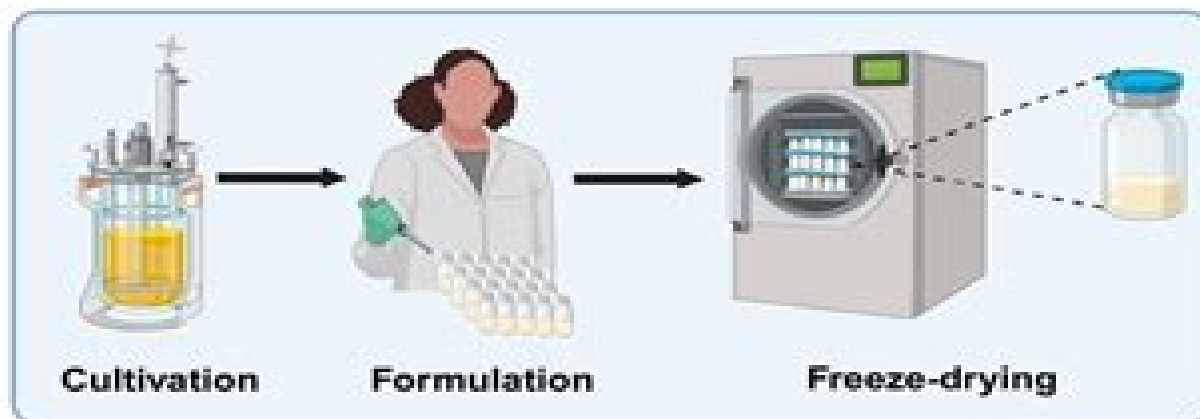
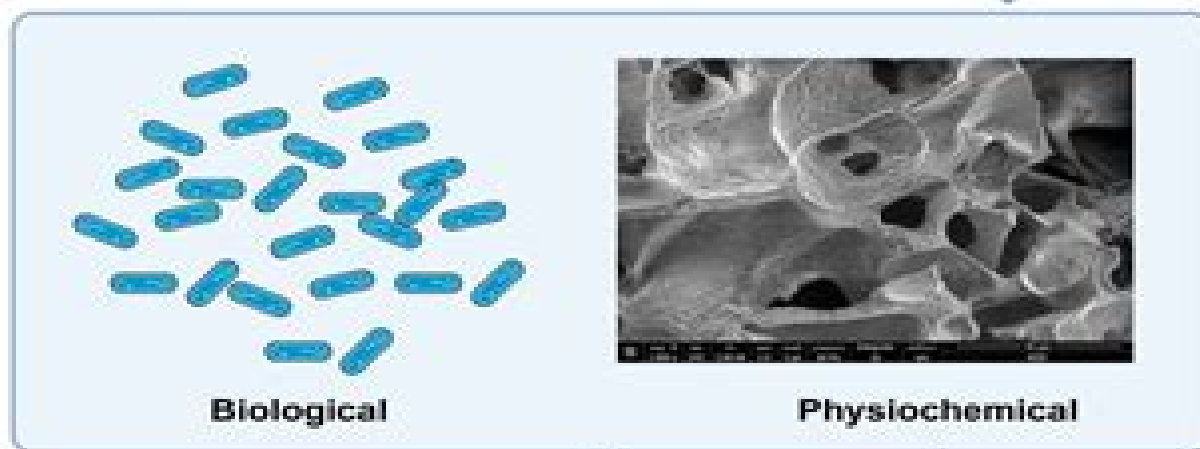


## Formulation & freeze-drying



## Characterization



↑ **Vitality**

Sucrose (15%)

Annealing

$10^{10}$  CFU/mL

↑ **Viability**

Sucrose (15%)

↑ **Stability**

Sucrose (15%)

$10^{10}$  CFU/mL

# Biological Product Freezedrying And Formulation

**Jessica J Manson**



## **Biological Product Freezedrying And Formulation:**

**Freeze-drying/lyophilization of Pharmaceutical and Biological Products** Louis Rey,Joan Christine May,1999  
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 *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 regulatio **International Symposium on Biological Product Freeze-Drying and Formulation** F. Brown,1992

