

Pharmaceutical Biotechnology - Volume 13

# **Rational Design of Stable Protein Formulations**

**Theory and Practice**

Edited by  
**John F. Carpenter**  
and  
**Mark C. Manning**

# Rational Design Of Stable Protein Formulations Theory And Practice

**Haifei Zhang**



## **Rational Design Of Stable Protein Formulations Theory And Practice:**

**Rational Design of Stable Protein Formulations** John F. Carpenter, Mark C. Manning, 2002-04-30 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.

**Rational Design of Stable Protein Formulations** John F. Carpenter, Mark C. Manning, 2012-12-06 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.

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.

**Ice Templating and Freeze-Drying for Porous Materials and Their Applications** Haifei Zhang, 2018-05-14 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, biomimetic 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.

*Therapeutic Peptides and Proteins* Ajay K. Banga, 2015-04-23 There are more than 500 biopharmaceuticals on the market, including more than 200 therapeutic proteins, making biologics the fastest growing sector in the biopharmaceutical market. These products include more than 40 monoclonal antibodies for indications ranging from treatment or mitigation of various types of cancer to rheumatoid arthritis. The c

Quality by Design for Biopharmaceutical Drug Product Development Feroz Jameel, Susan Hersenson, Mansoor A. Khan, Sheryl Martin-Moe, 2015-04-01 This volume explores the application of Quality by Design (QbD) to biopharmaceutical drug product development. Twenty-eight comprehensive chapters cover dosage forms, liquid and lyophilized drug products. The introductory chapters of this book define key elements of QbD and examine how these elements are integrated into drug product development. These chapters

also discuss lessons learned from the FDA Office of Biotechnology Products pilot program. Following chapters demonstrate how QbD is used for formulation development ranging from screening of formulations to developability assessment to development of lyophilized and liquid formats. The next few chapters study the use of small scale and surrogate models as well as QbD application to drug product processes such as drug substance freezing and thawing, mixing, sterile filtration, filling, lyophilization, inspection and shipping and handling. Later chapters describe more specialized applications of QbD in the drug product realm. This includes the use of QbD in primary containers, devices and combination product development. The volume also explores QbD applied to vaccine development, automation, mathematical modeling and monitoring and controlling processes and defining control strategies. It concludes with a discussion on the application of QbD to drug product technology transfer as well as overall regulatory considerations and lifecycle management.

*Quality by Design for Biopharmaceutical Drug Product Development* is an authoritative resource for scientists and researchers interested in expanding their knowledge on QbD principles and uses in creating better drugs.      *Aggregation of Therapeutic Proteins* Wei Wang, Christopher J. Roberts, 2010-12-28. This book gives pharmaceutical scientists an up to date resource on protein aggregation and its consequences and available methods to control or slow down the aggregation process. While significant progress has been made in the past decade the current understanding of protein aggregation and its consequences is still immature. Prevention or even moderate inhibition of protein aggregation has been mostly experimental. The knowledge in this book can greatly help pharmaceutical scientists in the development of therapeutic proteins and also instigate further scientific investigations in this area. This book fills such a need by providing an overview on the causes, consequences, characterization and control of the aggregation of therapeutic proteins.      *Drying Science and Technology* Suvanjan Bhattacharyya, 2024-02-28. *Drying Science and Technology* provides a thorough and current investigation of the complex area of drying processes. This book is a collaborative effort that brings together prominent professionals to give a comprehensive grasp of drying science's concepts, methodology and applications. The book opens by underlining the importance of drying operations in a variety of sectors including food preservation and materials processing. This opening portion provides the framework for a varied investigation that will appeal to a wide range of readers. The book covers fundamental ideas and digs into the heat and mass transport mechanisms that underpin drying processes. Readers are taken through the fundamentals that determine the efficiency and quality of drying processes, laying the groundwork for additional in depth research. A large portion of the book is dedicated to a variety of drying processes and procedures both traditional and cutting edge. From basic convection drying to modern technologies such as freeze drying and microwave drying, each strategy is evaluated for its uses, benefits and drawbacks. This broad cover guarantees that readers obtain a full understanding of the equipment available for various drying applications. The use of mathematical modeling provides a quantitative dimension to the book with chapters focused on the development, evaluation and application of models in drying science. This part is intended for scholars and

