Drug Formulation Manual

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.
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
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.
Pharmaceutical Manufacturing Handbook
A Manual of Adverse Drug Interactions
A Manual for Students and Practitioners

Handbook of Lung Targeted Drug Delivery Systems

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.
A book in pharmaceutical calculations laden with worked examples and making it easy for even the slowest leaner to grasp the concepts of mathematics in pharmaceutical practice. The author has been teaching pharmaceutical calculations at the university level for the past twenty-five years. The author also realized that students come from various backgrounds, some being good in mathematics and some lacking the proper background and hence, not as good. The manual is designed to simply provide a reference material in pharmaceutical calculations that can be used by students of all levels (dispensers, pharmaceutical assistants, and technicians as well as pharmacy degree students) regardless of their backgrounds. The manual is an asset to both students and tutors alike. It is also intended to impart ability to students to work independently and understand practical problems that occur in practice from time to time. In writing this manual, the author carefully followed various curricula of pharmacy at certificate, diploma, and degree levels of various institutions. The manual also addresses components of the curriculum of nursing courses, particularly calculations involving doses and dosages. Thus, trainers will choose topics relevant to the level they are dealing with. The manual is enriched with over 350 worked examples and about 150 practice questions with answers to make self-study possible. With many practical worked examples, even the slowest learner can be taken onboard. Furthermore, this manual will be a quick reference for practicing pharmaceutical technicians, nurses, and pharmacists.
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 determination of drugs contained in these formulations. Highlights from Semisolid Products, Volume Four include: coverage of over 350 formulations valuable information on the difficult area of compliance changes to approved new drug applications and abbreviated new drug applications the evolving guidelines of ICH and when to conduct a regulatory review
Pharmaceutical Calculations
Production and Processes
Husa's Pharmaceutical Dispensing
Selected Technical Publications
Cobert's Manual Of Drug Safety And Pharmacovigilance (Third Edition)
Drug Stability for Pharmaceutical Scientists is a clear and easy-to-follow guide on drug degradation in pharmaceutical formulation. This book features valuable content on both aqueous and solid drug solutions, the stability of proteins and peptides, acid-base catalyzed and solvent catalyzed reactions, how drug formulation can influence drug stability, the influence of external factors on reaction rates and much more. Full of examples of real-life formulation problems and step-by-step calculations, this book is the ideal resource for graduate students, as well as scientists in the pharmaceutical and related industries. Illustrates important theoretical concepts with numerous examples, figures, calculations, learning problems and questions for self-study and retention of material Provides answers and explanations to test your knowledge Enables you to better understand key concepts such as rate and order of reaction, reaction equilibrium, complex reaction mechanisms and more Includes an in-depth discussion of both aqueous and solid drug solutions and contains the latest international regulatory requirements on drug stability
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
The biotechnology/biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates (ADCs), Bispecific T-cell engager (BITES), Dual Variable Domain (DVD) antibodies, and fusion proteins that are currently being used as therapeutic agents for immunology, oncology and other disease conditions. Regulatory agencies have raised the bar for the development and manufacture of antibody-based products, expecting to see the use of Quality by Design (QbD) elements demonstrating an in-depth understanding of product and process based on sound science. Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self-administration are being marketed as combination products. A survey of the market indicates that there is a strong need for a new book that will provide “one stop shopping” for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development. The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry, academia or regulatory agencies. With insightful chapters from experts in the field, this new book reviews first principles, covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody-based products. It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development, formulation strategies for new modalities, and the analytical techniques used to characterize them. It also addresses important considerations for later stage development such as the development of robust formulations and processes, including process engineering and modeling of manufacturing unit operations, the design of analytical comparability studies, and characterization of primary containers (pre-filled syringes and vials).Finally, the latter half of the book reviews key considerations to ensure the development and approval of a patient-centered delivery system design. This involves the evolving regulatory framework with perspectives from both the US and EU industry experts, the role of international standards, design control/risk management, human factors and its importance in the product development and regulatory approval process, as well as review of the risk-based approach to bridging between devices used in clinical trials and the to-be-marketed device. Finally, case studies are provided throughout.The typical readership would have biology and/or engineering degrees and would include researchers, scientific leaders, industry specialists and technology developers working in the biopharmaceutical field.
