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Freeze-drying of Pharmaceuticals and Biopharmaceuticals

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Principles and Practices of Lyophilization in Product Development and Manufacturing

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), Chimeric Antigen Receptor - Modified Tcells (CART) that are currently being used as therapeutic agents for immunology and oncology disease conditions. In addition to other pharmaceuticals and biopharmaceuticals, all these novel formats are fragile with respect to their stability/structure under processing conditions meaning marginal stability in the liquid state and often require lyophilization to enhance their stability and shelf-life. This book contains chapters/topics that will describe every aspect of the lyophilization process and product development and manufacturing starting from the overview of lyophilization process, equipment required, characterization of the material, design and development of the formulation and lyophilization process, various techniques for characterization of the product, scale-up/tech-transfer and validation. It also describes the application of CFD coupled with mathematical modeling in the lyophilization process and product development, scale-up, and manufacturing. Additionally, Principles and Practice of Lyophilization Process and Product Development contains an entire dedicated section on “Preservation of Biologicals” comprised of nine chapters written by experts and including case studies.

Freeze-Drying of Pharmaceutical and Food Products

Freeze-drying is an important preservation technique for heat-sensitive pharmaceuticals and foods. Products are first frozen, then dried in a vacuum at low temperature by sublimation and desorption, rather than by the application of heat. The resulting items can be stored at room temperature for long periods. This informative text addresses both principles and practice in this area. The first chapter

introduces freeze-drying. The authors then review the fundamentals of the technique, heat-mass transfer analyses, modelling of the drying process and the equipment employed. Further chapters focus on freeze-drying of food, freeze-drying of pharmaceuticals and the protective agents and additives applied. The final chapter covers the important subjects of disinfection, sterilization and process validation. Freeze-drying of pharmaceutical and food products is an essential reference for food, pharmaceutical and refrigeration engineers and scientists with an interest in preservation techniques. It will also be of use to students in these fields. Addresses the principles and practices used in this important preservation technique Explains the fundamentals of heat-mass transfer analysis, modelling and the equipment used Discusses the importance of disinfection, sterilization and process validation

Lyophilization of Biopharmaceuticals

Humans have been experimenting with lyophilization, or freeze-drying, as a method to preserve biological structures for over a thousand years. This comprehensive volume, intended for scientists in both academia and industry, covers a wide range of topics relevant to the formulation of peptide and protein drugs in the freeze-dried state.

Freeze-drying/lyophilization of Pharmaceutical and Biological Products

Highlights the application of freeze-drying to pharmaceuticals-illustrating practical & industry-tested methods of preserving & reactivating delicate biologicals & biochemicals. Discusses the basic principles & engineering aspects of lyophilization, & also the role of bulking agents, additives, cryoprotectants, antioxidants, free radicals, & other products that protect the biological integrity of active substances during freezing, drying, & storage.

Good Pharmaceutical Freeze-Drying Practice

This text is devoted to pharmaceutical freeze-drying in all its forms and in all its technological variations. Whether you freeze-dry nonsterile tablets or you lyophilize injectables, this book covers all the technological and regulatory requirements. Written by a panel of leading practitioners in the pharmaceutical industry -- production experts, regulatory inspectors, technical consultants, and equipment suppliers -- the information is relevant, usable, and timely. Practical, "how to" chapters serve as training aids, and each section stands on its own as a concise, easy-to-access resource for both managers and technicians.

Freeze Drying of Pharmaceutical Products

Freeze Drying of Pharmaceutical Products provides an overview of the most recent and cutting-edge developments and technologies in the field, focusing on formulation developments and process monitoring and considering new technologies for process development. This book contains case studies from freeze dryer manufacturers and pharmaceutical companies for readers in industry and academia. It was contributed to by lyophilization experts to create a detailed analysis of the subject matter, organically presenting recent advancements in freeze-drying research and technology. It discusses formulation design, process optimization and control, new PAT-monitoring tools, multivariate image analysis, process scale-down and development using small-scale freeze-dryers, use of CFD for equipment design, and development of continuous processes. This book is for industry professionals, including chemical engineers and pharmaceutical scientists.

Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products, Third Edition

Freeze-drying, or lyophilization, is a well established technology used in the preservation of numerous pharmaceutical and biological products. This highly effective dehydration method involves the removal of water from frozen materials via the direct sublimation of ice. In recent years, this process has met with many changes, as have the regulations that impact lyophilization practices. This volume addresses these changes with revised chapters on emerging developments in lyophilization technology, research, and industry procedures. Providing both a scientific and industrial perspective, this comprehensive text is a valuable resource for all those who use freeze-drying technology.

Freeze-Drying/Lyophilization Of Pharmaceutical & Biological Products, Revised and Expanded

Thoroughly acquainting the reader with freeze-drying fundamentals, Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products, Second Edition carves practical guidelines from the very

latest theoretical research, technologies, and industrial procedures. It delineates the best execution of steps from closure preparation and regulatory control of products to equipment sterilization and process validation. With 13 new chapters providing state-of-the-art information, the book unveils innovations currently advancing the field, including LYOGUARD® packaging for bulk freeze-drying and the irradiation of pharmaceutical and biological products.

Freeze-Drying

This completely updated and enlarged third edition of the classic text adopts a practical approach to describe the fundamentals of freeze-drying, backed by many explanatory examples. Following an introduction to the fundamentals, the book goes on to discuss process and plant automation as well as methods to transfer pilot plant qualifications and process data to production. An entire section is devoted to a large range of different pharmaceutical, biological, and medical products. New to this edition are chapters on antibodies, freeze-dry microscopy, TEMPRIS, microwave freeze-drying, spray freeze-drying, and PAT. Their many years of experience in freeze-drying enable the authors to supply valuable criteria for the selection of laboratory, pilot and production plants, discussing the advantages, drawbacks and limitations of different plant designs. Alongside guidelines for the evaluation and qualification of plants and processes, the author also includes a troubleshooting section.

Development of Biopharmaceutical Drug-Device Products

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.

Freeze-Drying/Lyophilization Of Pharmaceutical & Biological Products, Second Edition, Revised and Expanded

Thoroughly acquainting the reader with freeze-drying fundamentals, Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products, Second Edition carves practical guidelines from the very latest theoretical research, technologies, and industrial procedures. It delineates the best execution of steps from closure preparation and regulatory control of products to equipment sterilization and process validation. With 13 new chapters providing state-of-the-art information, the book unveils

innovations currently advancing the field, including LYOGUARD® packaging for bulk freeze-drying and the irradiation of pharmaceutical and biological products.

Drying Technologies for Biotechnology and Pharmaceutical Applications

A comprehensive source of information about modern drying technologies that uniquely focus on the processing of pharmaceuticals and biologicals Drying technologies are an indispensable production step in the pharmaceutical industry and the knowledge of drying technologies and applications is absolutely essential for current drug product development. This book focuses on the application of various drying technologies to the processing of pharmaceuticals and biologicals. It offers a complete overview of innovative as well as standard drying technologies, and addresses the issues of why drying is required and what the critical considerations are for implementing this process operation during drug product development. Drying Technologies for Biotechnology and Pharmaceutical Applications discusses the state-of-the-art of established drying technologies like freeze- and spray- drying and highlights limitations that need to be overcome to achieve the future state of pharmaceutical manufacturing. The book also describes promising next generation drying technologies, which are currently used in fields outside of pharmaceuticals, and how they can be implemented and adapted for future use in the pharmaceutical industry. In addition, it deals with the generation of synergistic effects (e.g. by applying process analytical technology) and provides an outlook toward future developments. -Presents a full technical overview of well established standard drying methods alongside various other drying technologies, possible improvements, limitations, synergies, and future directions -Outlines different drying technologies from an application-oriented point of view and with consideration of real world challenges in the field of drug product development -Edited by renowned experts from the pharmaceutical industry and assembled by leading experts from industry and academia Drying Technologies for Biotechnology and Pharmaceutical Applications is an important book for pharma engineers, process engineers, chemical engineers, and others who work in related industries.

