Preformulation In Solid Dosage Form Development Drugs And The Pharmaceutical Sciences

This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the

Essentials of Pharmaceutical Preformulation is a study guide which describes the basic principles of pharmaceutical physicochemical characterisation. Successful preformulation requires knowledge of fundamental molecular concepts (solubility, ionisation, partitioning, hygroscopicity and stability) and macroscopic properties (physical form, such as the crystalline and amorphous states, hydrates, solvates and co-crystals and powder properties), familiarity with the techniques used to measure them and appreciation of their effect on product performance, recognising that often there is a position of compromise to be reached between product stability and bioavailability. This text introduces the basic concepts and discusses their wider implication for pharmaceutical development, with reference to many case examples of current drugs and drug products. Special attention is given to the principles and best-practice of the analytical techniques that underpin preformulation (UV spectrophotometry, TLC, DSC, XRPD and HPLC). The material is presented in the typical order that would be followed when developing a medicine and maps onto the indicative pharmacy syllabus of the Royal Pharmaceutical Society of Great Britain Undergraduate-level pharmacy students and R&D / analytical scientists working in the pharmaceutical sector (with or without a pharmaceutical background) will find this text easy to follow with relevant pharmaceutical examples. Essential study guide for pharmacy and pharmaceutical science students Covers the pharmaceutical preformulation components of the Royal Pharmaceutical Society of Great Britain’s indicative syllabus Easy to follow text highlighted with relevant pharmaceutical examples Self-assessment assignments in a variety of formats Written by authors with both academic and industrial experience Companion website with further information to maximise learning

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

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 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.

Preformulation in Solid Dosage Form DevelopmentCRC Press

This handbook features contributions from a team of expert authors representing

the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.
Preformulation studies are the physical, chemical, and biological studies needed to characterize a drug substance for enabling the proper design of a drug product, whereas the effectiveness of a drug product is determined during the formulation studies phase. Though the two disciplines overlap in practice, each is a significantly distinct phase of

Although the official compendia define a drug substance as to identity, purity, strength, and quality, they normally do not provide other physical or chemical data, nor do they list methods of synthesis or pathways of physical or biological degradation and metabolism. Such information is scattered throughout the scientific literature and the files of pharmaceutical laboratories. Edited by the Associate Director of Analytical Research and Development for the American Association of Pharmaceutical Scientists, Analytical Profiles of Drug Substances and Excipients brings this information together in one source. The scope of the series has recently been expanded to include profiles of excipient materials.

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

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

A range of new and innovative tools used for preformulation and formulation of medicines help optimize pharmaceutical development projects. Such tools also assist with the performance evaluation of the pharmaceutical process, allowing any potential gaps to be identified. These tools can be applied in both basic research and industrial environment. Formulation tools for pharmaceutical development considers these key research and industrial tools. Nine chapters by leading contributors cover: Artificial neural networks technology to model, understand, and optimize drug formulations; ME_expert 2.0: a heuristic decision support system for microemulsions formulation development; Expert system for the development and formulation of push-pull osmotic pump tablets containing poorly water-soluble drugs; SeDeM Diagram: an expert system for preformulation, characterization and optimization of tables obtained by direct compression; New SeDeM-ODT expert system: an expert system for formulation of orodispersible tablets obtained by direct compression; and 3D-cellular automata in computer-aided design of pharmaceutical formulations: mathematical concept and F-CAD software. Coverage of artificial intelligence tools, new expert systems, understanding of pharmaceutical processes, robust development of medicines, and new ways to develop medicines Development of drugs and medicines using mathematical tools Compilation of expert system developed around the world

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, prefomulation 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

