

Pharmaceutical Biotechnology • Volume 3

# **Stability and Characterization of Protein and Peptide Drugs**

## **Case Histories**

**Edited by  
Y. John Wang  
and  
Rodney Pearlman**

# Stability And Characterization Of Protein And Peptide Drugs

**Lars Hovgaard, Sven Frokjaer, Marco  
van de Weert**



## **Stability And Characterization Of Protein And Peptide Drugs:**

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

**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

*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

**Trends and Future Perspectives in Peptide and Protein Drug Delivery** Vincent Lee,1995-02-01 First published in 1995 Routledge is an imprint of Taylor Francis an informa company 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

**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

*Pharmaceutical Biotechnology* Daan J. A. Crommelin,Robert D. Sindelar,Bernd

Meibohm,2013-10-22 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 Fourth Edition will completely update the previous edition and will also include additional coverage on the newer approaches such as oligonucleotides siRNA gene therapy and nanotech Protein Formulation and Delivery Eugene J. McNally,Eugene McNally,Jayne E. Hastedt,2007-10-26 This title is intended to assist pharmaceutical scientists in the development of stable protein formulations during the early stages of the product development process providing a comprehensive review of mechanisms and causes of protein instability in formulation development coverage of accelerated stability testing methods and relevant analytical *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 **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.

**Bioactive Proteins and Peptides as Functional Foods and Nutraceuticals** Yoshinori Mine, Eunice Li-Chan, Bo Jiang, 2011-06-09 Bioactive Proteins and Peptides as Functional Foods and Nutraceuticals highlights recent developments of nutraceutical proteins and peptides for the promotion of human health. The book considers fundamental concepts and structure-activity relations for the major classes of nutraceutical proteins and peptides. Coverage includes functional proteins and peptides from numerous sources including soy, Pacific hake, bovine muscle, peas, wheat, fermented milk, eggs, casein, fish collagen, bovine lactoferrin and rice. The international panel of experts from industry and academia also reviews current applications and future opportunities within the nutraceutical proteins and peptides sector.

*Foye's Principles of Medicinal Chemistry* David A. Williams, William O. Foye, Thomas L. Lemke, 2002 This comprehensive Fifth Edition has been fully revised and updated to meet the changing curricula of medicinal chemistry courses. The new emphasis is on pharmaceutical care that focuses on the patient and on the pharmacist, a therapeutic clinical consultant rather than chemist. Approximately 45 contributors respected in the field of pharmacy education augment this exhaustive reference. New to this edition are chapters with standardized formats and features such as Case Studies, Therapeutic Actions, Drug Interactions and more. Over 700 illustrations supplement this must-have resource.

*Handbook of Pharmaceutical Biotechnology* Shayne Cox Gad, 2007-05-23 A practical overview of a full range of approaches to discovering, selecting and producing biotechnology-derived drugs. The Handbook of Pharmaceutical Biotechnology helps pharmaceutical scientists develop biotech drugs through a comprehensive framework that spans the process from discovery, development and manufacturing through validation and registration. With chapters written by leading practitioners in their specialty areas, this reference provides an overview of biotechnology used in the drug development process. Covers extensive applications plus regulations and validation methods. Features fifty chapters covering all the major approaches to the challenge of identifying, producing and formulating new biologically derived therapeutics. With its unparalleled breadth of topics and approaches, this handbook is a core reference for pharmaceutical scientists including development researchers, toxicologists, biochemists, molecular biologists, cell biologists, immunologists and formulation chemists. It is also a great resource for quality assurance, assessment control managers, biotechnology technicians and others in the biotech industry.

*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     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     *National Library of Medicine Current Catalog* National Library of Medicine (U.S.),1993     Novel Formulations and Future Trends Amit Kumar Nayak,Kalyan Kumar Sen,2024-03-25 Novel Formulations and Future Trends Volume Three in the Recent and Future Trends in Pharmaceutics series explores aspects of pharmaceutics with an original approach focused on technology novelties and future trends It discusses the most important developments in drug delivery including important and exciting areas such as mucosal implantable transdermal gastroretentive vaccine and targeted drug delivery systems The field of pharmaceutics is highly dynamic and rapidly expanding day by day so it demands a variety of amplified efforts for designing and developing pharmaceutical processes and formulation strategies This is an essential reference for researchers in academia and industry as well as advanced graduate students New technologies are also explored including 3D printing and computational pharmaceutics Explores the most recent technologies in drug delivery in detail Contains contributions from the leading experts from academia research industry and regulatory agencies Includes high quality illustrations flow charts and tables for easy understanding of concepts Discusses practical examples and research case studies     **Pharmaceutical Dosage Forms** Sandeep Nema,John D. Ludwig,2010-08-26 Pharmaceutical Dosage Forms Parenteral Medications explores the administration of medications through other than the enteral route First published in 1984 as two volumes and then last revised in 1993 this three volume set presents the plethora of changes in the science and considerable advances in the technology associated with these products     **Foye's Principles of Medicinal Chemistry** Thomas L. Lemke,David A. Williams,2012-01-24 Acclaimed by students and instructors alike Foye s Principles of Medicinal Chemistry is now in its Seventh Edition featuring updated chapters plus new material that meets the needs of today s medicinal chemistry courses This latest edition offers an unparalleled presentation of drug discovery and pharmacodynamic agents integrating principles of medicinal chemistry with pharmacology pharmacokinetics and clinical pharmacy All the chapters have been written by an international team of respected researchers and academicians Careful editing ensures thoroughness a consistent style and format and easy navigation throughout the text

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