Chemical Stability Of Pharmaceuticals A Handbook For Pharmacists

This book comprehensively reviews drug stability and chemical kinetics: how external factors can influence the stability of drugs, and the reaction rates that trigger these effects. Explaining the important theoretical concepts of drug stability and chemical kinetics, and providing numerous examples in the form of illustrations, tables and calculations, the book helps readers gain a better understanding of the rates of reactions, order of reactions, types of degradation and how to prevent it, as well as types of stability studies. It also offers insights into the importance of the rate at which the drug is degraded and/or decomposed under various external and internal conditions, including temperature, pH, humidity and light. This book is intended for researchers, PhD students and scientists working in the field of pharmacy, pharmacology, pharmaceutical chemistry, medicinal chemistry and biopharmaceutics.

Amorphous pharmaceuticals are becoming increasingly important because different drying procedures such as freeze-drying and spray-drying used for biotechnology based products like proteins produce amorphous solids, or glasses. In amorphous solids, the translational and rotational motions occur much more slowly than in the solution state, but the mobility is sufficient to allow degradation on the time scale of normal pharmaceutical storage. The physical and chemical properties of formulations in the solid state depend on the dynamics in the amorphous state. Different types of motions, i.e., global Î± motions, secondary Î2 motions, and fast dynamics are suspected to play a key role in determining the overall stability of glasses and their relative contributions are affected by formulation and processing conditions. For any type of degradation reaction, physical (e.g., crystallization) or chemical (e.g., cyclization) molecular motion is necessary, and there is sufficient mobility in the glass below room temperature to allow these reactions, which makes stabilization a challenging subject for pharmaceutical scientists. The nature and consequences of molecular motions in amorphous pharmaceuticals is reviewed. Glassy systems experience an increase in relaxation time, i.e., decrease in overall molecular mobility, upon aging at temperatures below the glass transition temperature (Tg). By experimental studies (Differential Scanning Calorimetery-DSC) and theoretical analysis (Tool-Narayanaswamy-Moynihan phenomenology-TNM), the optimum annealing conditions to obtain maximum structural relaxation in lyophilized glasses, composed of a saccharide excipient and a small concentration of aspartame as a model "drug" were determined. The optimum aging temperature was found to be about 15-20Â° below Tg which resulted in maximum structural relaxation. The fast dynamics measured using NMR T1 and T 1Ï spin-lattice relaxation times indicated that a maximal relaxed state can be obtained by annealing at the optimum temperature, where a minimum in global mobility estimated by Ï„Î2 measured using Isothermal Microcalorimetry (IMC) and DSC and modeled using TNM occurs. Chemical stability results showed that thermal conditioning of samples under protocols that were predicted and shown to produce optimum annealing for "mobility" were close to those conditions that produce optimum chemical stability as measured by degradation rate. The comparison between chemical stability in sucrose and trehalose formulation suggest that mobility measured by structural relaxation is not a perfect surrogate for the mobility critical to chemical decomposition. That is, it is possible that the "fast motions" rather than the Î±-relaxations are critical to stability under some circumstances.

The International Conference of Harmonization (ICH) has worked on har- nizing the stability regulations in the US, Europe, and Japan since the early 1990s. Even though the Stability Guidelines Q1A (R2) was issued over a decade ago, issues surrounding this arena continue to surface as the principles described in the guideline are applied to different technical concentrations. As a result, the stability community has continued to discuss concerns and find ways of harmonizing regulatory requirements, streamlining practices, improving processes in order to bring safe and effective medical supplies to the patients around the world. In 2007, the American Association of Pharmaceutical Scientists (AAPS) Stability Focus Group organized two workshops – the Stability Workshop and the Degradation Mechanism Workshop. These meetings attracted many industry scientists as well as representatives from several regulatory agencies in the world to discuss important topics related to pharmaceutical stability practices. Recognizing the importance of documenting these discussions and with the permission of AAPS, I have worked with speakers to assemble a collection of 30 articles from presentations given at these two meetings, mainly the Stability Workshop. I trust that this book will be beneficial to all of you in providing guidance and up-to-date information for building quality stability programs. v Freedom of our mind is Mother of all inventions.