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Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products

Freeze-drying, or lyophilization, is a well established technology used in the preservation of numerous pharmaceutical and biological products. This highly effective dehydration method involves the removal of water from frozen materials via the direct sublimation of ice. In recent years, this process has met with many changes, as have the regulatio

Freeze Drying of Food Products

An accessible guide to safely dehydrating food Freeze drying, or lyophilization, is a method for dehydrating food or other substances through the use of pressure instead of heat. This allows for the preservation and storage of high-value food products without altering their essential properties or causing a reduction in quality or value. For these reasons, freeze drying is the most reliable method for preserving and distributing high-quality products. Freeze Drying of Food Products provides a concise, accessible overview of freeze-drying techniques and their modern applications. Beginning with the basic principles and processes of freeze drying, it incorporates specific discussion of freeze-drying different categories of food products, before moving to an analysis of recent developments in freeze-drying technology. The result is a key publication in the fight to extend the shelf-life of food products and expand the distribution of high-quality freeze-dried foods. Freeze Drying of Food Products readers will also find: An editorial team with a wide range of pertinent research experience Detailed discussion of different freeze-drying processes such as vacuum drying, atmospheric drying, and spray drying Commercial Applications of freeze-dried food products Freeze Drying of Food Products is ideal for researchers and industry professionals involved in food production, food distribution, or food biotechnology, as well as students studying these and other related fields.

Spray-Freeze-Drying of Foods and Bioproducts

Spray-freeze-drying (SFD) is a synergistic drying technology that imbibes in it the merits of both spray drying and freeze-drying, whilst overcoming the limitations of these predecessor technologies. SFD produces uniquely powdered food and pharmaceutical products with porous microstructure and superior quality attributes. Owing to its atomization step and ultra-low-temperature operation, SFD is a competent drying technique for the production of valuable but sensitive bioactive components. Despite the costs and complexities involved, SFD has a competitive edge over the conventional drying techniques in providing distinctive product attributes. The applications of spray-freeze-drying in the area of food and bioproducts span across the product categories of instant food powders, dry flavors, active pharmaceutical ingredients, poorly water-soluble drugs, probiotics, proteins, enzymes and vaccines. Spray-Freeze-Drying of Foods and Bioproducts: Theory, Applications and Perspectives is the first exclusive title on this interesting drying technique. It provides a comprehensive understanding of the fundamentals of SFD and its food and pharmaceutical applications. The scope of this book, comprising 12 chapters, has been organizedunder four major headings: fundamentals of process-stages, applications with case-studies, recent advancements and the processing bottlenecks and solutions. Key Features Provides examples and case studies of nuances and intricacies associated with each stage of the spray-freeze-drying process Highlights the applications of spray-freeze-drying in the production of food products including soluble coffee, dairy powders, probiotics and flavors Serves as a ready-reckoner of characterization methods for spray-freeze-dried products Contains 200+ illustrations and tabulations The contents of this book are organized to cater to the knowledge needs of students, academicians, researchers and professionals in the food and pharmaceutical industry.

Ice Templating and Freeze-Drying for Porous Materials and Their Applications

Filling a gap in the literature, this is the first book to focus on the fabrication of functional porous materials by using ice templating and freeze drying. Comprehensive in its scope, the volume covers such techniques as the fabrication of porous polymers, porous ceramics, biomimic strong composites, carbon nanostructured materials, nanomedicine, porous nanostructures by freeze drying of colloidal or nanoparticle suspensions, and porous materials by combining ice templating and other techniques. In addition, applications for each type of material are also discussed. Of great benefit to those working in the freeze-drying field and researchers in porous materials, materials chemistry, engineering, and the use of such materials for various applications, both in academia and industry.

Aulton's Pharmaceutics E-Book

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

delivery science, pharmaceutical manufacturing and medicines regulation Designed and written for newcomers to the design and manufacture of dosage forms Relevant pharmaceutical science covered throughout Includes the science of formulation and drug delivery Reflects current practices and future applications of formulation and drug delivery science to small drug molecules, biotechnology products and nanomedicines Key points boxes throughout Over 400 online multiple choice questions

Rational Design of Stable Protein Formulations

Recombinant proteins and polypeptides continue to be the most important class of biotechnology-derived agents in today's pharmaceutical industry. Over the past few years, our fundamental understanding of how proteins degrade and how stabilizing agents work has made it possible to approach formulation of protein pharmaceuticals from a much more rational point of view. This book describes the current level of understanding of protein instability and the strategies for stabilizing proteins under a variety of stressful conditions.

Encyclopedia of Pharmaceutical Technology

Covers the discovery development,regulation, manufacturing, and commercialization of drugs and dosage forms. Includes pharmaceuticals,pharmacokinetics, analytical chemistry, quality assurance, toxicology and the manufacturing process.