The majority of pharmaceutical formulations are solid state preparations and generally crystalline. A number of crystal properties affect the particulate and bulk properties of materials and the physical form of the excipients and active ingredient(s) can influence the manufacturing process and properties of the dosage form. Preformulation studies are therefore necessary to optimise the physico-chemical characteristics of the materials and assure subsequent smooth progress of pharmaceutical product through formulation development. Particle engineering of the active ingredient(s), together with extensive characterisation of its physical properties, are essential parts of preformulation studies. In order to explain and ultimately understand the physical processes leading to polymorphism and behaviour of materials it is necessary to examine materials at the molecular level with high resolution analytical methods and molecular modelling procedures. The aim of this study was to obtain physical data of different crystal forms of an interesting drug entity, alprazolam and at the same time to test the feasibility of the methods to predict various solid state properties. Results indicating formation of polymorphic forms in solution state were obtained in situ by Raman spectroscopy. A small scale particle engineering study revealed two polymorphic forms and one hydrate form for alprazolam, named I, 2 and 3 respectively. Structures of alprazolam forms

l and 3 were determined by single crystal X-ray study and the unit cell constants for form 2 were obtained with powder X-ray diffraction pattern indexing. The packing properties of crystal form l were demon- strated using atomic charges calculated by computational chemistry. The physico-chemical characteristics, such as thermal stability, appearance and intrinsic dissolution rate of the crystal forms were clearly different when investigated with various analytical methods. Predictions of crystal habit and spectroscopic vibrational characteristics were attempted using molecular modelling. Whilst predictions of the vibrational characteristics were not successful, an agreement with the predicted and experimental habit was achieved for the alprazolam crystal form.

During the onset of any clinical trial there are many factors and variables to consider. Funding, time restraints, and regulatory agency guidelines are factors that often influence which variables will be studied, leaving other important information out of the study. Preformulation in Solid Dosage Form Development covers every topic of critical importance to the preformulation stages of drug development. Serving as a handbook or stand-alone reference, this text equips those in academia and the pharmaceutical industry with both basic and applied principles for the characterization of drugs, excipients, and products, and deals with the issues relating to predictability, identification, and product development during preformulation stages through Phase I of clinical trials. With contributions from an international panel of experts in the field, this guide: outlines an updated preformulation program for modern drug development issues that includes particle morphology, characterization, thermal analysis, and solubility methods contains rational designs for the structure of formulation studies covers the importance of preformulation design using artificial neural networks and computational prediction techniques, and examines the concepts of preliminary-preformulation discusses the typical drug-excipient interactions that could occur during the course of development and methods of characterization includes novel methods to determine the physical and chemical stability of new formulations reviews the structure, content, and format of the preformulation report examines the significance of drug substance physiochemical properties, in regulatory quality by design

Volumes in this widely revered series present comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and excipients. This organizational structure meets the needs of the pharmaceutical community and allows for the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series encompasses review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. * Presents comprehensive reviews covering all aspects of drug development and formulation of drugs * Profiles creatine monohydrate and fexofenadine hydrochloride, as well as five others * Meets the information needs of the drug development community

Wissenschaftliche Studie aus dem Jahr 2012 im Fachbereich Pharmazie, Institute of Pharmaceutical Education Boradi, Sprache: Deutsch, Abstract: Ideally, a drug should arrive rapidly at the site of action (receptor) in the optimum concentration, remain for

the desired time, be excluded from other sites, and be rapidly removed when the goal is achieved. Generally, the time course of a dosage form (pharmacokinetics) in man is considered to be controlled by the chemical structure of the drug. Decreasing the rate of absorption and/or changing the dosage form provide a useful adjunct. When it is not feasible or desirable to modify the drug compound on a molecular level, often sought is a product that will require less frequent administration to obtain the required biological activity time profile. It may be desirable to decrease the absorption rate in order to obtain a more acceptable clinical response. The goal of designing sustained release matrix delivery systems is to reduce frequency of dosing or to increase the effectiveness of the drug by localizing at the site of action, reducing the dose required, or providing uniform drug delivery. Hence, designing a sustained release formulation for an antihypertensive drug may prolong therapeutic concentration of drug in the blood and decrease the frequency of dosing and also improve the patient compliance. So in the present study, attempts will be made to formulate a sustained release matrix tablets containing an antihypertensive drug. In December 1843, a patent was granted to the Englishman, William Brockedon for a machine to compress powders to form compacts. This very simple device consisted essentially a hole (or die) bored through which the powder was compressed between the two cylindrical punches; one was inserted into the base of die and at a fixed depth, the other was inserted at the top of die and struck with hammer. The invention was first used to produce compacts of potassium bicarbonate and caught the imagination of no. of pharmaceutical companies. Later, welcome in Britain was the first company to use the term “tablet” to describe the compressed dosage form.

