Handbook Of Pharmaceutical Manufacturing Formulations Second Edition Handbook Of Pharmaceutical Manufacturing Formulations Semisolid Products

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Pharmaceutical Manufacturing Handbook - Shayne Cox Gad 2008-03-21
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.
Safe Management of Wastes from Health-care Activities - A. Prüss 1999

Handbook of Pharmaceutical Manufacturing Formulations Third Edition - Sarfaraz K. Niazi 2019
"The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this six-volume set compiles data from FDA new drug applications, patent applications, and other sources of generic and proprietary formulations to cover the broad spectrum of GMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent"--
Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition - Stephen P. Denyer 2006-12-26
Microbiological matters continue to exercise considerable influence on product quality. In both the pharmaceutical and medical device industries, products of greater sophistication, along with evolving regulatory requirements, are elevating the challenges related to maintaining microbiological integrity. Updated to reflect technological and regulatory changes, the Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition covers thoseprincipal aspects of microbiology that arerelevant to the preformulation, formulation, manufacturing, and license application stages involved with the production of pharmaceuticals and medical devices. In recognition of the diverse disciplines involved in pharmaceutical and medical device production, this work provides a brief introduction to microbiology geared towards the nonmicrobiologist. Covering good manufacturing practice in the control of contamination, the text explores quality control, the preservation of formulations, and principles of sterilization, including microbiological-specific considerations for biotechnological products and other medical devices. It also provides additional materials on package integrity and contamination risks in clean rooms. The editors have produced a companion text, the Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices (see reverse), which when paired with the Guide offers a complete theoretical and practical treatment of microbiological control. This book provides a comprehensive distillation of information concerning methodology and regulations that would otherwise remain scattered throughout the literature. It allows scientists from many fields to address potential problems in advance and implement suitable strategies at the earliest stages of development.
Pharmaceutical Suspensions - Alok K. Kulshreshtha 2009-11-05
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.
Handbook of Pharmaceutical Manufacturing Formulations - Sarfaraz K Niazi 2019-08-30
Providing methodologies that can serve as a reference point for new formulations, the second volume covers uncompressed solids, which include formulations of powders, capsules, powders ready for reconstitution, and other similar products. Highlights from Uncompressed Solid Products, Volume Two include: the fundamental issues of good manufacturing practices formulations for more than 400 pharmaceutical products, including currently approved products and innovative products such as small proteins, instantly liquifiable powders, and nanoparticles access to US FDA guidelines, as well as all major guidelines around the world identification and inclusion of the most often approved capsules and powders in the US
Handbook of Nutraceuticals Volume I - Yashwant Vishnupant Pathak 2009-11-24
As soon as Dr. Stephen DeFelice coined the phrase nutraceutical, product and supplement developers swung into action. Yet among the numerous books available on nutraceuticals, there is none that systematically lists, categorizes, and analyzes nutraceutical extracts and formulations in a pharmacopoeia-like manner. Handbook of Nutraceuticals, Volume 1: Ingredients, Formulations, and Applications lists information on many ingredients used in nutraceuticals, developing their formulations and applications. The book includes contributions from experts with pharmaceutical backgrounds, providing an examination of nutraceuticals from a pharmaceutical perspective. Building a foundation with coverage of historical background, definitions, and challenges, the book offers insight into nutraceutical ingredients from plant,

animal, and mineral origin. It then covers the characterization of nutraceuticals' physicochemical, analytical, pharmacological, and pharmacokinetic classification, followed by information on regulatory requirements. The book highlights applications in cardiovascular disease, bone and joint treatments, diabetes management, weight management, skin health, probiotics and prebiotics, tranquilizing medicinal plants, dietary foods, and more. Interest in new diet regimens and new products for increased health and longevity will continue to grow, giving dietary supplements an increasing amount of cupboard space in most households. With quality of content unsurpassed by many resources, the book discusses the characterization processes for nutraceuticals based on the contributors' experience in pharmaceuticals. It then explores how those proven techniques may be applied to the development and manufacture of nutraceutical products.

