

Pharmaceutical Biotechnology - Volume 7

Physical Methods to Characterize Pharmaceutical Proteins

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Physical Methods To Characterize Pharmaceutical Proteins

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Physical Methods To Characterize Pharmaceutical Proteins:

Physical Methods to Characterize Pharmaceutical Proteins James N. Herron, Wim Jiskoot, Daan J.A.

Crommelin, 2013-11-21 Proteins are still gaining importance in the pharmaceutical world where they are used to improve our arsenal of therapeutic drugs and vaccines and as diagnostic tools. Proteins are different from traditional low molecular weight drugs. As a group they exhibit a number of biopharmaceutical and formulation problems. These problems have drawn considerable interest from both industrial and academic environments forcing pharmaceutical scientists to explore a domain previously examined only by peptide and protein chemists. Biopharmaceutical aspects of proteins e.g. low oral bioavailability have been extensively investigated. Although all possible conventional routes of administration have been examined for proteins no real generally applicable alternative to parenteral administration in order to achieve systemic effects has yet been discovered. Several of these biopharmaceutical options have been discussed in Volume 4 of this series. **Biological Barriers to Protein Delivery**. Proteins are composed of many amino acids several of which are notorious for their chemical instability. Rational design of formulations that optimize the native structure and/or bioactivity of a protein is therefore of great importance when long shelf life is required as it is for pharmaceutical products. This issue has also been examined in two prior volumes of this series. Volume 2 **Stability of Protein Pharmaceuticals Part A** and Volume 5 **Stability and Characterization of Protein and Peptide Drugs**.

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 This ready reference also features recent data and an abundance of previously unpublished information.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. *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.

Modern Pharmaceutics, Two Volume Set Alexander T. Florence, Juergen

Siepmann, 2016-04-19 This new edition brings you up to date on the role of pharmaceutics and its future paradigms in the design of medicines. Contributions from over 30 international thought leaders cover the core disciplines of pharmaceutics and the impact of biotechnology, gene therapy and cell therapy on current findings. *Modern Pharmaceutics* helps you stay current.

Methods for Structural Analysis of Protein Pharmaceuticals Wim Jiskoot, Daan Crommelin, 2005-12-05 Protein

pharmaceuticals form a fast growing category in the arsenal of drugs. This book explores the nature of different analytical

techniques and the way in which they are related to pharmaceutical proteins In addition to serving the analytical chemist this book is needed by the formulation scientist who is responsible for design and formulation of a pharmaceutical protein that can be monitored during production and over time *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 **Modern Pharmaceuticals,**

Volume 2 Alexander T. Florence, Juergen Siepmann, 2016-04-19 Volume 2 addresses the applications and approaches in advanced drug delivery systems including transdermal pulmonary and ocular routes In addition this text discusses the impact of the shift to personalized medicines in the fields of pharmaceutical biotechnology pharmacogenomics and nanotechnology Volume 2 investigates sustained and contr *Integration of Pharmaceutical Discovery and Development* Ronald T.

Borchardt, Roger M. Freidinger, Tomi K. Sawyer, Philip L. Smith, 2006-01-19 In the late 1980s it became painfully evident to the pharmaceutical industry that the old paradigm of drug discovery which involved highly segmented drug sign and development activities would not produce an acceptable success rate in the future Therefore in the early 1990s a paradigm shift occurred in which drug design and development activities became more highly integrated This new strategy required medicinal chemists to design drug candidates with structural features that optimized pharmacological e.g high affinity and specificity for the target receptor pharmaceutical e.g solubility and chemical stability biopharmaceutical e.g cell membrane permeability and metabolic pharmacokinetic e.g metabolic stability clearance and protein binding properties Successful implementation of this strategy requires a multidisciplinary team effort including scientists from drug design e.g medicinal chemists cell biologists endocrinologists pharmacologists and drug development e.g analytical chemists pharmaceutical scientists physiologists and molecular biologists representing the disciplines of pharmaceuticals biopharmaceuticals and pharmacokinetics drug metabolism With this new highly integrated approach to drug design now widely utilized by the pharmaceutical industry the editors of this book have provided the scientific community with case histories to illustrate the nature of the interdisciplinary interactions necessary to successfully implement this new approach to drug discovery In the first chapter Ralph Hirschmann provides a historical perspective of why this paradigm shift in drug discovery has occurred

