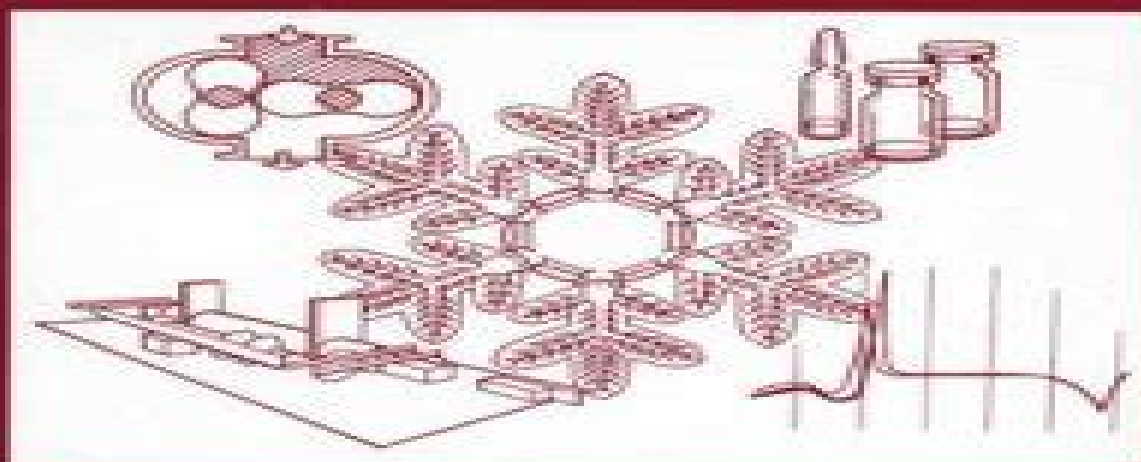


Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products



edited by
Louis Rey
Joan C. May

Freeze Drying And Lyophilization Of Pharmaceutical And Biological Products Drugs And The Pharmaceutical Sciences

SA Adler



Freeze Drying And Lyophilization Of Pharmaceutical And Biological Products Drugs And The Pharmaceutical Sciences:

Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products Louis Rey, 2016-04-19 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

Freeze-Drying/Lyophilization Of Pharmaceutical & Biological Products, Revised and Expanded Louis Rey, Joan C. May, 2004-01-21 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/lyophilization of Pharmaceutical and Biological Products Louis Rey, Joan Christine May, 2004 **Integrated Pharmaceutics** Antoine Al-Achi, Mali Ram Gupta, William Craig Stagner, 2022-09-07 This work is an examination of all aspects of the science in developing effective dosage form for drug delivery Pharmaceutics refers to the subfield of pharmaceutical sciences that develops drug delivery products or devices to optimize the drug s performance once administered This multidisciplinary field draws on physical chemistry organic chemistry and biophysics to generate and refine these crucial elements of medical care Moreover incorporating such disparate dimensions of drug product design as material properties and legal regulation bridges the gap between effective chemicals and viable medical treatments Integrated Pharmaceutics provides a comprehensive introduction to the creation and manufacture of effective dosage forms for drug delivery It presents its subject following the principles of physical pharmacy product design and drug regulations This tripartite structure allows readers to move from theory to practice beginning from a firm foundation of physical pharmacy principles including drug solubility and stability estimation rheology and interfacial properties From there it proceeds to discussions of drug product design and of harmonizing pharmaceutical design with the regulatory regimens and technological standards of the United States European Union and Japan Readers of the second edition of Integrated Pharmaceutics will also find A glossary defining key terms extensive informative appendices and a list of references leading to the primary literature in the field for each chapter Earlier chapters are expanded with additional new chapters including one entitled Biotechnology Products Supplementary instructor guide with questions and solutions available online for registered professors Updated regulatory guidelines including quality by design design space analysis process analytical technology polymorphism characterization blend sample uniformity and stability protocols

Integrated Pharmaceutics is a useful textbook for graduate students in pharmaceutical sciences drug formulation and design and biomedical engineering In addition professionals in the pharmaceutical industry including regulatory bodies will find it a helpful reference guide

