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Encapsulation Technologies and Delivery Systems for Food Ingredients and Nutraceuticals
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Lyophilization of Biopharmaceuticals

CHRISTINE MORSE

Production, Processing and Food Applications Springer Science & Business Media
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.
New Technologies and Approaches Elsevier
Vaccine Manufacturing and Production is an invaluable reference on how to produce a vaccine - from beginning to end - addressing all classes of vaccines from a processing, production, and regulatory viewpoint. It will provide comprehensive information on the various fields involved in the production of vaccines, from fermentation, purification, formulation, to regulatory filing and facility designs. In recent years, there have been tremendous advances in all aspects of vaccine manufacturing. Improved technology and growth media have been developed for the production of cell culture with high cell density or fermentation. Vaccine Manufacturing and Production will serve as a reference on all aspects of vaccine production by providing an in-depth description of the available technologies for making different types of vaccines and the current thinking in facility designs and supply issues. This book will provide insight to the issues scientists face when producing a vaccine, the steps that are involved, and will serve as a reference tool regarding state-of-the-art vaccine manufacturing technologies and facility set-up. Highlights include: Comprehensive coverage of vaccine production : from a process point of view- fermentation to purification to formulation developments; from a production point of view - from facility design to manufacturing; and from a regulatory point of view - requirements from government agencies Authors from different major pharmaceutical and biotechnology companies Describes the challenges and issues involved in vaccine production and manufacturing of the different classes of vaccines, an area not covered by other books currently on the market
Protein Purification Protocols John Wiley & Sons
Many food ingredients are supplied in powdered form, as reducing water content increases shelf life and aids ease of storage, handling and transport. Powder technology is therefore of great importance to the food industry. The Handbook of food powders explores a variety of processes that are involved in the production of food powders, the further processing of these powders and their functional properties. Part one introduces processing and handling technologies for food powders and includes chapters on spray, freeze and drum drying, powder mixing in the production of food powders and safety issues around food powder production processes. Part two focusses on powder properties including surface composition, rehydration and techniques to analyse the particle size of food powders. Finally, part three highlights speciality food powders and includes chapters on dairy powders, fruit and vegetable powders and coating foods with powders. The Handbook of food powders is a standard reference for professionals in the food powder production and handling industries, development and quality control professionals in the food industry using powders in foods, and researchers, scientists and academics interested in the field. Explores the processing and handling technologies in the production of food powders Examines powder properties, including surface composition, shelf life, and techniques used to examine particle size Focusses on speciality powders such as dairy, infant formulas, powdered egg, fruit and vegetable, and culinary and speciality products
Development and Manufacture of Protein Pharmaceuticals John Wiley & Sons
Improved technologies for the encapsulation, protection, release and enhanced bioavailability of food ingredients and nutraceutical components are vital to the development of future foods. Encapsulation technologies and delivery systems for food ingredients and nutraceuticals provides a comprehensive guide to current and emerging techniques. Part one provides an overview of key requirements for food ingredient and nutraceutical delivery systems, discussing challenges in system development and analysis of interaction with the human gastrointestinal tract. Processing technologies for encapsulation and delivery systems are the focus of part two. Spray drying, cooling and chilling are reviewed alongside coextrusion, fluid bed microencapsulation, microencapsulation methods based on biopolymer phase separation, and gelation phenomena in aqueous media. Part three goes on to investigate physicochemical approaches to the production of encapsulation and delivery systems, including the use of micelles and microemulsions, polymeric amphiphiles, liposomes, colloidal emulsions, organogels and hydrogels. Finally, part four reviews characterization and applications of delivery systems, providing industry perspectives on flavour, fish oil, iron micronutrient and probiotic delivery systems. With its distinguished editors and international team of expert contributors, Encapsulation technologies and delivery systems for food ingredients and nutraceuticals is an authoritative guide for both industry and academic researchers interested in encapsulation and controlled release systems. Provides a comprehensive guide to current and emerging techniques in encapsulation technologies and delivery systems Chapters in part one provide an overview of key requirements for food ingredient and nutraceutical delivery systems, while part two discusses processing technologies for encapsulation and delivery systems Later sections investigate physicochemical approaches to the production of encapsulation and delivery systems and review characterization and applications of delivery systems

