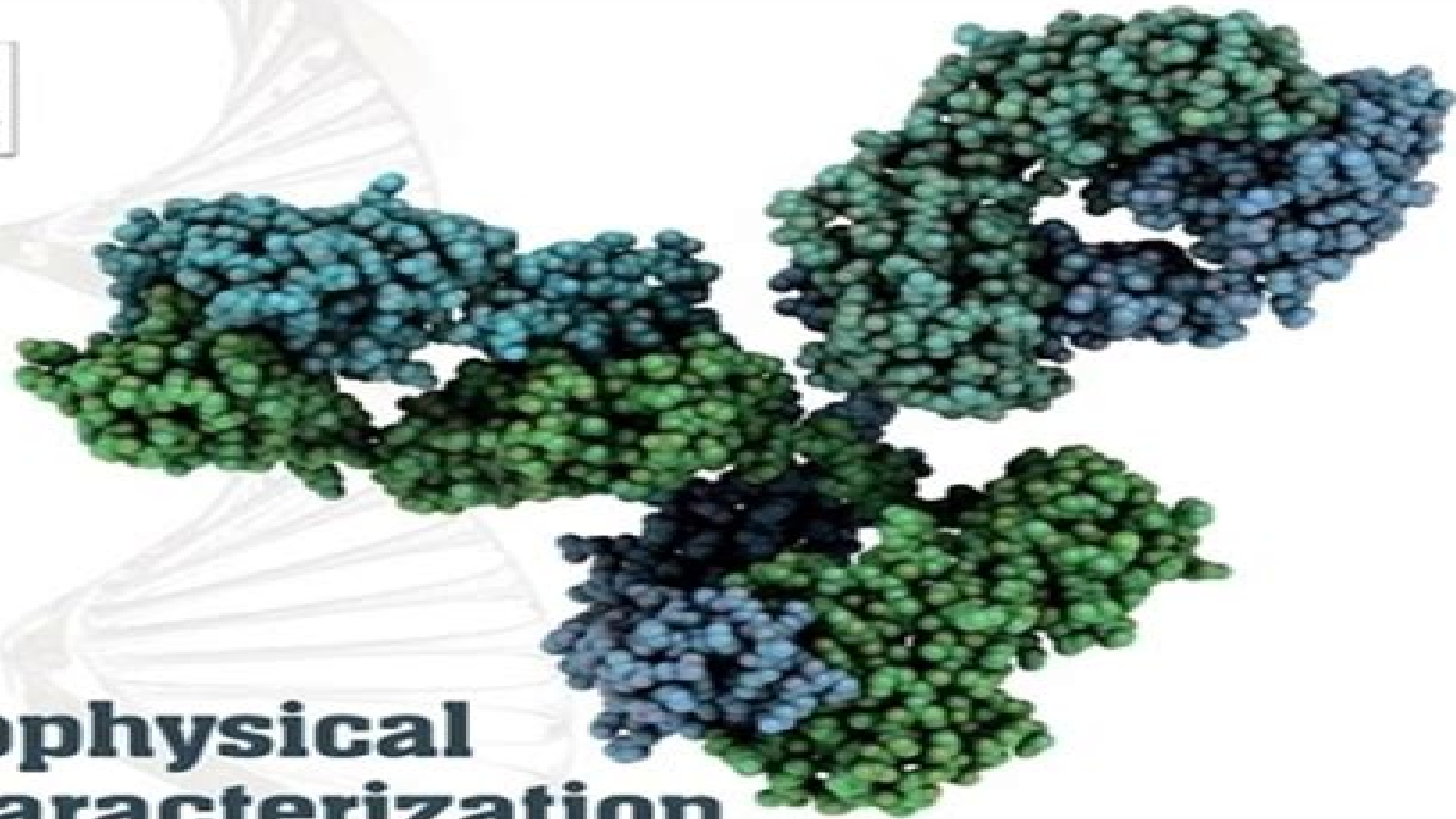




Biophysical Characterization of Proteins in Developing Biopharmaceuticals

**Edited by Damian J. Houde
Steven A. Berkowitz**



Biophysical Characterization Of Proteins In Developing Biopharmaceuticals

KJ Lindholm-Leary



Biophysical Characterization Of Proteins In Developing Biopharmaceuticals:

