

Guodong Chen *Editor*

Characterization of Protein Therapeutics using Mass Spectrometry

Characterization Of Protein Therapeutics Using Mass Spectrometry

Jennie R. Lill, Wendy Sandoval



Characterization Of Protein Therapeutics Using Mass Spectrometry:

Characterization of Protein Therapeutics using Mass Spectrometry Guodong Chen, 2014-07-08 This book highlights current approaches and future trends in the use of mass spectrometry to characterize protein therapies As one of the most frequently utilized analytical techniques in pharmaceutical research and development mass spectrometry has been widely used in the characterization of protein therapeutics due to its analytical sensitivity selectivity and specificity This book begins with an overview of mass spectrometry techniques as related to the analysis of protein therapeutics structural identification strategies quantitative approaches followed by studies involving characterization of process related protein drug impurities degradants metabolites higher order structures of protein therapeutics Both general practitioners in pharmaceutical research and specialists in analytical sciences will benefit from this book that details step by step approaches and new strategies to solve challenging problems related to protein therapeutics research and development **Protein Analysis**

using Mass Spectrometry Mike S. Lee, Qin C. Ji, 2017-05-26 Presents Practical Applications of Mass Spectrometry for Protein Analysis and Covers Their Impact on Accelerating Drug Discovery and Development Covers both qualitative and quantitative aspects of Mass Spectrometry protein analysis in drug discovery Principles Instrumentation Technologies topics include MS of peptides proteins and ADCs instrumentation in protein analysis nanospray technology in MS protein analysis and automation in MS protein analysis Details emerging areas from drug monitoring to patient care such as Identification and validation of biomarkers for cancer targeted MS approaches for biomarker validation biomarker discovery and regulatory perspectives Brings together the most current advances in the mass spectrometry technology and related method in protein analysis *Characterization of Impurities and Degradants Using Mass Spectrometry* Guodong Chen, 2011-04-27

The book highlights the current practices and future trends in structural characterization of impurities and degradants It begins with an overview of mass spectrometry techniques as related to the analysis of impurities and degradants followed by studies involving characterization of process related impurities including potential genotoxic impurities and excipient related impurities in formulated products Both general practitioners in pharmaceutical research and specialists in analytical chemistry field will benefit from this book that will detail step by step approaches and new strategies to solve challenging problems related to pharmaceutical research

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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

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

Selected Reaction Monitoring Mass Spectrometry (SRM-MS) in Proteomics Mahmud Hossain, 2020-09-26 Covering a wide ranging facet of a gold standard targeted mass spectrometry MS method for the consistent detection and accurate quantification of preselected proteins in complex biological matrices Selected Reaction Monitoring Mass Spectrometry SRM MS in Proteomics A Comprehensive View describes The knowledge based development of highly efficient SRM methodology including assay workflow selection of proteins peptides transitions and its validation and quality assessment Available bioinformatic tools for both pre acquisition method development and post MS acquisition data analysis and data repositories Various relative and absolute quantification techniques SRM MS widespread applications in biomarker development and in clinical studies as well as in the analysis of various posttranslational modifications PTMs Current challenges and contemporary trends to overcome those difficulties In addition it features the historical development of modern day mass spectrometry with its vivid applications and also covers basic MS instrumentation ionization techniques and various proteomics approaches Comprehensive discussion extensive references at the end of each chapter and the list of review articles in the bibliography offer invaluable resources for advanced readings Researchers from the undergraduate to postgraduate level and beyond in both academic or industry settings studying and working on mass spectrometry and or proteomics will benefit from this book

Ambient Mass Spectroscopy Techniques in Food and the Environment Leo M.L. Nollet, Basil Munjanja, 2019-01-30 Ambient mass spectrometry that is the use of mass spec but in the atmospheric environment has been widely employed in food and environmental analysis Ambient Mass Spectroscopy Techniques in Food and the Environment presents the theoretical underpinnings of mass spectrometry and the benefits and pitfalls of ambient mass spectrometry as well as the latest developments of the technique in the analysis of food and environmental parameters It describes methods that enable the detection of surface materials like waxes alkaloids flavors or pesticides by plainly exposing the corresponding items to the ionization region of the interface without harm to samples Features Explains the theoretical aspects of ambient mass spectrometry Describes how to use ambient MS techniques for food safety authenticity and traceability screening Lists the benefits of ambient MS in analysis of food and environmental parameters Covers recent developments of ambient MS in analysis of food and environmental parameters The specialized work provides insight to professionals practicing in food and the environment including food scientists food engineers food biotechnologists chemical engineers and those working in research labs universities and government regulatory agencies