Pharmaceutical formulations have evolved from simple and traditional systems to more modern and complex novel dosage forms. Formulation development is a tedious process and requires an enormous amount of effort from many different people. Developing a stable novel dosage form and further targeting it to the desired site inside the body has always been a challenge. The purpose of this book is to bring together scholarly articles that highlight recent developments and trends in pharmaceutical formulation science. Each article has been written by authors specializing in the subject area and hailing from top institutions around the world. The book has been written in a systematic and lucid style explaining all basic concepts and fundamentals in a very simple way. This book aims to serve the need of all individuals involved at any level in the pharmaceutical dosage form development. I sincerely hope that the book will be liked by inquisitive students and learned colleagues.

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.

Part B explores protein degradation occuring in vivo during protein synthesis in cells, examines the isolation and purification of proteins, details protein use in organisms, and reviews techniques to enhance protein stability.

The Practice of Medicinal Chemistry, Fourth Edition provides a practical and comprehensive overview of the daily issues facing pharmaceutical researchers and chemists. In addition to its thorough treatment of basic medicinal chemistry principles, this updated edition has been revised to provide new and expanded coverage of the latest technologies and approaches in drug discovery. With topics like high content screening, scoring, docking, binding free energy calculations, polypharmacology, QSAR, chemical collections and databases, and much more, this book is the go-to reference for all academic and pharmaceutical researchers who need a complete understanding of medicinal chemistry and its application to drug discovery and development. Includes updated and expanded material on systems biology, chemogenomics, computer-aided drug design, and other important recent advances in the field Incorporates extensive color figures, case studies, and practical examples to help users gain a further understanding of key concepts Provides high-quality content in a comprehensive manner, including contributions from international chapter authors to illustrate the global nature of medicinal chemistry and drug development research An image bank is available for instructors at www.textbooks.elsevier.com

The vast majority of drugs are organic molecular entities. A clear understanding of the organic chemistry of drug degradation is essential to maintaining the stability, efficacy, and safety of a drug product throughout its shelf-life. During analytical method development, stability testing, and pharmaceutical manufacturing troubleshooting activities, one of the frequently occurring and usually challenging events would be the identification of drug degradants and understanding of drug degradation mechanisms and pathways. This book is written by a veteran of the pharmaceutical industry who has first-hand experience in drug design and development, drug degradation mechanism studies, analytical development, and manufacturing process troubleshooting and improvement. The author discusses various degradation pathways with an emphasis on the mechanisms of the underlying organic chemistry, which should aid greatly in the efforts of degradant identification, formulation development, analytical development, and manufacturing process improvement. Organic reactions that are significant in drug degradation will first be reviewed and then illustrated by examples of drug degradation reported in the literature. The author brings the book to a close with a final chapter dedicated to the strategy for rapid elucidation of drug degradants with regard to the current regulatory requirements and guidelines. One chapter that should be given special attention is Chapter 3, Oxidative Degradation. Oxidative degradation is one of the most common degradation pathways but perhaps the most complex one. This chapter employs more than sixty drug degradation case studies with in-depth discussion in regard to their unique degradation pathways. With the increasing regulatory requirements on the quality and safety of pharmaceutical products, in particular with regard to drug impurities and degradants, the book will be an invaluable resource for pharmaceutical and analytical scientists who engage in formulation development, analytical development, stability studies, degradant identification, and support of manufacturing process improvement. In addition, it will also be helpful to scientists engaged in drug discovery and development as well as in drug metabolism studies.

