomethacin with magnesium stearate (0.25, 1, 5%) and sodium stearate (5%) by mechanofusion resulted in significantly reduced intrinsic cohesion. Initial increases in the dissolution of indomethacin were found to be dependent on the concentration of magnesium stearate that was mechanofused onto the drug powders; X-ray photoelectron spectroscopy analysis confirmed a thicker surface coating was achieved with increasing concentrations of the hydrophobic material. The dissolution enhancing effect of the indomethacin powders mechanofused with 5% sodium stearate was attributed to its surfactant properties that increased the dispersion of indomethacin agglomerates. Initial drug release (during the first 10 minutes of the dissolution study) from the coated powders was able to be described by a matrix-diffusion system in accordance with the Higuchi model. Application of these novel and innovative formulation strategies which demonstrated enhanced dissolution of indomethacin would greatly benefit in the development of poorly water-soluble drug formulations with potentially improved oral bioavailability.

Quality evaluation of Different Sulbutamol Tablets

Lulu.com

Applied Biopharmaceutics & Pharmacokinetics, Fifth Edition

McGraw Hill Professional The most comprehensive text on the practical applications of biopharmaceuticals and pharmacokinetics! 4 STAR DOODY'S REVIEW! "The updated edition provides the reader with a solid foundation in the basic principles of pharmacokinetics and biopharmaceutics. Students will be able to apply the information to their clinical practice and researchers will find this to be a valuable reference. This modestly priced book should be the gold standard for student use."--Doody's Review Service The primary emphasis of this book is on the application and understanding of concepts. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided, along with illustrative examples and practice problems and solutions to help the student gain skill in practical problem solving.

Bentley's Textbook of Pharmaceutics - E-Book

Elsevier Health Sciences This adaptation of Bentley's Textbook of Pharmaceutics follows the same goals as those of the previous edition, albeit in a new look. The content of the old edition has been updated and expanded and several new chapters, viz. Complexations, Stability Testing as per ICH Guidelines, Parenteral Formulations, New Drug Delivery Systems and Pilot Plant Manufacturing, have been included, with an intention to make the book more informative for the modern pharmacists. The book has six sections: Section I deals with the physicochemical principles. Two new chapters: Complexations and ICH Guidelines for Stability Testing, have been added to make it more informative. Section II conveys the information regarding pharmaceutical unit operations and processes. Section III describes the area of pharmaceutical practice. Extensive recent updates have been included in many chapters of this section. Two new chapters: Parenteral Formulations and New Drug Delivery Systems, have been added. Section IV contains radioactivity principles and applications. Section V deals with microbiology and animal products. Section VI contains the formulation and packaging aspects of pharmaceuticals. Pilot Plant Manufacturing concepts are added as a new chapter, which may be beneficial to readers to understand the art of designing of a plant from the pilot plant model.

The Quality Control of Medicines

Proceedings of the 35th International Congress of Pharmaceutical Sciences, Dublin, 1975

Elsevier The Quality Control of Medicines documents the proceedings of the 35th International Congress of Pharmaceutical Sciences, organized by the Pharmaceutical Society of Ireland on behalf of the Federation Internationale Pharmaceutique, held in Dublin, on 1-5 September 1975. The theme chosen for the Congress was ""the basis for the quality control of medicines"", because of the importance and relevance of quality control in the production and distribution of medicines at national and international levels. This volume is arranged according to the manner in which the theme of the Congress was developed by the eminent invited speakers. Following the inaugural address a main symposium was held where five speakers presented a review of the quality control of medicines under the general headings of (i) chemical and physical aspects; (ii) biological aspects; (iii) control of drug delivery systems; (iv) storage problems; and (v) problems of international control. Certain aspects of the content of the main symposium were then developed in greater depth in parallel symposia. In the first parallel symposium some novel physicochemical aspects of the quality control of medicines were treated under the headings of spectrofluorimetry, mass spectrometry, detection in gas chromatography, and automation in pharmaceutical analysis. The second parallel symposium developed certain microbiological aspects of quality control under the headings of sterility testing and microbiological control of non-sterile products and ophthalmic preparations. The final symposium on submissions to regulatory bodies and international aspects of drug control covered aspects of politics in submissions, regulatory problems in small countries, and various pharmacopoeial problems.

