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Formulation, Characterization, and Stability of Protein Drugs

Case Histories

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Y. John Wang

Formulation Characterization And Stability Of Protein Drugs Case Histories

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Formulation Characterization And Stability Of Protein Drugs Case Histories:

Formulation, Characterization, and Stability of Protein Drugs Rodney Pearlman,Y. John Wang,1996-10-31 Leading scientists offer detailed profiles of ten protein drugs currently in development The case histories of these important new compounds are described from the perspective of their formulation characterization and stability This ready reference also features recent data and an abundance of previously unpublished information The in depth coverage includes a highly useful compendium of degradation sites occurring in over 70 proteins An invaluable aid in the rapid identification of potential hot spots in proteins this accessible compilation allows for inspection of the protein s primary structure and preparation of a hydroflex plot **Formulation, Characterization, And Stability Of Protein Drugs: Case Histories** Pearlman,2009-08-01 *Formulation, Characterization, and Stability of Protein Drugs* Rodney Pearlman,Y. John Wang,2006-04-11 Leading scientists offer detailed profiles of ten protein drugs currently in development The case histories of these important new compounds are described from the perspective of their formulation characterization and stability This ready reference also features recent data and an abundance of previously unpublished information The in depth coverage includes a highly useful compendium of degradation sites occurring in over 70 proteins An invaluable aid in the rapid identification of potential hot spots in proteins this accessible compilation allows for inspection of the protein s primary structure and preparation of a hydroflex plot *Formulation, Characterization, and Stability of Protein Drugs* Rodney Pearlman,Y. John Wang,2014-01-15 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 **Peptide and Protein Drug Analysis** Ronald Reid,1999-11-12 Furthering efforts to simulate the potency and specificity exhibited by peptides and proteins in healthy cells this remarkable reference supplies pharmaceutical scientists with a wealth of techniques for tapping the enormous therapeutic potential of these molecules providing a solid basis of knowledge for new drug design Provides a broad comp **Interdisciplinary Medicine, Health and Bioscience Researches-2024** Neriman MOR,Hacı Ahmet DEVECİ,2024-12-22 *Stability and Characterization of Protein and Peptide Drugs* Rodney Pearlman,Y. John Wang,2013-06-29 This is the first volume to make available specific case histories of therapeutic proteins and peptides that have been marketed or are currently under clinical testing The editors have selected a wide range of molecules derived from monoclonal antibodies recombinant DNA and natural and chemical sources to provide formulation scientists with practical examples of the development of pharmaceutical products Biophysical Chemistry of Proteins Engelbert Buxbaum,2025-07-10 This textbook designed for all scientists interested in protein research provides a thorough overview of laboratory methods for the biophysical chemistry of proteins This new edition completely restructured and expanded for ease

of learning includes sections on analytical techniques working with proteins protein size and shape protein structure enzyme kinetics industry enzymology and a new section on special statistics **Handbook of Stability Testing in Pharmaceutical Development** Kim Huynh-Ba,2008-11-16 This handbook is the first to cover all aspects of stability testing in pharmaceutical development Written by a group of international experts the book presents a scientific understanding of regulations and balances methodologies and best practices **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 **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 **Pharmaceutical Dosage Forms - Parenteral Medications** Sandeep Nema,John D. Ludwig,2016-04-19 This three volume set of Pharmaceutical Dosage Forms Parenteral Medications is an authoritative comprehensive reference work on the formulation and manufacture of parenteral dosage forms effectively balancing theoretical considerations with the practical aspects of their development As such it is recommended for scientists and engineers in the **Biosimilarity** Sarfaraz K. Niazi,2018-10-03 Summary The focus of this book is on how the U S FDA will approve biosimilar drugs as learned from recent approvals by the FDA Understanding the limitations of the statutory limits and non inferiority testing are presented as tools to obviate patient trials and minimize testing of immunogenicity An in depth scientific mathematical and statistical view of the tools required to establish biosimilarity of biological drugs of different complexity a must for every developer of biosimilars Features First comprehensive analysis based on new guidelines and approval packages of several biosimilars Presents the first approach to challenge FDA in reducing or eliminating any testing

in patients Provides a comprehensive understanding of the U S statutory requirements vis a vis the regulatory guidelines Provides model CQA and Analytical Similarity testing protocols for cytokines and monoclonal antibodies Allow creation of a fast to market pathway to develop biosimilars Antibody-Drug Conjugates Jennica L. Zaro,Jeffrey Wang,2025-04-15 The field of antibody drug conjugates ADCs has undergone remarkable advancements in recent years marked by significant progress in both drug approvals and ongoing clinical development Since the approval of the first ADC in 2010 gemtuzumab ozogamicin Mylotarg the landscape has expanded dramatically Today there are 11 FDA approved ADCs targeting a variety of cancers across multiple indications The approved ADCs include a range of payloads linkers and antibodies each optimized for a variety of specific therapeutic targets The increasing diversity of ADCs reflects the growing potential of these innovative treatments to address a wide array of malignancies from hematologic cancers to solid tumors This book aims to provide a comprehensive overview of the current state of the ADC field including the latest developments challenges and emerging trends comprising expertise from a broad range of disciplines from basic research industry clinical practice and regulatory affairs We explore not only the scientific and technical aspects of ADC design such as payloads linkers and antibody selection but also the developmental hurdles and regulatory complexities that influence the success of ADCs in clinical practice Real world examples of ADCs that have made it from the lab to the clinic offer invaluable insights into the trials and triumphs that shape this dynamic field It is our hope that this book will serve as both a valuable resource for experts in the field and an accessible introduction for those new to the exciting world of ADCs **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 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 **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 sectionss 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 **Development and Manufacture of Protein Pharmaceuticals** Steve L. Nail,Michael J. Akers,2012-12-06 In this era of biotechnology there have been many books covering the fundamentals of recombinant DNA technology and protein chemistry However not many sources are available for the pharmaceutical develop ment scientist and other personnel responsible for the commercialization of the finished dosage forms of these new biopharmaceuticals and other products from biotechnology This text will help to fill this gap Once active biopharmaceutical molecules are candidates for clinical trial investigation and subsequent commercialization a number of other activities must take place while research and

development on these molecules continues The active ingredient itself must be formulated into a finished dosage form that can be conveniently used by health care professionals and patients Properties of the biopharmaceutical molecule must be clearly understood so that the appropriate finished product formulation can be developed Finished product formulation development includes not only the chemical formulation but also the packaging system the manufacturing process and appropriate control strategies to assure such good manufacturing practice attributes as safety identity strength purity and quality Pharmaceutical Manufacturing Handbook Shayne Cox Gad,2008-03-17 This handbook features contributions from a team of expert authors representing the many disciplines within science engineering and technology that are involved in pharmaceutical manufacturing They provide the information and tools you need to design implement operate and troubleshoot a pharmaceutical manufacturing system The editor with more than thirty years experience working with pharmaceutical and biotechnology companies carefully reviewed all the chapters to ensure that each one is thorough accurate and clear

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