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

Document from the year 2018 in the subject Pharmicology, grade: 1, , course: Pharmaceutical Technology, language: English, abstract: The aim of this book is to provide a brief but comprehensive overview on the issue of drug bioavailability improvement by preparation of a perspective dosage form – liquisolid systems. The introduction chapter about drug solubility and bioavailability is followed by a description of the general methods which could be used to improve drug bioavailability using approaches of chemistry, physical modification, and primarily pharmaceutical technology. Benefits and practical use of each method are documented by examples. The main part of the book is aimed at characterization and description of liquisolid systems (LSS) – perspective dosage form for bioavailability improvement. Elementary principles of LSS formulation are described in detail, e.g. how to perform a preformulation study; how to choose the correct type and amount of excipients; how to evaluate the dosage forms, etc. All the above mentioned principles are documented with practical examples. The book could be used as a textbook for students of natural, medical and pharmaceutical sciences as well as by researchers in this field or industrial area. Contemporary pharmacotherapy is characterized by the increasing amount of active substances that are only poorly soluble in water. This may lead to the limitation

of their systemic absorption on oral administration which is closely related to the bioavailability. This category is estimated to include more than forty percent of active substances that are in general use. So far, this poor aqueous solubility has been improved by physical or chemical modification of the active substance. In general, such changes are very expensive and troublesome, often leading to problems in stability, marketing authorization process, or administration comfort of the particular drug. This is one of the reasons why modern pharmaceutical technology has focused on those dosage forms that can increase the bioavailability of some active substances while maintaining suitable stability and administration comfort. Several processes that improve solubility, respectively bioavailability have been described and published. These include micronization, nanocrystals, and formulation of solid dispersions. Only recently, a novel trend has appeared – to take advantage of good solubility of active substances in chosen solvents, that is, to use the active substances in a liquid phase.
This book is a no non-sense, practical, how-to-do book on surviving and even coming out ahead from mergers, acquisitions and reorganizations. The author has shared 29 years of first-hand experience during which he has survived through seven mergers and several reorganizations and even moved up in the company. The book has provided an in-depth discussion on pre-merger activities and three phases of merger, acquisition and reorganization activity. The book also provides work sheets to assess where one is in doing the right things during merger, acquisition and reorganization. The reader will benefit in his or her career by following the teachings of this book.
Tablets -- Excipients -- SeDeM Expert Diagram System -- Direct compression -- Preformulation -- Formulation prediction -- Paracetamol -- Furosemide -- Pyridoxine -- Tablette -- Vulstowwe -- SeDeM Deskundige Diagram Sisteem -- Direkte samepersing -- Tablet preformuleringstudies -- Tabletmengsel voorspelling -- Parasetamol -- Furosemied -- Piridoksien.
Profiles of Drug Substances, Excipients, and Related Methodology, Volume 44, presents comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and excipients. The series encompasses review articles, with this release focusing on Cefpodoxime proxetil, Levetiracetam, Paclitaxel, Sorafenib, Sucrose octaacetate, Thiouracil, Topiramate, Spectrophotometric analysis, and Cocrystal Systems of Pharmaceutical Interest: 2012-2014. Contains contributions from leading authorities Informs and updates on all the latest developments in the field of drug substances, excipients and methodologies
This book describes the theories, applications, and challenges for different oral controlled release formulations. This book differs from most in its focus on oral controlled release formulation design and process development. It also covers the related areas like preformulation, biopharmaceutics, in vitro-in vivo correlations (IVIVC), quality by design (QbD), and regulatory issues.
Although the United States (U.S.) and the more developed nations of the remainder of the world are blessed with a variety of pharmaceuticals, feed additives, and biological products to treat, prevent, and control animal diseases, there is a healthy desire among persons involved in animal health issues to