Of the thousands of novel compounds that a drug discovery project team invents and that bind to the therapeutic target, typically only a fraction of these have sufficient ADME/Tox properties to become a drug product. Understanding ADME/Tox is critical for all drug researchers, owing to its increasing importance in advancing high quality candidates to clinical studies and the processes of drug discovery. If the properties are weak, the candidate will have a high risk of failure or be less desirable as a drug product. This book is a tool and resource for scientists engaged in, or preparing for, the selection and optimization process. The authors describe how properties affect in vivo pharmacological activity and impact in vitro assays. Individual drug-like properties are discussed from a practical point of view, such as solubility, permeability and metabolic stability, with regard to fundamental understanding, applications of property data in drug discovery and examples of structural modifications that have achieved improved property performance. The authors also review various methods for the screening (high throughput), diagnosis (medium throughput) and in-depth (low throughput) analysis of drug properties. * Serves as an essential working handbook aimed at scientists and students in medicinal chemistry * Provides practical, step-by-step guidance on property fundamentals, effects, structure-property relationships, and structure modification strategies * Discusses improvements in pharmacokinetics from a practical chemist's standpoint

Significant progress has been made in the study of three-dimensional quantitative structure-activity relationships (3D QSAR) since the first publication by Richard Cramer in 1988 and the first volume in the series. 3D QSAR in Drug Design. Theory, Methods and Applications, published in 1993. The aim of that early book was to contribute to the understanding and the further application of CoMFA and related approaches and to facilitate the appropriate use of these methods.