Development and Manufacture of Protein Pharmaceuticals

In this era of biotechnology there have been many books covering the fundamentals of recombinant DNA technology and protein chemistry. However, not many sources are available for the pharmaceutical develop ment scientist and other personnel responsible for the commercialization of the finished dosage forms of these new biopharmaceuticals and other products from biotechnology. This text will help to fill this gap. Once active biopharmaceutical molecules are candidates for clinical trial investigation and subsequent commercialization, a number of other activities must take place while research and development on these molecules continues. The active ingredient itself must be formulated into a finished dosage form that can be conveniently used by health care professionals and patients. Properties of the biopharmaceutical molecule must be clearly understood so that the appropriate finished product formulation can be developed. Finished product formulation development includes not only the chemical formulation, but also the packaging system, the manufacturing process, and appropriate control strategies to assure such good manufacturing practice attributes as safety, identity, strength, purity, and quality.

Aulton's Pharmaceutics

"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.

Cryopreservation and Freeze-Drying Protocols

In addition to outlining the fundamental principles associated with the conservation of biological resources, freeze-drying and cryopreservation, this text is a compilation of cryptopreservation and freeze-drying methodologies applicable to different biological materiels, developed by expert laboratories.

Lyophilization of Pharmaceuticals and Biologicals

The use of thermal and calorimetric methods has shown rapid growth over the past few decades, in an increasingly wide range of applications. The original text was published in 2001; since then there have been significant advances in various analytical techniques and their applications. This second edition supplies an up to date, concise and readable account of the principles, experimental apparatus and practical procedures used in thermal analysis and calorimetric methods of analysis. Written by experts in their field, brief accounts of the basic theory are reinforced with detailed technical advances and contemporary developments. Where appropriate, applications are used to highlight particular operating principles or methods of interpretation. As an important source of information for many levels of readership in a variety of areas, this book will be an aid for students and lecturers through to industrial and laboratory staff and consultants.

International Research in Engineering Sciences VI

This five-volume series provides a comprehensive overview of all important aspects of modern drying technology, concentrating on the transfer of cutting-edge research results to industrial use. Volume 3 discusses how desired properties of foods, biomaterials, active pharmaceutical ingredients, and fragile aerogels can be preserved during drying, and how spray drying and spray fluidized bed processes can be used for particle formation and formulation. Methods for monitoring product quality, such as process analytical technology, and modeling tools, such as Monte Carlo simulations, discrete particle modeling and neural networks, are presented with real examples from industry and academia.

Principles of Thermal Analysis and Calorimetry

This book provides a detailed account of the most recent developments, challenges and solutions to seamlessly advance and launch a lyophilized biologics or vaccine product, based on diverse modalities, ranging from antibodies (e.g., monoclonal, fused), complex biologics (e.g., antibody drug conjugate, PEGylated proteins), and vaccines (e.g., recombinant-protein based). The authors adeptly guide the reader through all crucial aspects, from biophysical and chemical stability considerations of proteins, analytical methods, advances in controlled ice nucleation and quality-by-design approaches, alternate drying technology, to latest regulatory, packaging and technology transfer considerations to develop a stable, safe and effective therapeutic protein, vaccine and biotechnology products. Lyophilized Biologics and Vaccines: Modality-Based Approaches is composed of four sections with a total of 17 chapters. It serves as a reference to all critical assessments and steps from early pre-formulation stages to product launch: Provides recent understanding of heterogeneity of protein environment and selection of appropriate buffer for stabilization of lyophilized formulations Details the latest developments in instrumental analysis and controlled ice nucleation technology Explains in-depth lyophilized (or dehydrated) formulation strategies considering diverse modalities of biologics and vaccines, including plasmid DNA and lipid-based therapeutics Details an exhaustive update on quality-by-design and process analytical technology approaches, illustrated superbly by case studies and FDA perspective Provides the latest detailed account of alternate drying technologies including spray drying, bulk freeze-drying and crystallization, supported exceptionally by case studies Provides a step-by-step guide through critical considerations during process scale-up, technology transfer, packaging and drug delivery device selection, for a successful lyophilization process validation, regulatory submission and product launch Chapters are written by one or more world-renowned leading authorities from academia, industry or regulatory agencies, whose expertise cover lyophilization of the diverse modalities of biopharmaceuticals. Their contributions are based on the exhaustive review of literature coupled with excellent hands-on experiences in laboratory or GMP setup, making this an exceptional guide to all stages of lyophilized or dehydrated product development.