Report of Investigations

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

Pulmonary Drug Delivery

Advances and Challenges

John Wiley & Sons Drug therapy via inhalation route is at the cutting edge of modern drug delivery research. There has been significant progress on the understanding of drug therapy via inhalation products. However, there are still problems associated with their formulation design, including the interaction between the active pharmaceutical ingredient(s) (APIs), excipients and devices. This book seeks to cover some of the most pertinent issues and challenges of such formulation design associated with industrial production and desirable clinical outcome. The chapter topics have been selected with a view to integrating the factors that require consideration in the selection and design of device and formulation components which impact upon patient usability and clinical effectiveness. The challenges involved with the delivery of macromolecules by inhalation to both adult and pediatric patients are also covered. Written by leading international experts from both academia and industry, the book will help readers (formulation design scientists, researchers and post-graduate and specialized undergraduate students) develop a deep understanding of key aspects of inhalation formulations as well as detail ongoing challenges and advances associated with their development.

Applied Physical Pharmacy, Third Edition

McGraw Hill Professional Publisher's Note: Products purchased from Third Party sellers are not guaranteed by the publisher for quality, authenticity, or access to any online entitlements included with the product. A complete practice-oriented introduction to physical pharmacy Written to clearly and simply explain how drugs work, this textbook explores the fundamental physicochemical attributes and processes important for understanding how a drug is transformed into a usable product that is administered to a patient to reach its pharmacological target, and then exists the body. Applied Physical Pharmacy, Third Edition begins with a review of the key biopharmaceutics concepts of drug liberation, absorption, distribution, metabolism, and excretion. These concepts, and others, set the framework for the subsequent chapters that describe physicochemical properties and process related to the fate of the drug. Other physical pharmacy topics important to drug formulation are discussed in the chapters that follow, which describe dispersal systems, interfacial phenomena, and rheology. The textbook concludes with an overview of the principles of kinetics that are important for understanding the rates at which many of the processes discussed in previous chapters occur. Chapters in this Third Edition retain the acclaimed learning aids of previous editions, including Learning Objectives, Practice Problems, Key Points, and Clinical Questions. In order to be of greater value to the pharmacy student, more clinical questions have been added, and many tables have been updated with more current products and excipients.

Pharmaceutical Experimental Design

CRC Press This useful reference describes the statistical planning and design of pharmaceutical experiments, covering all stages in the development process-including preformulation, formulation, process study and optimization, scale-up, and robust process and formulation development.Shows how to overcome pharmaceutical, technological, and economic constraint

10 Books that Screwed Up the World

And 5 Others That Didn't Help

Simon and Schuster You've heard of the "Great Books"? These are their evil opposites. From Machiavelli's The Prince to Karl Marx's The Communist Manifesto to Alfred Kinsey's Sexual Behavior in the Human Male, these "influential" books have led to war, genocide, totalitarian oppression, family breakdown, and disastrous social experiments. And yet these authors' bad ideas are still popular and pervasive--in fact, they might influence your own thinking without your realizing it. Here with the antidote is Professor Benjamin Wiker. In his scintillating new book, 10 Books That Screwed Up the World (And 5 Others That Didn't Help), he seizes each of these evil books by its malignant heart and exposes it to the light of day.

Practical guide of biopharmaceutics and pharmacokinetics for B.pharm students

Blue Rose Publishers This book is prepared to cover the practicals of biopharmaceutics and pharmacokinetics to be performed during the B.Pharm curriculum. The practicals cover different topics of biopharmaceutics and pharmacokinetics related to analysis of pharmacokinetic parameters by different methods. The special emphasis is given on the procedure of practicals which will be helpful for the teachers as well as students with greater ease of understanding the concepts of biopharmaceutics and pharmacokinetics. Many books are available which deal with theoretical aspects of the subject but very few such books are available that deal with practical aspects. So this book will be very helpful to the academicians as well as the industry in understanding the concepts of biopharmaceutics and pharmacokinetics. This book is written in simple language to help in understanding the concepts of biopharmaceutics and pharmacokinetics.