Since then, hundreds of papers have appeared using the quickly developing techniques of both 3D QSAR and computational sciences to study a broad variety of biological problems. Again the editor(s) felt that the time had come to solicit reviews on published and new viewpoints to document the state of the art of 3D QSAR in its broadest definition and to provide visions of where new techniques will emerge or new appli- tions may be found. The intention is not only to highlight new ideas but also to show the shortcomings, inaccuracies, and abuses of the methods. We hope this book will enable others to separate trivial from visionary approaches and me-too methodology from in- vative techniques. These concerns guided our choice of contributors. To our delight, our call for papers elicited a great many manuscripts.
Seventy years ago, Erwin Schrödinger posed a profound question: 'What is life, and how did it emerge from non-life?' Scientists have puzzled over it ever since. Addy Pross uses insights from the new field of systems chemistry to show how chemistry can become biology, and that Darwinian evolution is the expression of a deeper physical principle.
The second edition of Pharmaceutical Stress Testing: Predicting Drug Degradation provides a practical and scientific guide to designing, executing and interpreting stress testing studies for drug substance and drug product. This is the only guide available to tackle this subject in-depth. The Second Edition expands coverage from chemical stability into the physical aspects of stress testing, and incorporates the concept of Quality by Design into the stress testing construct / framework. It has been revised and expanded to include chapters on large molecules, such as proteins and antibodies, and it outlines the changes in stress testing that have emerged in recent years. Key features include: A renowned Editorial team and contributions from all major drug companies, reflecting a wealth of experience. 10 new chapters, including Stress Testing and its relationship to the assessment of potential genotoxic degradants, combination drug therapies, proteins, oligonucleotides, physical changes and alternative dosage forms such as liposomal formulations Updated methodologies for predicting drug stability and degradation pathways Best practice models to follow An expanded Frequently Asked Questions section This is an essential reference book for Pharmaceutical Scientists and those working in Quality Assurance and Drug Development (analytical sciences, formulations, chemical process, project management).
Chemical Stability of PharmaceuticalsA Handbook for PharmacistsJohn Wiley & Sons
An introduction to pharmaceutical chemistry for undergraduate pharmacy, chemistry and medicinal chemistry students. Essentials of Pharmaceutical Chemistry is a chemistry introduction that covers all of the core material necessary to provide an understanding of the basic chemistry of drug molecules. Now a core text on many university courses, it contains numerous worked examples and problems. The 4th edition includes new chapters on Chromatographic Methods of Analysis, and Medicinal Chemistry - The Science of Drug Design.
A Practical Guide to Molecular Cloning By Bernard Perbal Presents detailed procedures for all phases of DNA cloning experiments. Starting with laboratory equipment and safety considerations, this practical guide goes on to describe enzymes, vectors, purification and characterization techniques, genetic mapping, modification of DNA fragments with cohesive termini, ligation, preparation of genomic libraries, sequencing of DNA, and more. 1984 554 pp. Pharmaceutical Calculations, 2nd Ed. By Joel L. Zatz Expanded and updated, this examination of pharmaceutical calculations features a programmed format—designed for fast-paced learning—and a progression of topics that builds on previous instruction. The second edition of this popular text includes current unit designations and abbreviations, additional material on the alligation technique and infusion calculations, and many new problems. 1981 388 pp. Drug Level Monitoring, Volume 2 Analytical Techniques, Metabolism, and Pharmacokinetics By Emil T. Lin and Wolfgang Sadée The second volume in a series that describes drug level assays in biological fluid. Reviews of the analysis, metabolism and pharmacokinetics of 16 major classes are included. Details are presented on therapeutic drug concentrations in plasma, pharmacokinetic parameters, and a large number of drug assay procedures applicable to biological specimens. All of these subject areas have been carefully combined to render this book a unique reference source, teaching tool, and guide to drug level monitoring. 1985 250 pp.
From crystal structure prediction to totally empirical screening, the quest for new crystal forms has become one of the most challenging issues in the solid state science and particularly in the pharmaceutical world. In this context, multi-component crystalline materials like co-crystals have received renewed interest as they offer the prospect of optimized physical properties. As illustrated in this first book_ entirely dedicated to this emerging class of pharmaceutical compounds_ the outcome of such endeavours into crystal engineering have demonstrated clear impacts on production, marketing and intellectual property protection of active pharmaceutical ingredients (APIs). Indeed, co-crystallization influences relevant physico-chemical parameters (such as solubility, dissolution rate, chemical stability, melting point, hygroscopicity, à) and often offers solids with properties superior to those of the free drug. Combining both reports of the latest research and comprehensive overviews of basic principles, with contributions from selected experts in both academia and industry, this unique book is an essential reference, ideal for pharmaceutical development scientists and graduate students in pharmaceutical science.
This book explains theoretical and technological aspects of amorphous drug formulations. It is intended for all those wishing to increase their knowledge in the field of amorphous pharmaceuticals. Conversion of crystalline material into the amorphous state, as described in this book, is a way to overcome limited water solubility of drug formulations, in this way enhancing the chemical activity and bioavailability inside the body. Written by experts from various fields and backgrounds, the book introduces to fundamental physical aspects (explaining differences between the ordered and the disordered solid states, the enhancement of solubility resulting from drugs amorphization, physical instability and how it can be overcome) as well as preparation and formulation procedures to produce and stabilize amorphous pharmaceuticals. Readers will thus gain a well-funded understanding and find a multi-faceted discussion of the properties and advantages of amorphous drugs and of the challenges in producing and stabilizing them. The book is an ideal source of information for researchers and students as well as professionals engaged in research and development of amorphous pharmaceutical products.
The first book devoted to the topic, this reference discusses the predictive power and limitations of current stress testing strategies and emphasizes the critical role of stress testing in the determination of the stability characteristics of pharmaceuticals-offering an extensive compilation of drug degradation studies from real-world examples in the literature.
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.
This book examines statistical techniques that are critically important to Chemistry, Manufacturing, and Control (CMC) activities. Statistical methods are presented with a focus on applications unique to the CMC in the pharmaceutical industry. The target audience consists of statisticians and other scientists who are responsible for performing statistical analyses within a CMC environment. Basic statistical concepts

are addressed in Chapter 2 followed by applications to specific topics related to development and manufacturing. The mathematical level assumes an elementary understanding of statistical methods. The ability to use Excel or statistical packages such as Minitab, JMP, SAS, or R will provide more value to the reader. The motivation for this book came from an American Association of Pharmaceutical Scientists (AAPS) short course on statistical methods applied to CMC applications presented by four of the authors. One of the course participants asked us for a good reference book, and the only book recommended was written over 20 years ago by Chow and Liu (1995). We agreed that a more recent book would serve a need in our industry. Since we began this project, an edited book has been published on the same topic by Zhang (2016). The chapters in Zhang discuss statistical methods for CMC as well as drug discovery and nonclinical development. We believe our book complements Zhang by providing more detailed statistical analyses and examples.