A Manual on the Formulation of Pharmaceutical Products, the Dispensing of Prescriptions, and the Professional Practice of Pharmacy
A Practical Manual on the Formulation and Dispensing of Pharmaceutical Products
Dispensing of Medication
Handbook of Pharmaceutical Manufacturing Formulations
Official Gazette of the United States Patent and Trademark Office
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
Fundamentals of Pharmacology for Paramedics provides students with the insight and understanding of pharmacological essentials needed to respond effectively to the patients' needs. This textbook will help students improve, expand, and enhance their expertise and the overall health and wellbeing of their patients, while boosting their self-confidence as paramedics in the process. This textbook integrates the extensive knowledge of pharmacology into a workable and accessible plan of care that will help to improve patient care. The book also includes: Thorough introductions to pharmacology and how to use pharmaceutical, and prescribing reference guides Comprehensive explorations of the legal and ethical issues of pharmacology within paramedicine and the role of the paramedic in medicines management Practical discussions of pharmacodynamics, pharmacokinetics, drug formulations, and adverse drug reactions In-depth examinations of a wide variety of medicines, including analgesics, antibacterials, and medications used in the cardiovascular, renal, respiratory, gastrointestinal, and nervous systems Written for students of paramedicine, Fundamentals of Pharmacology for Paramedics would also prove an indispensable resource for practicing paramedics seeking a practical, one-stop reference on a challenging subject.
No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products, for obvious reasons. With the increasing number of potent products, particularly the new line of small protein products, joining the long list of proven sterile products, the technology of manufacturing ster
Sterile Products
Handbook of Drug Administration via Enteral Feeding Tubes, 3rd edition
Handbook of Pharmaceutical Excipients
Bacteriological Analytical Manual
A Regulatory Affairs Quality Manual
This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.
Drugs and pharmaceutical industry plays a vital role in the economic development of a nation. It is one of the largest and most advanced sectors in the world, acting as a source for various drugs, medicines and their intermediates as well as other pharmaceutical formulations. India has come a long way in this field, from a country importing more than 95% of its requirement of drugs and pharmaceuticals; India now is exporting it even to developed countries. Being the intense knowledge driven industry, it offers innumerable business opportunities for the investors/ corporate the world over. The existence of well defined and strong pharmaceutical industry is important for promoting and sustaining research and developmental efforts and initiatives in an economy as well as making available the quality medicines to all at affordable prices. That is, it is essential to improve the health status of the individuals as well as the society as a whole, so that positive contributions could be made to the economic growth and regional development of a country. On the global platform, India holds fourth position in terms of volume and thirteenth position in terms of value of production in pharmaceuticals. The pharmaceutical industry has been producing bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing processes as well as a wide range of pharmaceutical machinery and equipments. The modern Indian Pharmaceutical Industry is recent and its foundation was laid in the beginning of the current century. The pharmaceutical industry can be broadly categorised as bulk drugs, formulations, IV fluids and pharmaceutical aids (such as medical equipment, hospital disposables, capsules, etc.). Special feature of the pharmaceutical industry is a large number of manufacturers in the small scale sector. The government is also encouraging the SSI sector providing some incentives. The recent developments in the technology and R & D work in this field have led to the increased growth rate of industries and have established Indian Pharmaceutical industries in the international market. The content of the book includes information about properties, general methods of analysis, methods of manufacture, of different types of drugs and pharmaceuticals. Some of the fundamentals of the book are polymeric materials used in drug delivery systems , theoretical aspects of friction and lubrication , a convenient method for conversion of quinine to quinidine, formulation and evaluation of bio-available enteric-coated erythromycin and metronidazole tablets, extraction of virginiamycin, antipyretics and analgesics, column chromatographic assay of aspirin tablets, differentiating titration of phenacetin and caffeine, infrared spectra of some compounds of pharmaceutical interest etc. This book covers an intensive study on manufacturing, production, formulation and quality control of drugs and pharmaceuticals with technology involved in it. This book is an invaluable resource for technologists, professionals and those who want to venture in this field.