Microbial Limit and Bioburden Tests - Lucia Clontz 2008-10-14

In recent years, the field of pharmaceutical microbiology has experienced numerous technological advances, accompanied by the publication of new and harmonized compendial methods. It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical/biopharmaceutical products to keep abreast of the latest changes. Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements guides readers through the various microbiological methods listed in the compendia with easy-to-follow diagrams and approaches to validations of such test methodologies. Includes New and Updated Material Now in its second edition, this work is the culmination of research and discussions with technical experts, as well as USP and FDA representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products, materials, equipment, and manufacturing facilities. New in this edition is an entire chapter dedicated to the topic of biofilms and their impact on pharmaceutical and biopharmaceutical operations. The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a case study on microbial identification in support of a product contamination investigation. Substantially updated and revised, this book assists readers in understanding the fundamental issues associated with pharmaceutical microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility.

Pharmaceutical Dosage Forms - Herbert Lieberman 2020-08-26

Stressing the theory involved in formulating suspensions, emulsions, and colloidal drug products, this Second Edition of a well-received reference test highlights typical formulations, the avoidance of formulation pitfalls, and compliance with established regulatory principles.

Dictionary of Pharmaceutical Dosage Forms - Jeffrey T. Solate 2020-12-04

The study of pharmaceutical dosage forms has many connections to biological and medical sciences including physiology, biochemistry, pharmacology, pharmacotherapy, therapeutics, pharmacodynamics, pharmacokinetics, and pharmacognosy. Dictionary of Pharmaceutical Dosage Forms is a collection of terms and definitions prepared to assist healthcare practitioners and students as a companion or reference resource when reading notes and completing routine care. It can also provide reference material for hospital and medical staff, consultants, nursing instructors, and pharmaceutical science students. This first edition classifies and organizes the forms in an easily readable format, so readers will find it a quick and simple reference. Features Collects terms and definitions to assist healthcare practitioners and students as a companion or reference resource when reading notes and completing routine care Focuses on product dosage forms and includes supplementary information, providing readers, particularly pharmacy and medical students and professionals, insights into choices of dosage forms made during drug product development Offers information on the indications, contraindications, side effects, and more, for a given drug Classifies and organizes the forms in a readable format, providing a quick and simple reference

Generic Drug Product Development - Leon Shargel 2013-10-24

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

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition - Sarfaraz K. Niazi 2019-12-06

The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume One, Compressed Solid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this first volume of a six-volume set, compiles data from FDA new drug applications, patent applications, and other sources of generic and proprietary formulations to cover the broad spectrum of GMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent.

Experiments in Pharmaceutical Chemistry, Second Edition - Charles Dickson 2014-02-21

Written by an author with more than 40 years of teaching experience in the field, Experiments in Pharmaceutical Chemistry, Second Edition responds to a critical classroom need for material on directed laboratory investigations in biological and pharmaceutical chemistry. This new edition supplies 75 experiments, expanding the range of topics to 22 major areas of pharmaceutical chemistry. These include biochemical groups, botanical classes important to pharmacy, and major drug classifications: Carbohydrates Lipids Proteins Enzymes Inorganics Vitamins Steroids Plant Acids Flavonoids Alkaloids Tannins Resins Glycosides Gums Balsams Volatile Oils Analgesics Anesthetics Sulfa Drugs (Sulfonamides) Psychotropic Drugs Antibiotics Nucleic Acids Sections contain introductions to basic concepts underlying the fields addressed and a specific bibliography relating to each field. Each experiment provides detailed instructions in a user-friendly format, and can be carried out, in most cases, without the need for expensive instrumentation. This comprehensive laboratory manual offers much-needed instructional material for teaching laboratory classes in pharmaceutical chemistry. The breadth of subject matter covered provides a variety of choices for structuring a laboratory course.