Fluorine chemistry is an expanding area of research that is attracting international interest, due to the impact of fluorine in drug discovery and in clinical and molecular imaging (e.g. PET, MRI). Many researchers and academics are entering this area of research, while scientists in industrial and clinical environments are also indirectly exposed to fluorine chemistry through the use of fluorinated compounds for imaging. This book provides an overview of the impact that fluorine has made in the life sciences. In the first section, the emphasis is on how fluorine substitution of amino acids, peptides, nucleobases and carbohydrates can provide invaluable information at a molecular level. The following chapters provide answers to the key questions posed on the importance of fluorine in drug discovery and clinical applications. For examples, the reader will discover how fluorine has found its place as a key element improving drug efficacy, with reference to some of the best-selling drugs on the market. Finally, a thorough review on the design, synthesis and use of 18F-radiotracers for positron emission tomography is provided, and this is complemented with a discussion on how 19F NMR has advanced molecular and clinical imaging.

Presents a detailed discussion of important solid-state properties, methods, and applications of solid-state analysis Illustrates the various phases or forms that solids can assume and discussesvarious issues related to the relative stability of solid forms and tendencies to undergo transformation Covers key methods of solid state analysis including X-ray powder diffraction, thermal analysis, microscopy, spectroscopy, and solid state NMR Reviews critical physical attributes of pharmaceutical materials, mainly related to drug substances, including particle size/surface area, hygroscopicity, mechanical properties, solubility, and physical and chemical stability Showcases the application of solid state material science in rational selection of drug solid forms, analysis of various solid forms within drug substance and the drug product, and pharmaceutical product development Introduces appropriate manufacturing and control procedures using Quality by Design, and other strategies that lead to safe and effective products with a minimum of resources and time

Chemically stable solids are in demand for many applications, including pharmaceuticals and organic electronics. Previous efforts in crystals have established the importance of molecular packing in influencing chemical stability by comparing reaction kinetics in different polymorphs. However, efforts to improve chemical stability by modulating molecular packing in amorphous materials have seen much smaller effects. Recently, physical vapor deposition (PVD), a common method to prepare thin films for organic electronics, is reported to create organic glasses with exceptional properties that cannot be accessed by any other method. By vapor-depositing molecules onto a substrate maintained at the temperature below the glass transition temperature (Tg), PVD glasses can demonstrate significantly enhanced thermal stability and increased density relative to traditional liquid-cooled glasses; the optimum substrate temperature usually occurs near 0.85 Tg. The discovery of high-density and high-thermal stability glasses by vapor-deposition provides an opportunity to address questions of how chemical stability can be improved in glasses. The body of this work deals with the characterization of a variety of chemical reactions in organic glasses and establishes the connection between enhanced chemical stability and the distinctive glass packing achieved by vapor-deposition. Films of azobenzenes, photochromic molecules that can undergo trans to cis photoisomerization, were prepared by vapor-deposition at a wide range of substrate temperature. Photostability of vapor-deposited Disperse Orange 37, a push-pull azobenzene with fast cis-trans thermal isomerization, is found to increase by as much as a factor of 50 relative to the liquid-cooled glass. Photostability was determined by measuring density and molecular orientation changes by ellipsometry during irradiation to induce photoisomerization. We further show that the enhanced photostability in vapor-deposited glasses is a general phenomenon by using a non-push-pull azobenzene, 4,4'-diphenyl azobenzene (DPA). By mixing DPA into the glass host of celecoxib, we directly measure populations of trans and cis DPA via UV-Vis spectroscopy and show that the rate of photoisomerization varies as a function of the substrate temperature. Photostability correlates with the density of packing, where the optimum glass is about one order of magnitude more photostable than the liquid-cooled glass. These results show substantially increased photostability of azobenzenes in both neat films and mixtures and provide a molecular explanation for enhanced photostability in glasses. We further investigate the influence of dense glass packing on photodegradation, an important reaction type responsible for degradation in pharmaceuticals and failure in organic electronics. Indomethacin, a pharmaceutical molecule that can undergo photodecarboxylation reaction when irradiated by UV light, was studied as a model system. Photodegradation of indomethacin was assessed through the light-induced mass decrease in glassy thin films caused by the loss of CO2, as characterized by a quartz crystal microbalance (QCM). For the most stable glass, vapor-deposited at 0.85 Tg, the photodegradation rate is about 50% slower than for the liquid-cooled glass when irradiated by a 312 nm UV light. The enhanced stability against degradation correlates with glass density. We speculate that high-density glasses limit the local molecular reconfiguration required for photodecarboxylation. Additionally, to broaden the impact of vapor-deposition on chemical stability, we performed the solid-gas reaction of indomethacin with ammonia. Indomethacin has a carboxylic acid group that can react with ammonia to yield ammonium salt. In this case, chemical reactivity is assessed through the increase in mass induced by the addition of ammonia to glassy thin films, as characterized by a QCM. Vapor-deposited indomethacin with increased density shows slower reaction rates with ammonia relative to the liquid-cooled glass, and the maximum difference in reaction rates is over one order of magnitude. We suggest that the diminished solubility of ammonia in vapor-deposited glasses contributes to their remarkable chemical stability.