Good Pharmaceutical Freeze-Drying Practice Elsevier
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.
Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products, Third Edition Elsevier
In this new edition of the very successful Protein Purification Protocols (1996), Paul Cutler completely updates the existing protocols to reflect recent advances and adds an enormous new array of proteomic techniques for protein isolation and analysis. These cutting-edge techniques include not only two-dimensional gel electrophoresis for analysis and characterization, but also analytical chromatography for multidimensional separations of proteins and peptides, and mass spectrometry for isolating proteins. With the many recent advances in technology, simple spectrometric detection is no longer the only option for separating proteins, and the authors treat in full detail all the newer methods for these separations. Comprehensive and highly practical, Protein Purification Protocols, Second Edition, brings together all the key methodologies that both novice and experienced investigators need to carry out successful experimental work on proteins and their functions today.
Acceleration and Automation of Solid Sample Treatment Springer Nature
Classical theory of sublimation. Heat transfer. Vapour transfer. Drying rate. Physical mechanism of cyclic-pressure freeze-drying. Analytical cyclic process. Drying plant and equipment. Laboratory apparatus and techniques. Drying plant and equipment for freeze-drying. foodstuffs. Effects of freeze-drying. Miscellaneous aspects of freeze-drying. Biological aspects.
Lyophilization of Pharmaceuticals and Biologicals John Wiley & Sons
Many modern pharmaceutical and biological products, e.g. blood derivatives, vaccines, cytostatic drugs, antibiotics, bacteria cultures but also consumer goods such as soluble coffee are freeze-dried to transform perishable substances into a form that can be stored and reconstituted to their almost original state without loss of quality. The book describes the up-to-date fundamentals of freeze-drying, not just presenting the process in all its seven steps theoretically, but explaining it with many practical examples. Many years of experience in freeze-drying allow 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. In this second, completely revised edition, process and plant automation are introduced in a separate section and methods to transfer pilot plant qualifications and process data to production are presented. The guidelines for process and plant evaluation and qualifications have been updated and enlarged. Trouble shooting is concentrated in a section of its own and literature has been updated with 100 new quotations to include references as recent as 2002, and 100 new tables and figures have been added.
Proceedings of a Symposium CRC Press
Comprehensive Assessment of This Globally Relevant Practice As a centuries-old food preservation method, dehydration technology has advanced significantly in the past decades as a result of new methods, sophisticated analytical techniques, and improved mathematical modeling. Providing practical and expert insight from an international panel of experts, Advances in Food Dehydration encompasses these revolutionary advances and effectively supplies the knowledge base required to optimize natural resources and reduce energy requirements in order to meet growing demand for low-cost, high-quality food products. Discusses Ways to Best Optimize Natural Resources Under the editorial guidance of food engineering and dehydration authority Cristina Ratti, this resource addresses the three biggest challenges associated with food dehydration: The complex nature of food systems together with the deep structural and physico-chemical changes that foodstuffs undergo during processing The difficulty to define quality in quantitative terms and to develop appropriate control techniques The lack of realistic models and simulations to represent the phenomena The book’s well-developed chapters explain the structural and physico-chemical changes that food undergoes during dehydration, while discussing ways to optimize natural resources. In addition to describing non-convectional heating sources such as microwaves, infrared, and radio frequency, the text also examines the impact of drying on nutraceutical compounds, the bases of rehydration of dry food particles and the stresses on microorganisms during drying and their stability during storage. Advances in Food Dehydration is a user-friendly volume that concisely links the gamut of dehydration concepts into one cohesive reference. About the Editor: Cristina Ratti, Ph.D., is a food engineering professor in the Soils and Agri-Food Engineering Department at the Université Laval (Quebec). She is the coordinator of the Food Engineering Program and a member of the Institute of Nutraceutical and Function Foods (INAF). She has published numerous scientific manuscripts related to her research interests in food dehydration as well as physiochemical and quality properties of foodstuffs related to drying.
Handbook of Drying for Dairy Products Springer Science & Business Media
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.

Vaccine Development and Manufacturing CRC PressI Llc

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.

Handbook of Food Powders Elsevier

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

Introduction and Basic Principles CRC Press

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.