Handbook of Bioequivalence Testing, Second Edition - Sarfaraz K. Niazi 2014-10-29

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 made bioequivalence testing more complex. The second edition of Handbook of Bioequivalence Testing has been completely updated to include the most current information available, including new findings in drug delivery and dosage form design and revised worldwide regulatory requirements. New topics include: A historical perspective on generic pharmaceuticals New guidelines governing submissions related to bioequivalency studies, along with therapeutic code classifications Models of noninferiority Biosimilarity of large molecule drugs Bioequivalence of complementary and alternate medicines Bioequivalence of biosimilar therapeutic proteins and monoclonal antibodies New FDA guidelines for bioanalytical method validation Outsourcing and monitoring of bioequivalence studies The cost of generic drugs is rising much faster than in the past, partly because of the increased costs required for approval—including those for bioequivalence testing. There is a dire need to re-examine the science behind this type of testing to reduce the burden of development costs—allowing companies to develop generic drugs faster and at a lower expense. The final chapter explores the future of bioequivalence testing and proposes radical changes in the process of biowaivers. It suggests how the cost of demonstrating bioequivalence can be reduced through intensive analytical investigation and proposes that regulatory agencies reduce the need for bioequivalence studies in humans. Backed by science and updated with the latest research, this book is destined to spark continued debate on the efficacy of the current bioequivalence testing paradigm.

Handbook of Pharmaceutical Manufacturing Formulations - Sarfaraz K. Niazi 2004-04-27

The third volume in the six-volume Handbook of Pharmaceutical Manufacturing Formulations, this book covers liquid drugs, which include formulations of non-sterile drugs administered by any route in the form of solutions (monomeric and multimeric), suspensions (powder and liquid), drops, extracts, elixirs, tinctures, paints, sprays, colloidons, emul

Handbook of Pharmaceutical Manufacturing Formulations - Sarfaraz K. Niazi 2004-04-27

The second volume in the six-volume Handbook of Pharmaceutical Manufacturing Formulations, this book

covers uncompressed solids, which include formulations of powders, capsules, powders ready for reconstitution and other similar products from publicly available but widely dispersed information from FDA New Drug Applications (NDA), patent applications, and other sources of generic and proprietary formulations. Each entry begins with a fully validated scaleable manufacturing formula and a summary of manufacturing process. The book provides a detailed discussion on the difficulties encountered in formulating and manufacturing uncompressed drugs and the common elements of formulations.

Pharmaceutical Preformulation and Formulation - Mark Gibson 2016-04-19

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.

Pharmaceutical Formulation Development of Peptides and Proteins, Second Edition - Lars Hovgaard 2012-11-14

The rapid advances in recombinant DNA technology and the increasing availability of peptides and proteins with therapeutic potential are a challenge for pharmaceutical scientists who have to formulate these compounds as drug products. Pharmaceutical Formulation Development of Peptides and Proteins, Second Edition discusses the development of therapeutic peptides and proteins, from the production of active compounds via basic pre-formulation and formulation to the registration of the final product. Providing integrated solutions, this book discusses: The synthesis of peptides and the biotechnological production of proteins through recombinant DNA technology The physicochemical characteristics and stability of peptides and proteins The formulation of proteins as suspensions, solutions, and (mostly freeze-dried) solids The opportunities and challenges of non-parenteral delivery of peptides and proteins Risk factors, specifically the development of an unwanted immune response A simulation approach to describe the fate of peptides and proteins upon administration to a biological system The documentation required to register a protein-based drug Scientists in the pharmaceutical industry and academia as well as postgraduate students in pharmaceutical science will find this a valuable resource.

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition - Sarfaraz K. Niazi 2019-12-09

The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume Six, Sterile Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this sixth volume of a six-volume set, compiles data from FDA and EMA new drug applications, patents and patent applications, and other sources of generic and proprietary formulations including author’s own experience, to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. Features: Largest source of authoritative and practical formulations, cGMP compliance guidance and self-audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing, bioequivalence testing, and full compliance with drug product safety elements Written by a well-recognized authority on drug and dosage form development including biological drugs and alternative medicines

Handbook of Pharmaceutical Manufacturing Formulations - Sarfaraz K. Niazi 2004-04-27

Pharmaceutical formulations remain as much an art today as they have evolved into complex science. With exponential growth of generic formulations, the need for ready formulations has increased. Essentially a cookbook for making drugs, the six-volume handbook contains the recipes and process steps for over 2000 drugs, including a number of biotechnology drugs. This first volume covers tablets, both coated and uncoated and oral powders. The author has painstakingly assembled this book from FDA New Drug Applications, patent applications and the BASF book of generic formulations, all supplemented by his 30-plus years of experience in pharmaceutical formulations.