Advancements of Mass Spectrometry in Biomedical Research Alisa G. Woods, Costel C. Darie, 2019-07-25 This volume explores the use of mass spectrometry for biomedical applications Chapters focus on specific therapeutic areas such as oncology infectious disease and psychiatry Additional chapters focus on methodology technologies and instrumentation as well as on analysis of protein protein interactions protein quantitation and protein post translational modifications Various omics fields such as proteomics metabolomics

glycomics lipidomics and adductomics are also covered Applications of mass spectrometry in biotechnological and pharmaceutical industry are also discussed This volume provides readers with a comprehensive and informative manual that will allow them to appreciate mass spectrometry and proteomic research but also to initiate and improve their own work This book acts as a technical guide as well as a conceptual guide to the newest information in this exciting field **ADME and**

Translational Pharmacokinetics / Pharmacodynamics of Therapeutic Proteins Honghui Zhou, Frank-Peter Theil, 2015-11-23 With an emphasis on the fundamental and practical aspects of ADME for therapeutic proteins this book helps readers strategize plan and implement translational research for biologic drugs Details cutting edge ADME absorption distribution metabolism and excretion and PKPD pharmacokinetic pharmacodynamics modeling for biologic drugs Combines theoretical with practical aspects of ADME in biologic drug discovery and development and compares innovator biologics with biosimilar biologics and small molecules with biologics giving a lessons learned perspective Includes case studies about leveraging ADME to improve biologics drug development for monoclonal antibodies fusion proteins pegylated proteins ADCs bispecifics and vaccines Presents regulatory expectations and industry perspectives for developing biologic drugs in USA EU and Japan Provides mechanistic insight into biodistribution and target driven pharmacokinetics in important sites of action such as tumors and the brain **Antibody-Drug Conjugates** Kenneth J. Olivier, Jr., Sara A. Hurvitz, 2016-11-14 Providing

practical and proven solutions for antibody drug conjugate ADC drug discovery success in oncology this book helps readers improve the drug safety and therapeutic efficacy of ADCs to kill targeted tumor cells Discusses the basics drug delivery strategies pharmacology and toxicology and regulatory approval strategies Covers the conduct and design of oncology clinical trials and the use of ADCs for tumor imaging Includes case studies of ADCs in oncology drug development Features contributions from highly regarded experts on the frontlines of ADC research and development **Modern Proteomics -**

Sample Preparation, Analysis and Practical Applications Hamid Mirzaei, Martin Carrasco, 2016-12-14 This volume serves as a proteomics reference manual describing experimental design and execution The book also shows a large number of examples as to what can be achieved using proteomics techniques As a relatively young area of scientific research the breadth and depth of the current state of the art in proteomics might not be obvious to all potential users There are various books and review articles that cover certain aspects of proteomics but they often lack technical details Subject specific literature also lacks the broad overviews that are needed to design an experiment in which all steps are compatible and coherent The objective of this book was to create a proteomics manual to provide scientists who are not experts in the field with an overview of 1 The types of samples can be analyzed by mass spectrometry for proteomics analysis 2 Ways to convert biological or ecological samples to analytes ready for mass spectral analysis 3 Ways to reduce the complexity of the proteome to achieve better coverage of the constituent proteins 4 How various mass spectrometers work and different ways they can be used for proteomics analysis 5 The various platforms that are available for proteomics data analysis 6 The various

applications of proteomics technologies in biological and medical sciences This book should appeal to anyone with an interest in proteomics technologies proteomics related bioinformatics and proteomics data generation and interpretation With the broad setup and chapters written by experts in the field there is information that is valuable for students as well as for researchers who are looking for a hands on introduction into the strengths weaknesses and opportunities of proteomics