Models for Assessing Drug Absorption and Metabolism Ronald T. Borchardt, Philip L. Smith, Glynn Wilson, 2013-06-29 Pharmaceutical scientists in industry and academia will appreciate this single reference for its detailed experimental procedures for conducting biopharmaceutical studies This well illustrated guide allows them to establish validate and implement commonly used in situ and in vitro model systems Chapters provide ready access to these methodologies for

studies of the intestinal buccal nasal and respiratory vaginal ocular and dermal epithelium as well as the endothelial and elimination barriers **Membrane Transporters as Drug Targets** Gordon L. Amidon, Wolfgang Sadée, 2006-04-11 Because progress in the field of transporters has been extraordinary this volume will focus on recent advances in our understanding of the structure function physiology and molecular biology of membrane transporters There will be an emphasis on transporters as molecular targets for drug delivery and disposition in the body **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 development 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 **Biomaterials for Delivery and**

Targeting of Proteins and Nucleic Acids Ram I. Mahato, 2004-12-28 Newcomers to the field of biopharmaceuticals require an understanding of the basic principles and underlying methodology involved in developing protein and nucleic acid based therapies for genetic and acquired diseases Biomaterials for Delivery and Targeting of Proteins and Nucleic Acids introduces the principles of polymer science and chemistry **Methods in Protein Structure and Stability Analysis** Vladimir N.

Uversky, Evgenii Anatol'evich Permiakov, 2007 **Handbook of Composites from Renewable Materials, Structure and Chemistry** Vijay Kumar Thakur, Manju Kumari Thakur, Michael R. Kessler, 2017-03-08 This unique multidisciplinary 8 volume set focuses on the emerging issues concerning synthesis characterization design manufacturing and various other aspects of composite materials from renewable materials and provides a shared platform for both researcher and industry The Handbook of Composites from Renewable Materials comprises a set of 8 individual volumes that brings an interdisciplinary perspective to accomplish a more detailed understanding of the interplay between the synthesis structure characterization processing applications and performance of these advanced materials The Handbook comprises 169 chapters from world renowned experts covering a multitude of natural polymers reinforcement fillers and biodegradable materials Volume 1 is solely focused on the Structure and Chemistry of renewable materials Some of the important topics include but not limited to carbon fibers from sustainable resources polylactic acid composites and composite foams based on

natural fibres composites materials from other than cellulosic resources microcrystalline cellulose and related polymer composites tannin based foam renewable feedstock vanillin derived polymer and composites silk biocomposites bioderived adhesives and matrix polymers biomass based formaldehyde free bioresin isolation and characterization of water soluble polysaccharide biobased fillers keratin based materials in biotechnology structure of proteins adsorbed onto bioactive glasses for sustainable composite effect of filler properties on the antioxidant response of starch composites composite of chitosan and its derivate magnetic biochar from discarded agricultural biomass biodegradable polymers for protein and peptide conjugation polyurethanes and polyurethane composites from biobased recycled components Studies on Stable Formulations for a Hydrophobic Cytokine Andrea Hawe,2006 **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 bio pharmaceutical 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 **Preclinical Development Handbook** Shayne Cox Gad, 2008-03-21 A clear straightforward resource to guide you through preclinical drug development Following this book s step by step guidance you can successfully initiate and complete critical phases of preclinical drug development The book serves as a basic comprehensive reference to prioritizing and optimizing leads dose formulation ADME pharmacokinetics modeling and regulations This authoritative easy to use resource covers all the issues that need to be considered and provides detailed instructions for current methods and techniques Each chapter is written by one or more leading experts in the field These authors representing the many disciplines involved in preclinical toxicology screening and testing give you the tools needed to apply an effective multidisciplinary approach The editor has carefully reviewed all the chapters to ensure that each one is thorough accurate and clear Among the key topics covered are Modeling and informatics in drug design Bioanalytical chemistry Absorption of drugs after oral administration Transporter interactions in the ADME pathway of drugs

Metabolism kinetics Mechanisms and consequences of drug drug interactions Each chapter offers a full exploration of problems that may be encountered and their solutions The authors also set forth the limitations of various methods and techniques used in determining the safety and efficacy of a drug during the preclinical stage This publication should be readily accessible to all pharmaceutical scientists involved in preclinical testing enabling them to perform and document preclinical safety tests to meet all FDA requirements before clinical trials may begin **Pharmaceutical Biotechnology**

Oliver Kayser,Heribert Warzecha,2012-03-27 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

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 *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

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