Modern Drying Technology, Volume 3

Finding consistent, analytical discussions of processes and principles of lyophilization can be challenging and often frustrating. The first resource to gather information about the field, Lyophilization: Introduction and Basic Principles is still the book to have on lyophilization. Presenting information in an easy-to-read style, the book comprehensively and authoritatively covers the field. Using plain, unpretentious language, author Thomas A. Jennings pulls together information from diverse sources to provide an authoritative compendium of the lyophilization process and its basic principles. He provides important discussions about the nature of the container-closure system and the equipment, tools, and

environments required. Case studies and examples of solutions illustrate the many ways problems can be addressed in the lyophilization process. The book covers: Properties of lyophilized materials Product formulation requirements and the thermal properties of formulations Importance of process water Phase changes Thermal analytical methods Freezing, primary, and secondary drying processes Effect of vacuum freeze-dryers, both now and in the future Including over 150 illustrations, global symbols, and more than 350 references, this book is the complete guide to lyophilization, its analytical methods, measurement of process parameters, and equipment.

Lyophilized Biologics and Vaccines

On July 30-31, 2018, the National Academies of Sciences, Engineering, and Medicine held a workshop titled Continuous Manufacturing for the Modernization of Pharmaceutical Production. This workshop discussed the business and regulatory concerns associated with adopting continuous manufacturing techniques to produce biologics such as enzymes, monoclonal antibodies, and vaccines. The participants also discussed specific challenges for integration across the manufacturing system, including upstream and downstream processes, analytical techniques, and drug product development. The workshop addressed these challenges broadly across the biologics domain but focused particularly on drug categories of greatest FDA and industrial interest such as monoclonal antibodies and vaccines. This publication summarizes the presentations and discussions from the workshop.

Lyophilization

A guide to the important chemical engineering concepts for the development of new drugs, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry offers a guide to the experimental and computational methods related to drug product design and development. The second edition has been greatly expanded and covers a range of topics related to formulation design and process development of drug products. The authors review basic analytics for quantitation of drug product quality attributes, such as potency, purity, content uniformity, and dissolution, that are addressed with consideration of the applied statistics, process analytical technology, and process control. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The contributors explore technology transfer and scale-up of batch processes that are exemplified experimentally and computationally. Written for engineers working in the field, the book examines in-silico process modeling tools that streamline experimental screening approaches. In addition, the authors discuss the emerging field of continuous drug product manufacturing. This revised second edition: Contains 21 new or revised chapters, including chapters on quality by design, computational approaches for drug product modeling, process design with PAT and process control, engineering challenges and solutions Covers chemistry and engineering activities related to dosage form design, and process development, and scale-up Offers analytical methods and applied statistics that highlight drug product quality attributes as design features Presents updated and new example calculations and associated solutions Includes contributions from leading experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduation students, and professionals in the field of pharmaceutical sciences and manufacturing, Chemical Engineering in the Pharmaceutical Industry, Second Edition contains information designed to be of use from the engineer's perspective and spans information from solid to semi-solid to lyophilized drug products.

Continuous Manufacturing for the Modernization of Pharmaceutical Production

This detailed volume brings together leading practitioners in the freeze-drying community to address recent progress, not only in new analytical tools and applications of the data derived in cycle design but also in the manufacturing of lyophilized products in the healthcare sector – whether these be therapeutics, vaccines or diagnostic products - and indeed the equipment to deliver this scale of freeze-drying. Areas of focus include analytical and formulation issues, process monitoring and control, as well as post-lyophilization analysis. Written for the Methods in Pharmacology and Toxicology series, chapters include the type of expert advice that leads to superior results in the lab. Authoritative and practical, Lyophilization of Pharmaceuticals and Biologicals: New Technologies and Approaches serves as an ideal guide for researchers working in or just seeking an update on this rapidly changing field.

Chemical Engineering in the Pharmaceutical Industry

Martin's Physical Pharmacy and Pharmaceutical Sciences is considered the most comprehensive text available on the application of the physical, chemical and biological principles in the pharmaceutical sciences. It helps students, teachers, researchers, and industrial pharmaceutical scientists use elements of biology, physics, and chemistry in their work and study. Since the first edition was published in 1960, the text has been and continues to be a required text for the core courses of Pharmaceutics, Drug Delivery, and Physical Pharmacy. The Sixth Edition features expanded content on drug delivery, solid oral dosage forms, pharmaceutical polymers and pharmaceutical biotechnology, and updated sections to cover advances in nanotechnology.