**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 *Biological Product Freeze-Drying and Formulation* J. C. May,Center for Biologics Evaluation and Research,F. Brown,1992 *International Symposium on Biological Product Freeze-Drying and Formulation* F. Brown,1992 **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 *Lyophilization* Thomas A. Jennings,1999-08-31 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 comprehe Downstream Industrial Biotechnology Michael C. Flickinger,2013-07-17 DOWNSTREAM INDUSTRIAL BIOTECHNOLOGY An affordable easily accessible desk reference on biomanufacturing focused on downstream recovery and purification Advances in the fundamental knowledge surrounding biotechnology novel materials and advanced engineering approaches continue to be translated into bioprocesses that bring new products to market at a significantly faster pace than most other industries Industrial scale biotechnology and new manufacturing methods are revolutionizing medicine environmental monitoring and remediation consumer products food production agriculture and forestry and continue to be a major area of research The downstream stage in industrial biotechnology refers to recovery isolation and purification of the microbial products from cell debris processing medium and contaminating biomolecules from the upstream process into a finished product such as biopharmaceuticals and vaccines Downstream process design has the greatest impact on overall biomanufacturing cost because not only does the biochemistry of different products e g peptides proteins hormones antibiotics and complex antigens dictate different methods for the isolation and purification of these products but contaminating byproducts can also reduce overall process yield and may have serious consequences on clinical safety and efficacy Therefore downstream separation scientists and engineers are continually seeking to eliminate or combine unit operations to minimize the number of process steps in order to maximize product recovery at a specified concentration and purity Based on Wiley s Encyclopedia of Industrial Biotechnology Bioprocess Bioseparation and Cell Technology this volume features fifty articles that provide information on down stream recovery of cells and protein capture process development and facility design equipment PAT in downstream processes downstream cGMP operations and regulatory compliance It covers Cell wall disruption and lysis Cell recovery by centrifugation and filtration Large scale protein chromatography Scale down of biopharmaceutical purification operations Lipopolysaccharide removal Porous media in biotechnology Equipment used in industrial protein purification Affinity chromatography Antibody purification monoclonal and polyclonal Protein aggregation precipitation and crystallization Freeze drying of biopharmaceuticals Biopharmaceutical facility design and validation Pharmaceutical bioburden testing Regulatory requirements Ideal for graduate and advanced undergraduate courses on biomanufacturing biochemical engineering biopharmaceutical facility design biochemistry industrial microbiology gene expression technology and cell culture technology Downstream Industrial Biotechnology is also a highly recommended resource for industry

professionals and libraries      *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

**Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals** Feroz Jameel, Susan Hersenson, 2010-08-09 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 Biopharmaceuticals 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

Spray-Freeze-Drying of Foods and Bioproducts S. Padma Ishwarya, 2022-04-19 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

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**Medicus**, 1989 *Lyophilized Biologics and Vaccines* Dushyant Varshney, Manmohan Singh, 2015-05-19 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 *Pharmaceutical Manufacturing Formulations* Dr. Priyanka Gupta Manglik,2024-08-15 This book provides detailed insight into the various aspects of pharmaceutical manufacturing covering formulations process design technology and regulatory requirements essential for professionals in the pharma industry *Sterile Drug Products* Michael J. Akers,2016-04-19 Sterile Drug Products Formulation Packaging Manufacturing and Quality teaches the basic principles of the development and manufacture of high quality sterile dosage forms The author has 38 years of experience in the development and manufacture of sterile dosage forms including solutions suspensions ophthalmics and freeze dried products This book is based on the courses he has delivered for over three decades to over 3000 participants and is intended to remain relevant for the indefinite future even as new technologies and new applications of old technologies become common This is an ideal reference book for those working directly and indirectly with sterile dosage forms be it product development formulation package process analytical manufacturing quality control quality assurance regulatory purchasing or project management This book is also intended as an educational resource for the pharmaceutical and biopharmaceutical industry and pharmacy schools providing basic knowledge and principles in four main areas of parenteral science and technology Product development including formulation packaging and process development Manufacturing including basic teaching on all the primary unit operations involved in preparation of sterile products and the underlying importance of contamination control Quality and regulatory including the application of good manufacturing practice regulations aseptic processing guidelines and unique quality control testing methods for the sterile dosage form Clinical aspects including administration potential hazards and biopharmaceuticals of sterile products in a clinical setting Handbook of Pharmaceutical Manufacturing Formulations Safaraz K. Niazi,2016-04-19 No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products for obvious reasons With the increasing number of potent products particularly the new line of small protein products joining the long list of proven sterile products the technology of manufacturing ster **Optimization in Food Engineering** Ferruh Erdogdu,2008-12-09 While mathematically sophisticated methods can be used to better understand and improve processes the nonlinear nature of food processing models can make their dynamic optimization a daunting task With contributions from a virtual who's who in the food processing industry Optimization in Food Engineering evaluates the potential uses and limitations *Protein Formulation and Delivery* Eugene J. McNally,Eugene McNally,Jayne E. Hastedt,2007-10-26 This title is intended to assist pharmaceutical scientists in the development of stable protein formulations during the early stages of the product development process

providing a comprehensive review of mechanisms and causes of protein instability in formulation development coverage of accelerated stability testing methods and relevant analytical

**Advanced Drug Formulation Design to Optimize Therapeutic Outcomes** Robert O. Williams, David R. Taft, Jason T. McConville, 2007-09-25 This title demonstrates how advanced formulation designs and delivery technologies can be used to improve drug efficacy and treatment outcomes in particular therapeutic categories or disease states It discusses nanoparticle systems for cancer treatments and also presents cutting edge immunoregulation agents for transplantation and the local target



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