practitioners who want a better knowledge of the quantitative features that underpin the discipline The book highlights the dynamic nature of drying research and includes the most recent advances in drying technology Innovations in equipment and approaches highlight the changing landscape of drying research providing insights into cutting edge discoveries that will impact the field's future With a balanced combination of theoretical insights and practical applications Drying Science and Technology is an invaluable resource for students researchers and professionals working in the various fields of drying

Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals Feroz Jameel, Susan Hersenson, 2010-07-13 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

**Pharmaceutical Biotechnology** Oliver Kayser, Heribert Warzecha, 2012-05-21 This second edition of a very successful book is thoroughly updated with existing chapters completely rewritten while the content has more than doubled from 16 to 36 chapters As with the first edition the focus is on industrial pharmaceutical research written by a team of industry experts from around the world while quality and safety management drug approval and regulation patenting issues and biotechnology fundamentals are also covered In addition this new edition now not only includes biotech drug development but also the use of biopharmaceuticals in diagnostics and vaccinations With a foreword by Robert Langer Kenneth J. Germeshausen Professor of Chemical and Biomedical Engineering at MIT and member of the National Academy of Engineering and the National Academy of Sciences 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

**Therapeutic Fc-Fusion Proteins** Steven M. Chamow,Thomas Ryll, Henry B. Lowman, Deborah Farson, 2013-12-18

Edited by three pioneers in the field each with longstanding experience in the biotech industry and a skilled scientific writer this is the first book to cover every step in the development and production of immunoglobulin Fc fusion proteins as therapeutics for human disease from choosing the right molecular design to pre clinical characterization of the purified product through to batch optimization and quality control for large scale cGMP production The whole of the second part is devoted to case studies of Fc fusion proteins that are now commercially successful products In this section the authors several of whom were personally involved in clinical development of the products themselves detail the product s background and give insight into issues that were faced and how these issues were overcome during clinical development This section also includes a chapter on promising new developments for the future An invaluable resource for professionals already working on Fc fusion proteins and an excellent and thorough introduction for physicians researchers and students entering the field

**Handbook of Food Powders** Bhesh Bhandari, Nidhi Bansal, Min Zhang, Pierre Schuck, 2023-11-11 Handbook of Food Powders Chemistry and Technology Second Edition covers current developments in food powder technology such as Microbial decontamination of food powders Gas and oil encapsulated powders and Plant based protein powders among other important topics Sections introduce processing and handling technologies for food powders focus on powder properties including surface composition rehydration and techniques to analyze the particle size of food powders and highlight specialty food powders such as dairy powders fruit and vegetable powders and coating foods with powders Edited by a team of international experts in the field this book continues to be the only quality reference on food powder technology available for the audiences of professionals in the food powder production and handling industries It is also ideal for development and quality control professionals in the food industry who use powders in foods and for researchers scientists and academics interested in the field Introduces six new chapters that incorporate the current developments in food powder technology Examines powder properties including surface composition shelf life and techniques used to examine particle size Focuses on specialty powders such as dairy infant formulas powdered egg fruit and vegetable and culinary and specialty products

*Parenteral Medications, Fourth Edition* Sandeep Nema, John D. Ludwig, 2019-07-19 Parenteral Medications is an authoritative comprehensive reference work on the formulation and manufacturing of parenteral dosage forms effectively balancing theoretical considerations with practical aspects of their development Previously published as a three volume set all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science

and considerable advances in the technology associated with these products and routes of administration

**Key Features**

- Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms
- Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration
- Includes 13 new chapters and updated chapters throughout
- Contains the contributors of leading researchers in the field of parenteral medications
- Uses full color detailed illustrations enhancing the learning process