Completely revised and updated, Cobert's Manual of Drug Safety and Pharmacovigilance, Third Edition, is a how-to manual for those working in the fields of drug safety, clinical research, pharmacology, regulatory affairs, risk management, quality/compliance, and in government and legal professions.This comprehensive and practical guide discusses the theory and the practicalities of drug safety (also known as pharmacovigilance), and provides essential information on drug safety and regulations in the United States, Europe Union, and more, including: recognizing, monitoring, reporting, and cataloging serious adverse drug reactions.Cobert's Manual of Drug Safety and Pharmacovigilance, Third Edition, teaches the daily practice of drug safety in industry, hospitals, the FDA and other health agencies — both in the United States and around the world — and provides critical information about what to do when confronted with a drug safety problem.
Patents
Semisolid Products
Pharmaceutical Dosage Forms and Drug Delivery, Third Edition
Psychopharmacology Bulletin
Drug Stability for Pharmaceutical Scientists
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.
This book is an invaluable source designed to meet the needs of pharm.D and other pharmacy courses. This book was made according to the PCI syllabus. This book covers topics like syrups, elixirs, linctus, solutions, liniments, suspensions, emulsions, powders, suppositories, incompatibilities, with an introduction before it. This book helps the student to write the academic pharmaceutics record more easily. It has been noticed that practical of pharmaceutics leave students a little confused, especially during their examination. Finally, this book aims to present the practicals in a student friendly style so that they can easily grasp and do the practicals in the lab more easily by own which interns will help them to achieve the best grades in examinations.
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, emulsions, aerosols, and other fluid preparations 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 liquid drugs and the common elements of formulation. The section on regulatory and manufacturing guidance deals with the topics of changes to approved NDAs and aNDAs, post-approval changes to semisolid drugs, global manufacturing practices and guidelines, compliance program guidance manual for FDA staff covering drug manufacturing inspections program, waiver of in vivo bioavailability studies for immediate release solid drugs based on a biopharmaceutics classification, in addition to providing quick tips on resolving the common problems in formulating uncompressed drugs.
Good Drug Regulatory Practices
Drug Formulations Manual
Recent Trends and Clinical Evidences
Principles of Electronic Prescribing
Formulation tools for Pharmaceutical Development
This 2009 new and revised 2nd edition is now brought up-to-date with latest contemporary processing technology. The old edition has been revised thoroughly and obsolete information was deleted and necessary corrections made. New chapters on Super critical Fluid Extraction & Ultrasonic Extraction are examples of this new development. Due to rapid development in the fields of pharmacology and bio-availability and to enhance shelf-life of products, two new chapters have been added respectively; Herb Drug Interactions and a chapter on Liposomes and Phytosomes.
Handbook of Lung Targeted Drug Delivery Systems: Recent Trends and Clinical Evidences covers every aspect of the drug delivery to lungs, the physiology and pharmacology of the lung, modelling for lung delivery, drug devices focused on lung treatment, regulatory requirements, and recent trends in clinical applications. With the advent of nano sciences and significant development in the nano particulate drug delivery systems there has been a renewed interest in the lung as an absorption surface for various drugs. The emergence of the COVID-19 virus has brought lung and lung delivery systems into focus, this book covers new developments and research used to address the prevention and treatment of respiratory diseases. Written by well-known scientists with years of experience in the field this timely handbook is an excellent reference book for the scientists and industry professionals. Key Features: Focuses particularly on the chemistry, clinical pharmacology, and biological developments in this field of research. Presents comprehensive information on emerging nanotechnology applications in diagnosing and treating pulmonary diseases Explores drug devices focused on lung treatment, regulatory requirements, and recent trends in clinical applications Examines specific formulations targeted to pulmonary systems
Each no. represents the results of the FDA research programs for half of the fiscal year.
Development of Biopharmaceutical Drug-Device Products
An Introduction to Formulation and Production Aspects of Parenteral Products
Handbook of Preformulation
Fundamentals of Pharmacology for Paramedics
PHARMACEUTICAL LAB MANUAL
With over 400 drug monographs, this book covers the technical, practical and legal aspects that you should consider before prescribing or administering drugs via enteral feeding tubes.