increase our animal medicine chest. The interest stems from the desire to efficiently produce food that is safe and plentiful and from the desire to have more and better government-approved products available for the prevention and treatment of diseases of dogs, cats, and horses and for an increasing variety of minor animal species. For the animal health industry, increased drug availability means broader markets, increased revenues, and an opportunity to better serve their customers. For the veterinarian, more animal health products means that he or she is better able to treat the usual and the unusual conditions, and to prevent animal disease and suffering. No doubt, we are all winners when new technology and industrial and regulatory initiatives hasten the availability of safe and effective animal health products.

Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process, as well as the shift from developing small molecules to the growth of biopharmaceuticals. The book meets the need for advanced information for drug preformulation and formulation and addresses the current trends in the continually evolving pharmaceutical industry. Topics include: Candidate drug selection Drug discovery and development Preformulation predictions and drug selections Product design to commercial dosage form Biopharmaceutical support in formulation Development The book is ideal for practitioners working in the pharmaceutical arena—including R&D scientists, technicians, and managers—as well as for undergraduate and postgraduate courses in industrial pharmacy and pharmaceutical technology.

The study was designed to generate pre-formulation data on amlodpine besylate- and hydrocholoyhiazide for co-formulation into tablet dosage form using various tableting excipients. Compatibility between active drug substances and the additives was investigated using differential scanning calorimetry (DCS) and confirmed with the isothermal microcalorimetry.

This book describes the role modern pharmaceutical analysis plays in the development of new drugs. Detailed information is provided as to how the quality of drug products is assured from the point of discovery until the patient uses the drug. Coverage includes state-of-the-art topics such as analytics for combinatorial chemistry and high-throughput screening, formulation development, stability studies, international regulatory aspects and documentation, and future technologies that are likely to impact the field. Emphasis is placed on current, easy-to-follow methods that readers can apply in their laboratories. No book has effectively replaced the very popular text, Pharmaceutical Analysis, that was edited in the 1960s by Tak Higuchi. This book will fill that gap with an up-to-date treatment that is both handy and authoritative. Whilst following in the footsteps of previous volumes by presenting comprehensive reviews of drug substances and additional materials, this title also heralds a significant expansion of the scope of the series. Traditional

contributions will now also be augmented by publication of critical review chapters that summarize information related to the characterization of drug substances and excipients. This change is required to better meet the needs of the pharmaceutical communtiy and to allow the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series will encompass review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. * Presents comprehensive reviews covering all aspects of drug development and formulation of drugs * Now encompassing critical review chapters * Meets the information needs of the drug development community

Drug products are complex mixtures of drugs and excipients and, as such, their chemical and physical stability kinetics are complex. This book discusses the stability of these dosage forms with preformulation studies through to the studies on the final products. The book is intended for graduate students, researchers and professionals in the field of Pharmaceutics and Pharmaceutical Chemistry.

Pharmaceutics: Basic Principles and Application to Pharmacy Practice is an engaging textbook that covers all aspects of pharmaceutics with emphasis on the basic science and its application to pharmacy practice. Based on curricular guidelines mandated by the American Council for Pharmacy Education (ACPE), this book incorporates laboratory skills by identifying portions of each principle that can be used in a clinical setting. In this way, instructors are able to demonstrate their adherence to ACPE standards and objectives, simply by using this book. Written in a straightforward and student-friendly manner, Pharmaceutics enables students to gain the scientific foundation to understand drug physicochemical properties, practical aspects of dosage forms and drug delivery systems, and the biological applications of drug administration. Key ideas are illustrated and reinforced through chapter objectives and chapter summaries. A companion website features resources for students and instructors, including videos illustrating difficult processes and procedures as well as practice questions and answers. Instructor resources include Powerpoint slides and a full-color image bank. This book is intended for students in pharmaceutical science programs taking pharmaceutics or biopharmaceutics courses at the undergraduate, graduate and doctoral level. Chapter objectives and chapter summaries illustrate and reinforce key ideas Designed to meet curricular guidelines for pharmaceutics and laboratory skills mandated by the Accreditation Council for Pharmacy Education (ACPE) Companion website features resources for students and instructors, including videos illustrating difficult processes and procedures and practice questions and answers.