Handbook of Pharmaceutical Manufacturing Formulations, Second Edition - Sarfaraz K. Niazi 2009-09-21

An authoritative and practical guide to the art and science of formulating drugs. With thoroughly revised and expanded content, this Second Edition six-volume set compiles volumes from FDA New Drug Applications, patent applications, and other sources of generic and proprietary formulations to cover the broad spectrum of issues concerning drug manufacturing. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this set is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. As the largest reference on pharmaceutical formulations, this handbook also provides guidelines on how to file aNDAs in the shortest possible time, helping pharmaceutical companies to cut costs in the areas of pharmaceutical research and development. Divided conveniently into two parts—regulatory and manufacturing guidelines, and formulations—each volume in the set covers: cGMP compliance pre-approval inspections stability and bioequivalence testing packaging commodity development common difficulties in formulating drugs changes to aNDAs

Handbook for Chemical Process Research and Development - Wenyi Zhao 2016-11-03

The Handbook for Chemical Process Research and Development focuses on developing processes for chemical and pharmaceutical industries. Forty years ago there were few process research and development activities in the pharmaceutical industry, partially due to the simplicity of the drug molecules. However, with the increasing structural complexity, especially the introduction of chiral centers into the drug molecules and strict regulations set by the EMA and FDA, process R&D has become one of the critical departments for pharmaceutical companies. This book assists with the key responsibility of process chemists to develop chemical processes for manufacturing pharmaceutical intermediates and final drug substances for clinical studies and commercial production.

International Stability Testing - David J. Mazzo 2020-08-26

In this book, recognized industry experts and regulatory inspectors from the world's pharmaceutical manufacturing regions provide stability requirements in all the major markets and discuss all aspects of stability testing and biotechnology. Participants in the ICH debates interpret the ICH guidelines. Other discussions focus on European requirements, the ICH initiatives, the US SUPAC initiative, matrixing and bracketing approaches from the cGMP and FDA perspective, and stability requirements in Japan, Australia, and WHO. Stress programs, testing of preservatives, and physical stability topics are addressed as well as various protocols and statistical approaches.

Aulton's Pharmaceutics - Michael E. Aulton 2013

"Pharmaceutics is the art of pharmaceutical preparations. It encompasses design of drugs, their manufacture and the elimination of micro-organisms from the products. This book encompasses all of these areas."--Provided by publisher.

Handbook of Pharmaceutical Manufacturing Formulations, Second Edition - Sarfaraz K. Niazi 2009-09-21

Providing methodologies that can serve as a reference point for new formulations, the second volume covers uncompressed solids, which include formulations of powders, capsules, powders ready for reconstitution, and other similar products. Highlights from Uncompressed Solid Products, Volume Two include: the fundamental issues of good manufacturing practices formulations for more than 400 pharmaceutical products, including currently approved products and innovative products such as small proteins, instantly liquifiable powders, and nanoparticles access to US FDA guidelines, as well as all major guidelines around the world identification and inclusion of the most often approved capsules and powders in the US

Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems - Sushil Katdare 2006-07-28
To facilitate the development of novel drug delivery systems and biotechnology-oriented drugs, the need for new excipients to be developed and approved continues to increase. Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems serves as a comprehensive source to improve understanding of excipients and forge new avenue
Handbook of Pharmaceutical Manufacturing Formulations, Third Edition - Sarfaraz K. Niazi 2019-11-25
The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume Two, Uncompressed Solid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this second volume of a six-volume set, compiles data from FDA and EMA new drug applications, patents and patent applications, and other sources of generic and proprietary formulations including author's own experience, to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. Features: Largest source of authoritative and practical formulations, cGMP compliance guidance and self-audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing, bioequivalence testing, and full compliance with drug product safety elements Written by a well-recognized authority on drug and dosage form development including biological drugs and alternative medicines
Handbook of Pharmaceutical Manufacturing Formulations - Sarfaraz K. Niazi 2004-04-27
The fourth volume in the six-volume Handbook of Pharmaceutical Manufacturing Formulations, this book covers semi-solid drugs. It includes ointments, lotions, gels, and suppositories, from publicly available but widely dispersed information from FDA New Drug Applications (NDA), patent applications, and the BASF book of generic formulations. Each entry begins with a fully validated scaleable manufacturing formula that includes compendial specification requirement for each ingredient, in-process controls for manufacturing and release of product, a summary of manufacturing process, and details of packaging.
Introduction to Pharmaceutical Analytical Chemistry - Stig Pedersen-Bjergaard 2019-02-11
The definitive textbook on the chemical analysis of pharmaceutical drugs – fully revised and updated Introduction to Pharmaceutical Analytical Chemistry enables students to gain fundamental knowledge of the vital concepts, techniques and applications of the chemical analysis of pharmaceutical ingredients, final pharmaceutical products and drug substances in biological fluids. A unique emphasis on pharmaceutical laboratory practices, such as sample preparation and separation techniques, provides an efficient and practical educational framework for undergraduate studies in areas such as pharmaceutical sciences, analytical chemistry and forensic analysis. Suitable for foundational courses, this essential undergraduate text introduces the common analytical methods used in quantitative and qualitative chemical analysis of pharmaceuticals. This extensively revised second edition includes a new chapter on chemical analysis of biopharmaceuticals, which includes discussions on identification, purity testing and assay of peptide and protein-based formulations. Also new to this edition are improved colour illustrations and tables, a streamlined chapter structure and text revised for increased clarity and comprehension. Introduces the fundamental concepts of pharmaceutical analytical chemistry and statistics Presents a systematic investigation of pharmaceutical applications absent from other textbooks on the subject Examines various analytical techniques commonly used in pharmaceutical laboratories Provides practice problems, up-to-date practical examples and detailed illustrations Includes updated content aligned with the current European and United States Pharmacopeia regulations and guidelines Covering the analytical techniques and concepts necessary for pharmaceutical analytical chemistry, Introduction to Pharmaceutical Analytical Chemistry is ideally suited for students of chemical and pharmaceutical sciences as well as analytical chemists transitioning into the field of pharmaceutical analytical chemistry.
Handbook of Pharmaceutical Manufacturing Formulations - Sarfaraz K. Niazi 2016-04-19
While liquid drugs do not share the compression problems of solid dosage forms, the filling problems of powder dosage forms, or the consistency problems of semisolid dosage forms, they do have their own set of considerations in the formulation and manufacturing stages.Highlights from Liquid Products, Volume Three include:practical details invo
Handbook of Pharmaceutical Manufacturing Formulations - Sarfaraz K. Niazi 2016-04-19
The fourth volume in the series covers the techniques and technologies involved in the preparation of semisolid products such as ointments, creams, gels, suppositories, and special topical dosage forms. Drug manufacturers need a thorough understanding of the specific requirements that regulatory agencies impose on the formulation and efficacy deter
Introduction to Market Access for Pharmaceuticals - Mohsen Toumi 2017-01-12
Market access is the fourth hurdle in the drug development process and the primary driver for global income of any new drug. Without a strategy in place for pricing, showing value for effectiveness and an understanding of the target purchasers' needs, the drug will fail to reach its intended market value. Introduction to Market Access for Pharmaceuticals is based on an accredited course in this area, taken from the European Market Access University Diploma (EMAUD), and is affiliated with Aix Marseille University.
Developing Solid Oral Dosage Forms - Yihong Qiu 2009-03-10
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
Development and Formulation of Veterinary Dosage Forms - Gregory E Hardee 2021-04-30
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 Dosage Forms - Tablets - Larry L. Augsburger 2016-04-19
The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation

of the tablet dosage form, an

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition - Sarfaraz K. Niazi 2019-12-06