Lyophilization of Pharmaceuticals and Biologicals

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.

Martin's Physical Pharmacy and Pharmaceutical Sciences

A real-world guide to the production and manufacturing of biopharmaceuticals While much has been written about the science of biopharmaceuticals, there is a need for practical, up-to-date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products. This book helps fill the gap in the field, examining all areas of biopharmaceuticals manufacturing, from development and formulation to production and packaging. Written by a group of experts from industry and academia, the book focuses on real-world methods for maintaining product integrity throughout the commercialization process, clearly explaining the fundamentals and essential pathways for all development stages. Coverage includes: Research and early development phase–appropriate approaches for ensuring product stability Development of commercially viable formulations for liquid and lyophilized dosage forms Optimal storage, packaging, and shipping methods Case studies relating to therapeutic monoclonal antibodies, recombinant proteins, and plasma fractions Useful analysis of successful and failed products Formulation and Process Development Strategies for Manufacturing Biopharma-ceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries, for government and regulatory agencies, and for anyone with an interest in the latest developments in the field.

Handbook of Stability Testing in Pharmaceutical Development

In this unique book, experts describe practices applicable to the large-scale processing of biotechnological products. Beginning with processing and bulk storage preservation techniques, the book provides strategies for improving efficiency of process campaigns of multiple products and manufacturing facilities for such processing techniques. Large-scale chromatography for the purification of biomolecules in manufacturing and lyophilization of protein pharmaceuticals are discussed. Includes a case study on blow-fill-seal processing technology and a chapter on economic and cost factors for bioprocess engineering.

Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals

Book DescriptionFreeze drying has many applications in the Food and Pharmaceutical industry. This book is an authentic and supreme emblem of quality that covers the basic concepts related to the lyophilization process. Review of almost all the relevant books and scientific journals is made to make the book error-free. Specifically, this book focusses on the freeze-drying process and their operating parameters for the agricultural products. I want to especially thanks to Prof. Dr Yongbin Han, Department of Agricultural Products Processing and Storage Engineering, School of Food Science and Technology, Nanjing Agricultural University, China; to help me to complete this book.Key Features: -Introduction to Freeze Drying Technique-Defining of all related Process Parameters and Variables-Recent Researches in the Freeze-Drying Field-Chemistry of Agricultural Products and their Thermal Properties-Disadvantages of Freeze-Drying Technique-Different Mathematical Models proposed by different Researchers and their ComponentsWhat will you learn?After reviewing this book, you will be able to understand the freeze-drying technique and all related terminologies. Raw material treatment, it's freezing, primary and secondary drying; all these operations should be carried out under critical considerations to dry the product efficiently. Product quality is the ultimate goal in this process and it can best achieve using freeze-drying. Thermal properties and the nature of the raw material may change the operating parameters for each of the product. But specifically, this book focuses

on the freeze-drying process for agricultural products.Who is this Book for?This book is for: -Food Engineers -Freeze-drying researchers-Chemical Engineers (Those who are serving food industries as lab chemist, QC officers, and R&D officers) -Food nutritionists -Food professionals (Those who are working in food industries in freeze-drying related departments as quality officers, lab supervisors, product development officers, product audit chemists, and vicinities) -Food production compliance staff Table of Contents -Abstract-Introduction to Freeze Drying-Chemistry of Agricultural Products-Freeze Drying Stages-Freeze Drying Process Parameters -Thermal Properties of food-Disadvantages of Freeze-Drying Process-Components of Freeze Dryer-Mathematical Modeling-Conclusion-Nomenclature-ReferencesAbout this AuthorMuhammad Waseem Akbar is a food engineer by education. He is expert in nutritional, health and processing courses. Drying is a preservation technique. He has a special interest in the freeze-drying technique. This is one of the most emerging drying technique and has the potential to produce quality products with an extended shelf life for years. The author has written multiple books in the food science and engineering domain.

Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation

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.

Freeze Drying Or Lyophilization

Pharmaceutical Manufacturing Handbook