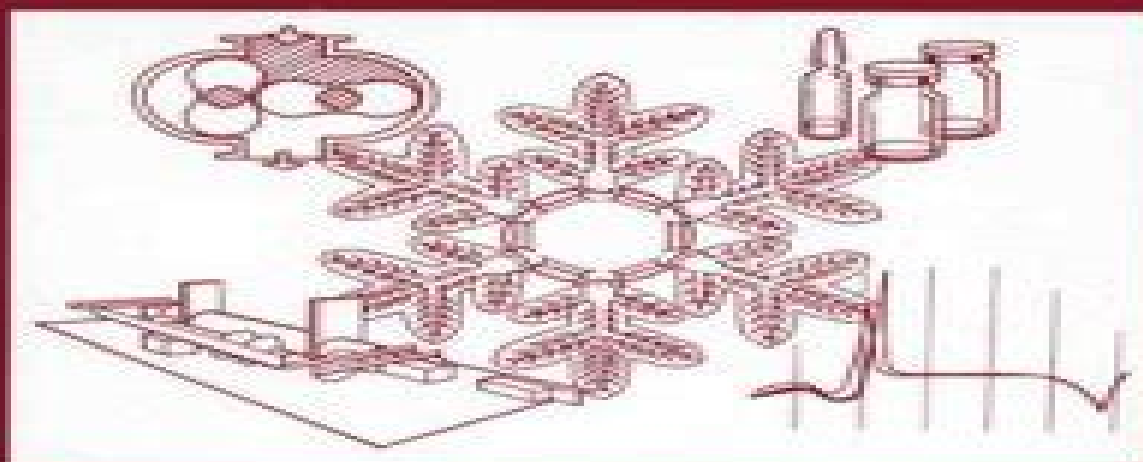


# Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products



edited by  
Louis Rey  
Joan C. May

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

**Michael Brown**



## **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

*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.

**Pharmaceutical Formulation Development of Peptides and Proteins, Second Edition** Lars Hovgaard, Sven Frokjaer, Marco van de Weert, 2012-11-14 The rapid advances in recombinant DNA technology and the increasing availability of peptides and proteins with therapeutic

potential are a challenge for pharmaceutical scientists who have to formulate these compounds as drug products  
Pharmaceutical Formulation Development of Peptides and Proteins Second Edition discusses the development of therapeutic peptides and proteins from the production of active compounds via basic pre formulation and formulation to the registration of the final product Providing integrated solutions this book discusses The synthesis of peptides and the biotechnological production of proteins through recombinant DNA technology The physicochemical characteristics and stability of peptides and proteins The formulation of proteins as suspensions solutions and mostly freeze dried solids The opportunities and challenges of non parenteral delivery of peptides and proteins Risk factors specifically the development of an unwanted immune response A simulation approach to describe the fate of peptides and proteins upon administration to a biological system The documentation required to register a protein based drug Scientists in the pharmaceutical industry and academia as well as postgraduate students in pharmaceutical science will find this a valuable resource **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 **Freeze Drying of**

**Pharmaceutical Products** Davide Fissore,Roberto Pisano,Antonello Barresi,2019-10-24 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

**Drug Stereochemistry** Krzysztof Jozwiak, W. J. Lough, Irving W. Wainer, 2012-04-23 Drug Stereochemistry Analytical Methods and Pharmacology Third Edition covers all aspects of chiral drugs from academic governmental industrial and clinical perspectives reflecting the many advances in techniques and methodology Topics include The use of enzymes in the synthesis and resolution of enantiometrically pure compounds in drug disc

*Effect of Collapse on Pharmaceutical Protein Lyophilizates* Kathrin Brigitte Schersch, 2011-02-03

**Vaccine Development and Manufacturing** Emily P. Wen, Ronald Ellis, Narahari S. Pujar, 2014-11-17 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 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 Dietary Supplement Good Manufacturing Practices William J. Mead, 2016-04-19 Dietary Supplement GMP is a one stop how to road map to the final dietary supplement GMP regulations recently issued by the FDA covering the manufacture packaging and holding of dietary supplement products The recent regulations outlining broad goals intentionally avoid specifics to allow for future technological advances leaving implementation Drying Technologies for Biotechnology and Pharmaceutical Applications Satoshi Ohtake, Ken-ichi Izutsu, David Lechuga-Ballesteros, 2020-02-03 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 Pharmaceutical Stress Testing Steven W. Baertschi, Karen M. Alsante, Robert A. Reed, 2016-04-19 The second edition of Pharmaceutical Stress Testing Predicting Drug Degradation provides a practical and scientific guide to designing executing and interpreting stress testing studies for drug substance and drug product This is the only guide available to tackle this subject in depth The Second Edition expands coverage from chemical stability **Good Design Practices for GMP Pharmaceutical Facilities** Terry Jacobs, Andrew A. Signore, 2016-08-19 This revised publication serves as a handy and current reference for professionals engaged in planning designing building validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U S and internationally The new edition expands on facility planning with a focus on the ever growing need to modify existing legacy facilities and on current trends in pharmaceutical

manufacturing which include strategies for sustainability and LEED building ratings All chapters have been re examined with a fresh outlook on current good design practices

### **Supercritical Fluid Technology for Drug Product Development**

Peter York,Uday B. Kompella,Boris Y. Shekunov,2004-03-23 Interconnecting the fundamentals of supercritical fluid SCF technologies their current and anticipated utility in drug delivery and process engineering advances from related methodological domains and pharmaceutical applications this volume unlocks the potential of supercritical fluids to further the development of improved pharmaceutical prod

### **Life in the Frozen State** Barry J. Fuller,Nick Lane,Erica E.

Benson,2004-05-10 While it is barely 50 years since the first reliable reports of the recovery of living cells frozen to cryogenic temperatures there has been tremendous growth in the use of cryobiology in medicine agriculture horticulture forestry and the conservation of endangered or economically important species As the first major text on cryobiolog

### **Advanced**

**Aseptic Processing Technology** James Agalloco,James Akers,2016-04-19 The preparation of sterile products using aseptic processing is considered perhaps the most critical process in the pharmaceutical industry and has witnessed continual improvement over the last half century New approaches that have transformed classical aseptic production methods are appearing almost daily This book reviews emerging technologies

### **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

**Tissue Engineering and Artificial Organs** Joseph D. Bronzino,Donald R. Peterson,2006-05-01 Over the last century medicine has come out of the black bag and emerged as one of the most dynamic and advanced fields of development in science and technology Today biomedical engineering plays a critical role in patient diagnosis care and rehabilitation As such the field encompasses a wide range of disciplines from biology and physiology to material science and nanotechnology Reflecting the enormous growth and change in biomedical engineering during the infancy of the 21st century The Biomedical Engineering Handbook enters its third edition as a set of three carefully focused and conveniently organized books Reviewing applications at the leading edge of modern biomedical engineering Tissue Engineering and Artificial Organs explores transport phenomena biomimetics systems biotechnology prostheses artificial organs and ethical issues The book features approximately 90% new material in the tissue engineering section integrates coverage of life sciences with a new section on molecular biology and includes a new section on bionanotechnology Prominent leaders from around the world share their expertise in their respective fields with many new and updated chapters New technologies and methods spawned by biomedical engineering have the potential to improve the quality of life for everyone and Tissue Engineering and Artificial Organs sheds light on the tools that will enable these advances

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