Instructor resources include Powerpoint slides and a full-color image bank Preformulation studies are the physical, chemical, and biological studies needed to characterize a drug substance for enabling the proper design of a drug product, whereas the effectiveness of a drug product is determined during the formulation studies phase. Though the two disciplines overlap in practice, each is a significantly distinct phase of new drug development. Entirely focused on preformulation principles, this fully revised and updated Handbook of Preformulation: Chemical, Biological, and Botanical Drugs, Second Edition provides detailed descriptions of preformulation methodologies, gives a state-of-the-art description of each technique, and lists the currently available tools useful in providing a comprehensive characterization of a new drug entity. Features: Addresses the preformulation studies of three different types of new active entities - chemical, biological, and botanical, which is the latest established class of active ingredient classified by the FDA Illustrates the activities comprised in preformulation studies and establishes a method of tasking for drug development projects Includes extensive flow charts for characterization decision making Gives extensive theoretical treatment of principles important for testing dissolution, solubility, stability, and solid state characterization Includes over 50% new material

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.

The suspension dosage form has long been used for poorly soluble active ingre-ents for various therapeutic indications. Development of stable suspensions over the shelf life of the drug product continues to be a challenge on many fronts. A

good understanding of the fundamentals of disperse systems is essential in the development of a suitable pharmaceutical suspension. The development of a s- pension dosage form follows a very complicated path. The selection of the proper excipients (surfactants, viscosity imparting agents etc.) is important. The particle size distribution in the finished drug product dosage form is a critical parameter that significantly impacts the bioavailability and pharmacokinetics of the product. Appropriate analytical methodologies and instruments (chromatographs, visco- ters, particle size analyzers, etc.) must be utilized to properly characterize the s- pension formulation. The development process continues with a successful scale- up of the manufacturing process. Regulatory agencies around the world require cli- cal trials to establish the safety and efficacy of the drug product. All of this devel- ment work should culminate into a regulatory filing in accordance with the regulatory guidelines. Pharmaceutical Suspensions, From Formulation Development to Manufacturing, in its organization, follows the development approach used widely in the pharmaceutical industry. The primary focus of this book is on the classical disperse system – poorly soluble active pharmaceutical ingredients s- pended in a suitable vehicle.

Focusing on the application of physical pharmacy, drug design, and drug regulations as they relate to produce effective dosage forms for drug delivery, Integrated Pharmaceutics provides a comprehensive picture of pharmaceutical product design, describing the science and art behind the concepts of dosage form development. Combining physical pharmacy, product design, and regulatory affairs issues in a single book, the authors address topics governing drug regulations of United States, European, and Japanese agencies and detail new regulatory guidelines, including quality by design, design space analysis, and blend sample uniformity.

Most of herbal formulations have lacking of preformulational and post formulational studies. Thus, an attempt was made to performed the preformulation and post formulation characteristics for senna leaf powder and calcium sennoside. The conventional tablet of senna leaf powder and calcium sennoside may release a significant amount of drug in the physiological environment of stomach before reaching at the site of action. Hence, enteric coated tablet of calcium sennoside and senna leaf powder was prepared using cellulose acetate phthalate for averting the initial loss of 5-8% sennoside in stomach. For this purpose different formulational factors were optimized. The in- vitro release of coated tablet was performed in 0.1 N Hcl and phosphate buffer of pH 6.8. After the enteric coating, the tablet ensured that it was more pH dependent and release the drug only at higher pH. This research work should be especially useful to professionals engaged in formulation development of herbal drugs, or anyone else who wants to perform the preformulation and post formulation study of herbal drugs.