The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume Four, Semisolid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this fourth volume of a six-volume set, compiles data from FDA and EMA new drug applications, patents and patent applications, and other sources of generic and proprietary formulations including author's own experience, to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. Features: Largest source of authoritative and practical formulations, cGMP compliance guidance and self-audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing, bioequivalence testing, and full compliance with drug product safety elements Written by a well-recognized authority on drug and dosage form development including biological drugs and alternative medicines

Fermentation and Biochemical Engineering Handbook, 2nd Ed. - Henry C. Vogel 1996-12-31

This is a well-rounded handbook of fermentation and biochemical engineering presenting techniques for the commercial production of chemicals and pharmaceuticals via fermentation. Emphasis is given to unit operations fermentation, separation, purification, and recovery. Principles, process design, and equipment are detailed. Environment aspects are covered. The practical aspects of development, design, and operation are stressed. Theory is included to provide the necessary insight for a particular operation. Problems addressed are the collection of pilot data, choice of scale-up parameters, selection of the right piece of equipment, pinpointing of likely trouble spots, and methods of troubleshooting. The text, written from a practical and operating viewpoint, will assist development, design, engineering and production personnel in the fermentation industry. Contributors were selected based on their industrial background and orientation. The book is illustrated with numerous figures, photographs and schematic diagrams.

Handbook of Hydrocolloids - Glyn O. Phillips 2009-05-28

Hydrocolloids are among the most widely used ingredients in the food industry. They function as thickening and gelling agents, texturizers, stabilisers and emulsifiers and in addition have application in areas such as edible coatings and flavour release. Products reformulated for fat reduction are particularly dependent on hydrocolloids for satisfactory sensory quality. They now also find increasing applications in the health area as dietary fibre of low calorific value. The first edition of Handbook of Hydrocolloids provided professionals in the food industry with relevant practical information about the range of hydrocolloid ingredients readily and at the same time authoritatively. It was exceptionally well received and has subsequently been used as the substantive reference on these food ingredients. Extensively revised and expanded and containing eight new chapters, this major new edition strengthens that reputation. Edited by two leading international authorities in the field, the second edition reviews over twenty-five hydrocolloids, covering structure and properties, processing, functionality, applications and regulatory status. Since there is now greater emphasis on the protein hydrocolloids, new chapters on vegetable proteins and egg protein have been added. Coverage of microbial polysaccharides has also been increased and the developing role of the exudate gums recognised, with a new chapter on Gum Ghatti. Protein-polysaccharide complexes are finding increased application in food products and a new chapter on this topic as been added. Two additional chapters reviewing the role of hydrocolloids in emulsification and their role as dietary fibre and subsequent health benefits are also included. The second edition of Handbook of hydrocolloids is an essential reference for post-graduate students, research scientists and food manufacturers. Extensively revised and expanded second edition edited by two leading international authorities Provides an introduction to food hydrocolliods considering regulatory aspects and thickening characteristics Comprehensively examines the manufacture, structure, function and applications of over twenty five hydrocolloids

Handbook of Pharmaceutical Manufacturing Formulations - Sarfaraz K. Niazi 2016-04-19

Over-the-Counter products comprise a special category of healthcare products. While these formulations have much in common with their prescription counterparts, they are presented in this series separately because of their development approach taken, labeling considerations required, and support available from suppliers of ingredients in designing

Handbook of Pharmaceutical Excipients - Raymond C. Rowe 2009-01-01

An internationally acclaimed reference work recognized as one of the most authoritative and comprehensive sources of information on excipients used in pharmaceutical formulation with this new edition providing 340 excipient monographs. Incorporates information on the uses, and chemical and physical properties of excipients systematically collated from a variety of international sources including: pharmacopeias, patents, primary and secondary literature, websites, and manufacturers' data; extensive data provided on the applications, licensing, and safety of excipients; comprehensively cross-referenced and indexed, with many additional excipients described as related substances and an international supplier's directory and detailed information on trade names and specific grades or types of excipients commercially available.