Biophysical Characterization of Proteins in Developing Biopharmaceuticals Damian J. Houde, Steven A. Berkowitz, 2014-09-05 Biophysical Characterization of Proteins in Developing Biopharmaceuticals is concerned with the analysis and characterization of the higher order structure HOS or conformation of protein based drugs Starting from the very basics of protein structure this book takes the reader on a journey on how to best achieve this goal using the key relevant and practical methods commonly employed in the biopharmaceutical industry today as well as up and coming promising methods that are now gaining increasing attention As a general resource guide this book has been written with the intent to help today's industrial scientists working in the biopharmaceutical industry or the scientists of tomorrow who are planning a career in this industry on how to successfully implement these biophysical methodologies In so doing a keen focus is placed on understanding the capability of these methodologies in terms of what information they can deliver Aspects of how to best acquire this biophysical information on these very complex drug molecules while avoiding potential pitfalls in order to make concise well informed productive decisions about their development are key points that are also covered Presents the reader with a clear understanding of the real world issues and challenges in using these methods Highlights the capabilities and limitations of each method Discusses how to best analyze the data generated from these methods Points out what one needs to look for to avoid making faulty conclusions and mistakes In total it provides a check list or road map that empowers the industrial scientists as to what they need to be concerned with in order to effectively do their part in successfully developing these new drugs in an efficient and cost effective manner

Biophysical Characterization of Proteins in Developing Biopharmaceuticals Damian J. Houde, Steven A. Berkowitz, 2019-11-13 Biophysical Characterization of Proteins in Developing Biopharmaceuticals Second Edition presents the latest on the analysis and characterization of the higher order structure HOS or conformation of protein based drugs Starting from the very basics of protein structure this book explains the best way to achieve this goal using key methods commonly employed in the biopharmaceutical industry This book will help today's industrial scientists plan a career in this industry and successfully implement these biophysical methodologies This updated edition has been fully revised with new chapters focusing on the use of chromatography and electrophoresis and the biophysical characterization of very large biopharmaceuticals In addition best practices of applying statistical analysis to biophysical characterization data is included along with practical issues associated with the concept of a biopharmaceutical's developability and the technical decision making process needed when dealing with biophysical characterization data Presents basic protein characterization methods and tools applicable to biopharmaceutical research and development Highlights the capabilities and limitations of each technique Discusses the underlining science of each tool Empowers industrial biophysical chemists by providing a roadmap for applying biophysical tools Outlines the needs for new characterization and analytical tools in the biopharmaceutical industry

Biosimilar Drug

Product Development Laszlo Endrenyi, Dr. Paul Declerck, Shein-Chung Chow, 2017-02-24 When a biological drug patent expires alternative biosimilar products are developed The development of biosimilar products is complicated and involves numerous considerations and steps The assessment of biosimilarity and interchangeability is also complicated and difficult Biosimilar Drug Product Development presents current issues for the development of biosimilars and gives detailed reviews of its various stages and contributing factors as well as relevant regulatory pathways and pre and post approval issues

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

Dispersity, Structure and Phase Changes of Proteins and Bio Agglomerates in Biotechnological Processes Arno Kwade, Ingo Kampen, 2024-09-26 This book serves as a comprehensive summary of the priority program SPP 1934 which focused on understanding the dispersity structure and phase changes of proteins and bio agglomerates in biotechnological processes Through contributions from various research groups the program explored how sensitive proteins and bio agglomerates are affected by the process environment during fermentation downstream processing and formulation It investigated these effects across three size scales microscale encompassing single proteins clusters crystals and virus like particles mesoscale focusing on cells and cell clusters and macroscale examining overall process dynamics The main objective was to enhance biotechnological process chains by elucidating the mechanical thermal and chemical stresses that impact protein and bio agglomerate structures By gaining insights into these stressors the program aimed to enable precise control measures to mitigate denaturation and unfavorable growth of proteins and cells This compilation seeks to contribute to the optimization of biotechnological processes facilitating