Principles and Practices of Lyophilization in Product Development and Manufacturing

Feroz Jameel,2023-04-24 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 Technology in Pharmaceutical and Biomedical Product Development Dalapathi Gugulothu,Sumit

Sharma,Meenakshi Kanwar Chauhan,2025-08-23 The book presents a comprehensive summary of the advances in methods applications and challenges in Freeze drying Technology for pharmaceutical product development Freeze drying sometimes referred to as lyophilization is an essential method in biomedical and pharmaceutical industries that allows for extremely accurate preservation of sensitive biological components This book highlights freeze drying operation the different types of freeze dryers development of the freeze drying cycle and characterization of freeze dried goods It also explores the crucial connection between freeze drying and colloidal dispersions stability illuminating the complex interactions between formulation composition processing variables and stability of the final product It focuses on the benefits of this method for stabilizing essential biopharmaceuticals such as probiotics recombinant proteins and monoclonal antibodies by preventing aggregation and degradation and sustaining their therapeutic effectiveness for longer periods of time Apart from the chemistry operations and benefits this book explores new possibilities for precisely and deeply describing freeze dried products by discussing the most recent developments in analytical methods The audience for this book will comprise of researchers clinicians graduate students and professionals in biotechnology and pharmaceutical industries This book also serves as a valuable resource for educators by providing them information that they can incorporate into their curricula for teaching pharmaceutical formulation and drug delivery

Freeze-drying of Pharmaceuticals and Biopharmaceuticals Felix

Franks, Tony Auffret, 2008 Freeze drying in the past popular in the food industry has more recently been adopted by the pharmaceutical industry as a standard method for the production of stable solid preparations Freeze drying of Pharmaceuticals and Biopharmaceuticals is the first book to specifically describe this process as related to the pharmaceutical industry The emphasis of this book is on the properties of the materials processed how effective formulations are arrived at and how they are stored and marketed Beginning with a historical overview of the process Freeze drying of Pharmaceuticals and Biopharmaceuticals briefly describes the processes and equipment involved including the physics chemistry and biochemistry associated with freezing aspects of formulation development primary and secondary drying the economics and engineering of scaling up and most importantly attributes of the dried product It also discusses in detail the science behind freeze drying such as the properties of crystalline and amorphous solids The book concludes with selected case studies and discusses the future of freeze drying advances in alternative drying methods and concludes with an extensive bibliography This book written by a leading expert in the field is aimed primarily at product and process developers in the biopharmaceutical industry and academia Extract from a review this book is a very useful and thorough overview of the processes in operation during freezing and lyophilization and should be read by all those who are interested in freeze drying and pharmaceutical formulation design I certainly will be returning to it as an excellent summary of these important issues CryoLetters c o Royal Veterinary College London UK

Drying Technologies for Biotechnology and Pharmaceutical Applications Satoshi Ohtake, Ken-ichi Izutsu, David Lechuga-Ballesteros, 2020-06-02 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 **International Symposium on Freeze-drying of Biological Products** V. J. Cabasso, Robert Henri Regamey, 1977 Freeze-Drying of Pharmaceutical and Food Products Tse-Chao Hua, Bao-Lin Liu, Haimei Zhang, 2010-07-30 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 Cumulated Index to the Books ,1999 □□□□□□□□ ,2000 Vols for 1975 contain the summaries of the staff publications *Lyophilization of Biopharmaceuticals* Henry R. Costantino, Michael J. Pikal, 2005-12-05 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 **Encyclopedia of Separation Science** Michael Cooke, C. F. Poole, 2000 Proceedings of the ASME Process Industries Division--2001 : Presented at the 2001 ASME Mechanical Engineering Congress and Exposition, November 11-16, 2001, New York, New York Riyaz A. Papar, 2001 **Bibliographic Index** ,1999 **Developments in Biological Standardization** ,1991 *Bulletin Parenteral Drug Association*, 1976 **International Symposium on Biological Product Freeze-Drying and Formulation** F. Brown, 1992 **Pharmaceutical Dosage Forms, Parenteral Medications** Kenneth E. Avis, Leon Lachman, Herbert A. Lieberman, 1984

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