Characterizing Biotherapeutics Jennie R. Lill, Wendy Sandoval, 2025-06-04 Provides detailed and up to date coverage of analytical approaches for biologic drug modalities The development of innovative biologic therapies has revolutionized medicine but their complexity demands equally advanced analytical approaches Characterizing Biotherapeutics Analytical Methods for Diverse Modalities introduces the tools and techniques used to analyze these groundbreaking therapies Designed to help readers characterize and troubleshoot increasingly diverse and sophisticated therapeutic molecules this in depth guide addresses different biologic drugs their unique analytical challenges and the methods that enable their analysis Organized into two comprehensive sections Characterizing Biotherapeutics first delves into the fundamentals of analytical platforms providing a robust foundation in techniques such as mass spectrometry and biophysical assays The second section applies these methods to real world scenarios focusing on drug discovery clinical evaluation and commercial considerations in drug development Authors Jennie R Lill and Wendy Sandoval provide clear guidance tailored to the evolving demands of therapeutic innovations such as structural characterization high throughput biophysical assays and RNA based therapeutics Equipping researchers with the knowledge to navigate the challenges posed by increasingly complex biologics Characterizing Biotherapeutics Analytical Methods for Diverse Modalities Discusses new and emerging biological molecule diversity and both traditional analytical methods Provides characterization strategies for large molecule protein antibody based therapeutics Summarizes cutting edge technologies for novel modalities and antibody protein therapeutics Incorporates the latest advancements in mass spectrometry functional assays and biophysical methods Addresses specialized analytical issues for membrane proteins and other challenging targets Presents methodologies for assessing safety and therapeutic potential Characterizing Biotherapeutics Analytical Methods for Diverse Modalities is an essential reference for analytical scientists biologists and mass spectrometrists involved in biomolecule analysis It is also a valuable resource for graduate students taking advanced courses in biotechnology drug development and biotherapeutic analysis as well as professionals in biotechnology and pharmaceutical industries working to advance biotherapeutic research and development

Capillary Electrophoresis-Mass Spectrometry James Q. Xia, Lichao Zhang, 2016-11-08 This book covers the latest developments in capillary electrophoresis mass spectrometry for the analysis of therapeutic proteins The application of capillary electrophoresis mass spectrometry CE MS coupling technology in the analysis of recombinant therapeutic proteins is detailed thoroughly Specific topics include recent developments in coupling capillary electrophoresis with mass spectrometry for the quality control of monoclonal antibody therapeutics top down analysis of monoclonal antibody using the

CE MS platform and detection of host cell protein impurities Comprehensive characterization of antibody drug conjugates ADCs by coupling capillary electrophoresis with mass spectrometry is also covered This is an ideal book for scientists in the life science and biopharmaceutical industry who are working on characterizing the PTMs of monoclonal antibodies as well as graduate students and researchers in the separation science and biological mass spectrometry fields **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

Hybrid Biomolecular Modeling Slavica Jonic,Osamu Miyashita,Isabelle Callebaut,2019-01-24 Models of biomolecular structure and dynamics are often obtained by combining simulation or prediction approaches e g comparative modeling Molecular Dynamics MD simulations Normal Mode Analysis NMA etc with experimental approaches e g Nuclear Magnetic Resonance NMR X ray crystallography Small Angle X ray Scattering SAXS Electron Microscopy EM etc Such hybrid modeling extends the capabilities of experimental techniques by enriching structural information and facilitating dynamics studies of biomolecules This eBook contains articles on methodological developments applications and challenges of hybrid biomolecular modeling that have been collected in the framework of the Frontiers Research Topic entitled Hybrid Biomolecular Modeling *Structure-function metrology of proteins* Alex Jones,Milena Quaglia,Isabel Moraes,2023-03-27

Heterologous Protein Production in CHO Cells Paula Meleady,2024-10-26 This detailed new edition explores the use of Chinese hamster ovary CHO cells in the production of therapeutic protein products Beyond updates on earlier methodologies the book also delves into the genetic manipulation of CHO cells for recombinant protein production analysis of CHO cells using proteomic and metabolomic approaches as well as methods for the characterization of recombinant protein

products such as glycosylation and host cell protein analysis Written for the highly successful Methods in Molecular Biology series chapters include introductions to their respective topics lists of the necessary materials and reagents step by step and readily reproducible laboratory protocols and tips on troubleshooting and avoiding known pitfalls Authoritative and up to date Heterologous Protein Production in CHO Cells Methods and Protocols Second Edition is an ideal guide for researchers working to enhance and accelerate CHO productive capabilities in the coming decades **Protein Analysis using Mass Spectrometry** Mike S. Lee, Qin C. Ji, 2017-06-19 Presents Practical Applications of Mass Spectrometry for Protein Analysis and Covers Their Impact on Accelerating Drug Discovery and Development Covers both qualitative and quantitative aspects of Mass Spectrometry protein analysis in drug discovery Principles Instrumentation Technologies topics include MS of peptides proteins and ADCs instrumentation in protein analysis nanospray technology in MS protein analysis and automation in MS protein analysis Details emerging areas from drug monitoring to patient care such as Identification and validation of biomarkers for cancer targeted MS approaches for biomarker validation biomarker discovery and regulatory perspectives Brings together the most current advances in the mass spectrometry technology and related method in protein analysis

Development and Application of Tandem Mass Spectrometry Methods for Phosphoprotein Analysis Amanda M. Palumbo, 2009

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


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