advancements in various industries Advances in Root Vegetables Research Prashant Kaushik, 2023-02-15 Root vegetables are the sections of underground plants that are harvested and consumed by humans for their nutritional value They are found in a wide variety of plant species Even though botany draws a distinction between real roots and non roots the term root vegetable refers to both kinds in the context of agriculture and cuisine despite botany classifying genuine roots as separate from non roots Root vegetables are often storage organs that store energy in the form of carbohydrates This book explores recent developments in root vegetable research against the background of current and impending environmental change **Mass Spectrometry in Biopharmaceutical Analysis** Igor A. Kaltashov, Shunhai Wang, Guanbo Wang, 2021-11-22 Biopharmaceuticals are a unique class of compounds due to their extreme structural complexity The current text puts together a variety of the state of the art approaches that use mass spectrometry to evaluate various aspects of biopharmaceutical products ranging from monitoring stress related structural changes to their quantitation in pharmacokinetic studies Analytical Characterization of Biotherapeutics Jennie R. Lill, Wendy Sandoval, 2017-07-10 The definitive guide to the myriad analytical techniques available to scientists involved in biotherapeutics research Analytical Characterization of Biotherapeutics covers all current and emerging analytical tools and techniques used for the characterization of therapeutic proteins and antigen reagents From basic recombinant antigen and antibody characterization to complex analyses for increasingly complex molecular designs the book explores the history of the analysis techniques and offers valuable insights into the most important emerging analytical solutions In addition it frames critical questions warranting attention in the design and delivery of a therapeutic protein exposes analytical challenges that may occur when characterizing these molecules and presents a number of tested solutions The first single volume guide of its kind Analytical Characterization of Biotherapeutics brings together contributions from scientists at the leading edge of biotherapeutics research and manufacturing Key topics covered in depth include the structural characterization of recombinant proteins and antibodies antibody de novo sequencing characterization of antibody drug conjugates characterization of bi specific or other hybrid molecules characterization of manufacturing host cell contaminant proteins analytical tools for biologics molecular assessment and more Each chapter is written by a recognized expert or experts in their field who discuss current and cutting edge approaches to fully characterizing biotherapeutic proteins and antigen reagents Covers the full range of characterization strategies for large molecule based therapeutics Provides an up to date account of the latest approaches used for large molecule characterization Chapters cover the background needed to understand the challenges at hand solutions to characterize these large molecules and a summary of emerging options for analytical characterization Analytical Characterization of Biotherapeutics is an up to date resource for analytical scientists biologists and mass spectrometrists involved in the analysis of biomolecules as well as scientists employed in the pharmaceuticals and biotechnology industries Graduate students in biology and analytical science and their instructors will find it to be fascinating and instructive

supplementary reading *Challenges in Protein Product Development* Nicholas W. Warne, Hanns-Christian Mahler, 2018-06-20 In this volume the authors discuss the many significant challenges currently faced in biotechnology dosage form development providing guidance shared experience and thoughtful reflection on how best to address these potential concerns As the field of therapeutic recombinant therapeutic proteins enters its fourth decade and the market for biopharmaceuticals becomes increasingly competitive companies are increasingly dedicating resources to develop innovative biopharmaceuticals to address unmet medical needs Often the pharmaceutical development scientist is encountering challenging pharmaceutical properties of a given protein or by the demands placed on the product by stability manufacturing and preclinical or clinical expectations as well as the evolving regulatory expectations and landscape Further there have been new findings that require close assessment as for example those related to excipient quality processing viscosity and device compatibility and administration solubility and opalescence and container closure selection The literature varies widely in its discussion of these critical elements and consensus does not exist This topic is receiving a great deal of attention within the biotechnology industry as well as with academic researchers and regulatory agencies globally Therefore this book is of interest for business leaders researchers formulation and process development scientists analytical scientists QA and QC officers regulatory staff manufacturing leaders and regulators active in the pharmaceutical and biotech industry and expert reviewers in regulatory agencies *The Journal of NIH Research* ,1993

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