Ice Templating and Freeze-Drying for Porous Materials and Their Applications S Karger Ag

The last two decades have seen a phenomenal growth of the field of genetic or biochemical engineering and have witnessed the development and ultimately marketing of a variety of products-typically through the manipulation and growth of different types of microorganisms, followed by the recovery and purification of the associated products. The engineers and biotechnologists who are involved in the full-scale process design of such facilities must be familiar with the variety of unit operations and equipment and the applicable regulatory requirements. This book describes current commercial practice and will be useful to those engineers working in this field in the design, construction and operation of pharmaceutical and biotechnology plants. It will be of help to the chemical or pharmaceutical engineer who is developing a plant design and who faces issues such as: Should the process be batch or continuous or a combination of batch and continuous? How should the optimum process design be developed? Should one employ a new revolutionary separation which could be potentially difficult to validate or use accepted technology which involves less risk? Should the process be run with ingredients formulated from water for injection, deionized water, or even filtered tap water? Should any of the separations be run in cold rooms or in glycol jacketed lines to minimize microbial growth where sterilization is not possible? Should the process equipment and lines be designed to be sterilized in-place, cleaned-in-place, or should every piece be broken down, cleaned and autoclaved after every turn?

Compendium of Biomedical Instrumentation, 3 Volume Set John Wiley & Sons

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.

Cryopreservation and Freeze-Drying Protocols John Wiley & Sons

The only comprehensive and authoritative reference guide to the ASME Bioprocessing Piping and

Equipment (BPE) standard This is a companion guide to the ASME Bioprocessing Piping and Equipment (BPE) Standard and explains what lies behind many of the requirements and recommendations within that industry standard. Following an introductory narrative to the Standard's early history, industry related codes and standards are explained; the design and engineering aspects cover construction materials, both metallic and nonmetallic; then components, fabrication, assembly and installation of piping systems are explored. Examination, Inspection and Testing then precede the ASME BPE certification process, concluding with a discussion on system design. The author draws on many years' experience and insights from first-hand involvement in the field of industrial piping design, engineering, construction, and management, which includes the bioprocessing industry. The reader will learn why dimensions and tolerances, process instrumentation, and material selection play such an integral part in the manufacture of components and instrumentation. This easy to understand and navigate guide will assist engineers (design, piping, chemical, etc.) who need to understand the basis for much of the Standard’s content, as do the contractors and inspectors who have to meet and validate compliance with the BPE Standard.

Freeze-Drying CRC Press

This widely expanded second edition offers a compilation of robust, reproducible techniques for the conservation of a wide range of biological materials. It includes novel approaches and protocols that were not preservable when the first edition was published. The book begins with a discussion of long term ex situ conservation of biological resources, the role of biological resource centers, and fundamental principles of freeze-drying and cryopreservation. Each chapter focuses on the preservation of specific biological materials, including proteins, mircroorganisms, cell lines, and multicellular structures.

Freeze-drying of Pharmaceuticals and Biopharmaceuticals CRC Press

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 Springer Science & Business Media

Nanobiomaterials in Soft Tissue Engineering brings together recent developments and the latest approaches in the field of soft tissue engineering at the nanoscale, offering a new perspective on the evolution of current and future applications. Leading researchers from around the world present the latest research and share new insights. This book covers the major conventional and unconventional fabrication methods of typical three-dimensional scaffolds used in regenerative medicine. Surface modification and spatial properties are included in an up-to-date overview, with the latest in vivo applications of engineered 3D scaffolds discussed. The book also considers the impact, advantages and future scope of the various methods. This book will be of interest to postdoctoral researchers, professors and students engaged in the fields of materials science, biotechnology and applied chemistry. It will also be highly valuable to those working in industry, including pharmaceutics and biotechnology companies, medical researchers, biomedical engineers and advanced clinicians. An informative handbook for researchers, practitioners and students working in biomedical, biotechnological and engineering fields. A detailed and invaluable overview of soft tissue engineering, including the most recent scientific developments. Proposes novel opportunities and ideas for developing or improving technologies in nanomedicine and nanobiology.

Freeze-Drying of Pharmaceutical and Food Products CRC Press

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