Completely revised and updated, this third edition of Pharmaceutical Dosage Forms and Drug Delivery elucidates the basic principles of pharmaceutics, biopharmaceutics, dosage form design, and drug delivery – including emerging new biotechnology-based treatment modalities. The authors integrate aspects of physical pharmacy, chemistry, biology, and biopharmaceutics into drug delivery.? This book highlights the increased attention that the recent spectacular advances in gene therapy and nanotechnology have brought to dosage form design and drug delivery. With the expiration of older patents and generic competition, the biopharmaceutical industry is evolving faster than ever. Apart from revising and updating existing chapters on the basic principles, this edition highlights the emerging emphasis on drug discovery, antibodies and antibody-drug conjugates as therapeutic moieties, individualized medicine including patient stratification strategies, targeted drug delivery, and the increasing role of modeling and simulation. Although there are numerous books on pharmaceutics and dosage forms, most cover different areas of the discipline and do not provide an integrated approach. The integrated approach of this book not only provides a singular perspective of the overall field, but also supplies a unified source of information for students, instructors and professionals, saving their time and money.
Accompanying CD-ROM contains ... "customizable client information handouts for 125 of the most commonly prescribed small animal drugs, with clear, concise instructions that encourage compliance."--P. [4] of cover.
Chemical, Biological, and Botanical Drugs
Parenteral Technology Manual
Introduction to Cosmetic Formulation and Technology
Liquid Products (Volume 3 of 6)
Herbal Drugs Industry
Designed as an educational and training text, this book provides a clear and easily understandable review of cosmetics and over the counter (OTC) drug-cosmetic products. The text features learning objectives, key concepts, and key terms at the beginning and review questions and glossary of terms at the end of each chapter section. • Overviews functions, product design, formulation and development, and quality control of cosmetic ingredients • Discusses physiological, pharmaceutical, and formulation knowledge of decorative care products • Reviews basic terms and definitions used in the cosmetic industry and provides an overview of the regulatory environment in the US • Includes learning objectives, key concepts, and key terms at the beginning and review questions and glossary of terms at the end of each chapter section • Has PowerPoint slides as ancillaries, downloadable from the book's wiley.com page, for adopting professors
Good Drug Regulatory Practices offers a series of policies and procedures to assure quality and timely regulatory submissions to national regulatory agencies. This book begins with introductory chapters describing the need for policy documentation, and the philosophy underlying the policies, and presents policies and standards that can be used as presented or adapted to individual situations in your company.
Scientists have attributed more than 40 percent of the failures in new drug development to poor biopharmaceutical properties, particularly water insolubility. Issues surrounding water insolubility can postpone, or completely derail, important new drug development. Even much-needed reformulation of currently marketed products can be significantly affected by these challenges. Water Insolubility is the Primary Culprit in over 40% of New Drug Development Failures The most comprehensive resource on the topic, this second edition of Water Insoluble Drug Formulation brings together a distinguished team of experts to provide the scientific background and step-by-step guidance needed to deal with solubility issues in drug development. Twenty-three chapters systematically describe solubility properties and their impact on formulation, from theory to industrial practice. With detailed discussion on how these properties contribute to solubilization and dissolution, the text also features six brand new chapters on water-insoluble drugs, exploring regulatory aspects, pharmacokinetic behavior, early phase formulation strategies, lipid based systems for oral delivery, modified release of insoluble drugs, and scalable manufacturing aspects. The book includes more than 15 water-insoluble drug delivery systems or technologies, illustrated with case studies featuring oral and parenteral applications. Highlighting the most current information and data available, this seminal volume reflects the significant progress that has been made in nearly all aspects of this field.
Water-Insoluble Drug Formulation
Saunders Handbook of Veterinary Drugs
Regulations, Methodologies, and Best Practices
Handbook of Stability Testing in Pharmaceutical Development
Drugs & Pharmaceutical Technology Handbook
Over the next few years, the Connecting for Health IT programme for the NHS in England is due to implement electronic prescribing systems at all hospitals in England. Furthermore, the other UK countries are likely to follow suit with clinical IT implementation programmes, and these developments will generate interest in electronic prescribing at European and international level. There is therefore likely to be an exponential growth in the significance of electronic prescribing over the next ten years. Principles of Electronic Prescribing discusses the basic principles of design and implementation of secondary care electronic medicines management systems, and how their design and configuration can impact on benefits realization, hospital workflow and clinical practice.
Compressed Solid Products (Volume 1 of 6)
Medical Subject Headings
A Textbook and Reference Manual on Drug Development, Pharmaceutical Compounding, and Dispensing
Annotated alphabetic list
Revised and Expanded