Provides a sound theoretical basis for understanding chemical kinetics and its uses in studying drug stability. Treats the calculations, approximations, and estimates that are useful to the pharmacist in professional practice, and presents a collection of selected drug-stability data from the pharmaceutical literature. This Handbook makes accessible to the pharmacist much of the information necessary to make pharmaceutical decisions about drug stability. Changes in this edition include thorough revision of the chapter on oxidation, addition of a new chapter on solid-state stability, and a tripling of the number of stability monographs. All monographs figures have been redrawn, most of them from published data, and all sources are cited.

The United States Food and Drug Administration (FDA) and other regulatory bodies around the world require that impurities in drug substance and drug product levels recommended by the International Conference on Harmonisation (ICH) be isolated and characterized. Identifying process-related impurities and degradation products also helps us to understand the production of

impurities and assists in defining degradation mechanisms. When this process is performed at an early stage, there is ample time to address various aspects of drug development to prevent or control the production of impurities and degradation products well before the regulatory filing and thus assure production of a high-quality drug product. This book, therefore, has been designed to meet the need for a reference text on the complex process of isolation and characterization of process-related (synthesis and formulation) impurities and degradation products to meet critical requlatory requirements. It's objective is to provide guidance on isolating and characterizing impurities of pharmaceuticals such as drug candidates, drug substances, and drug products. The book outlines impurity identification processes and will be a key resource document for impurity analysis, isolation/synthesis, and characterization. - Provides valuable information on isolation and characterization of impurities. - Gives a regulatory perspective on the subject. - Describes various considerations involved in meeting regulatory requirements. - Discusses various sources of impurities and degredation products.

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

A needed resource for pharmaceutical scientists and cosmetic chemists, Essential Chemistry for Formulators of Semisolid and Liquid Dosages provides insight into the basic chemistry of mixing different phases and test methods for the stability study of nonsolid formulations. The book covers foundational surface/colloid chemistry, which forms the necessary background for making emulsions, suspensions, solutions, and nano drug delivery systems, and the chemistry of mixing, which is critical for further formulation of drug delivery systems into semisolid (gels, creams, lotions, and ointments) or liquid final dosages. Expanding on these foundational principles, this useful guide explores stability testing methods, such as particle size, rheological/viscosity, microscopy, and chemical, and closes with a valuable discussion of regulatory issues. Essential Chemistry for Formulators of Semisolid and Liquid Dosages offers scientists and students the foundation and practical guidance to make and analyze semisolid and liquid formulations. Unique coverage of the underlying chemistry that makes possible stable dosages Quality content written by experienced experts from the drug development industry Valuable information for academic and industrial scientists developing topical and liquid dosage formulations for pharmaceutical as well as skin care and cosmetic products