The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation processing manufacturing parenteral technology including advanced delivery and cell therapies

The book is divided into seven sections

- Section 1 Parenteral Drug Administration and Delivery Devices
- Section 2 Formulation Design and Development
- Section 3 Specialized Drug Delivery Systems
- Section 4 Primary Packaging and Container Closure Integrity
- Section 5 Facility Design and Environmental Control
- Section 6 Sterilization and Pharmaceutical Processing
- Section 7 Quality Testing and Regulatory Requirements

**Pharmaceutical Biotechnology** Daan J. A. Crommelin, Robert D. Sindelar, Bernd Meibohm, 2019-04-13

This introductory text explains both the basic science and the applications of biotechnology derived pharmaceuticals with special emphasis on their clinical use

It serves as a complete one stop source for undergraduate graduate pharmacists pharmaceutical science students and for those in the pharmaceutical industry

The Fifth Edition completely updates the previous edition and also includes additional coverage on the newer approaches such as oligonucleotides siRNA gene therapy and nanotech and enzyme replacement therapy

*Development of Biopharmaceutical Drug-Device Products* Feroz Jameel, John W. Skoug, Robert R. Nesbitt, 2020-03-13

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

#### **Hydrogen Exchange Mass Spectrometry of Proteins** David D. Weis,2016-01-12

Hydrogen exchange mass spectrometry is widely recognized for its ability to probe the structure and dynamics of proteins The application of this technique is becoming widespread due to its versatility for providing structural information about challenging biological macromolecules such as antibodies flexible proteins and glycoproteins Although the technique has been around for 25 years this is the first definitive book devoted entirely to the topic Hydrogen Exchange Mass Spectrometry of Proteins Fundamentals Methods and Applications brings into one comprehensive volume the theory instrumentation and applications of Hydrogen Exchange Mass Spectrometry HX MS a technique relevant to bioanalytical chemistry protein science and pharmaceuticals The book provides a solid foundation in the basics of the technique and data interpretation to inform readers of current research in the method and provides illustrative examples of its use in bio and pharmaceutical chemistry and biophysics In depth chapters on the fundamental theory of hydrogen exchange and tutorial chapters on measurement and data analysis provide the essential background for those ready to adopt HX MS Expert users may advance their current understanding through chapters on methods including membrane protein analysis alternative proteases millisecond hydrogen exchange top down mass spectrometry histidine exchange and method validation All readers can explore the diversity of HX MS applications in areas such as ligand binding membrane proteins drug discovery therapeutic protein formulation biocomparability and intrinsically disordered proteins

*Biothermodynamics* Urs von Stockar,Luuk A. M. van der Wielen,2013-05-30 This book covers the fundamentals of the rapidly growing field of biothermodynamics showing how thermodynamics can best be applied to applications and processes in biochemical engineering It describes the rigorous application of thermodynamics in biochemical engineering to rationalize bioprocess development and obviate a substantial fraction of this need for tedious experimental work As such this book will appeal to a diverse group of readers ranging from students and professors in biochemical engineering to scientists and engineers for whom it will be a valuable reference



**Developability of Biotherapeutics** Sandeep Kumar, Satish Kumar Singh, 2015-11-18 Biopharmaceuticals are emerging as frontline medicines to combat several life threatening and chronic diseases. However, such medicines are expensive to develop and produce on a commercial scale, contributing to rising healthcare costs. *Developability of Biotherapeutics: Computational Approaches* describes applications of computational and molecular Understanding Enzymes Allan Svendsen, 2016-04-27 *Understanding Enzymes: Function, Design, Engineering, and Analysis* focuses on the understanding of enzyme function and optimization gained in the past decade. Past enzyme function analysis, enzyme engineering, and growing insights from the simulation work and nanotechnology measurement of enzymes in action in vitro or in silico. The book also pre-

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