An important resource that puts the focus on understanding and handling of organic crystals in drug development Since a majority of pharmaceutical solid-state materials are organic crystals, their handling and processing are critical aspects of drug development. Pharmaceutical Crystals: Science and Engineering offers an introduction to and thorough coverage of organic crystals, and explores the essential role they play in drug development and manufacturing. Written contributions from leading researchers and practitioners in the field, this vital resource provides the fundamental knowledge and explains the connection between pharmaceutically relevant properties and the structure of a crystal. Comprehensive in scope, the text covers a range of topics including: crystallization, molecular interactions, polymorphism, analytical methods, processing, and chemical stability. The authors clearly show how to find solutions for pharmaceutical form selection and crystallization processes. Designed to be an accessible guide, this book represents a valuable resource for improving the drug development process of small drug molecules. This important text: Includes the most important aspects of solid-state organic chemistry and its role in drug development Offers solutions for pharmaceutical form selection and crystallization processes Contains a balance between the scientific fundamental and pharmaceutical applications Presents coverage of crystallography, molecular interactions, polymorphism, analytical methods, processing, and chemical stability Written for both practicing pharmaceutical scientists, engineers, and senior undergraduate and graduate students studying pharmaceutical solid-state materials, Pharmaceutical Crystals: Science and Engineering is a reference and textbook for understanding, producing, analyzing, and designing organic crystals which is an imperative skill to master for anyone working in the field.

Aimed at product and process developers in the biopharmaceutical industry and academia, this is the first book to describe freeze-drying, as related to the pharmaceutical industry.

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.

Remington Education: Pharmaceutics covers the basic principles of pharmaceutics, from dosage forms to drug delivery and targeting. It addresses all the principles covered in an introductory pharmacy course. As well as offering a summary of key information in pharmaceutics, it offers numerous case studies and MCQs for self assessment.

Recent trends within the pharmaceutical industry through the Quality by Design initiatives have seen a greater emphasis on the development of a molecular-scale understanding in the development of efficient manufacturing processes for active pharmaceutical ingredients (APIs) and their formulation into drug products. This book examines the state-of-the-art computational approaches to guide solid form experiments to optimize the physical and chemical properties of API related to its stability, bioavailability and formulatability. The book is intended to be used as a professional reference to researchers in Pharmaceutical industry and in academia and potentially as a text book reference for undergraduate, graduate and postgraduate students in the field of Computational Chemistry, Solid State Chemistry, Pharmaceutical Science and Material Science.

Following its successful predecessor, this book covers the fundamentals, delivery routes and vehicles, and practical applications of drug delivery. In the 2nd edition, almost all chapters from the previous are retained and updated and several new chapters added to make a more complete resource and reference. • Helps readers understand progress in drug delivery research and applications • Updates and expands coverage to reflect advances in materials for delivery vehicles, drug delivery approaches, and therapeutics • Covers recent developments

including transdermal and mucosal delivery, lymphatic system delivery, theranostics • Adds new chapters on nanoparticles, controlled drug release systems, theranostics, protein and peptide drugs, and biologics delivery

Accelerated Predictive Stability (APS): Fundamentals and Pharmaceutical Industry Practices provides coverage of both the fundamental principles and pharmaceutical industry applications of the APS approach. Fundamental chapters explain the scientific basis of the APS approach, while case study chapters from many innovative pharmaceutical companies provide a thorough overview of the current status of APS applications in the pharmaceutical industry. In addition, up-to-date experiences in utilizing APS data for regulatory submissions in many regions and countries highlight the potential of APS in support of registration stability testing for certain regulatory submissions. This book provides high level strategies for the successful implementation of APS in a pharmaceutical company. It offers scientists and regulators a comprehensive resource on how the pharmaceutical industry can enhance their understanding of a product's stability and predict drug expiry more accurately and quickly. Provides a comprehensive, one-stop-shop resource for accelerated predictive stability (APS) Presents the scientific basis of different APS models Includes the applications and utilities of APS that are demonstrated through numerous case studies Covers up-to-date regulatory experience

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