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Wentworth Webster

Pharmaceutical Manufacturing Handbook Shayne Cox Gad,2008-03-21 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.

Tyrol and Its People Clive Holland, 1909

Basque Legends Wentworth Webster, 1877

Pharmaceutical Manufacturing Handbook Shayne Cox Gad,2008-04-04 With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

Handbook of Pharmaceutical Granulation Technology Dilip M. Parikh,2021-05-11 Theoretical discussions covering granulation and engineering perspectives. Covers new advances in expert systems, process modelling and bioavailability Chapters on emerging technologies in particle engineering Updated Current research and developments in granulation technologies

Reflectance Spectroscopy Gustav Kortüm,2012-12-06 Reflectance spectroscopy is the investigation of the spectral composition of surface-reflected radiation with respect to its angularly dependent intensity and the composition of the incident primary radiation. Two limiting cases are important: The first concerns regular (specular) reflection from a smooth surface, and the second diffuse reflection from an ideal matte surface. All possible variations are found in practice between these two extremes. For the two extreme cases, two fundamentally different methods of reflectance spectroscopy are employed: The first of these consists in evaluating the optical constants n (refractive index) and x (absorption index) from the measured regular reflection by means of the Fresnel equations as a function of the wave A. This rather old and very troublesome procedure, which is length incapable of very accurate results, has recently been modified by Fahren fort by replacing the air-sample phase boundary by the phase boundary between a dielectric of higher refractive index (n) and the sample (n). 1 2 If the sample absorbs no radiation and the angle of incidence exceeds a certain definite value, total reflection occurs. On close optical contact between the two phases, a small amount of energy is transferred into the less dense phase because of diffraction phenomena at the edges of the incident beam. The energy flux in the two directions through the phase boundary caused by this is equal, however, so that 'total reflection takes place.

GAMP Good Practice Guide ISPE,2002

Adhesion Measurement Methods Robert Lacombe, 2005-11-21 Adhesion Measurement Methods: Theory and Practice provides practical information on the most important measurement techniques, their unique advantages and disadvantages, and the selection of the proper method for a given application. It includes useful information and formulae on adhesion related matters such as driving force formulae for various m

Process Simulation and Data Modeling in Solid Oral Drug Development and Manufacture Marianthi G. Ierapetritou, Rohit Ramachandran, 2015-10-02 This thorough volume aims to provide pharmaceutical engineers with an introduction to the current state of the art in modeling and simulation of pharmaceutical processes and to summarize a number of practical applications of relevant methodologies in drug product development. Chapters include explorations of simulation and modeling methodologies, data collection and analysis, development of novel sensing techniques, development and integration of individual unit models, optimization approaches for data-based models, design space evaluation techniques, informatics-based methodologies, and emerging topics in pharmaceutical process development. As a part of the Methods in Pharmacology and Toxicology series, the chapters contain the kind of detail and implementation advice that will make the transition into the laboratory as smooth as possible. Authoritative and cutting edge, Process Simulation and Data Modeling in Solid Oral Drug Development and Manufacture seeks to promote research into process systems methodologies and their application in pharmaceutical product and process development, which will undoubtedly become an increasingly important area in the future.

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition Anurag S. Rathore, Gail Sofer, 2012-05-09 Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes. Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale-down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells Viral clearance validation studies for a product produced in a human cell line A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and inprocess samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help you and your team ascertain process validation is carried out and exceeds expectations.

Handbook Of Manufacturing Yong Huang,Lihui Wang,Steven Y Liang,2019-10-08 Handbook of Manufacturing provides a comprehensive overview of fundamental knowledge on manufacturing, covering various processes, manufacturing-related metrology and quality assessment and control, and manufacturing systems. Many modern processes such as additive manufacturing, micro- and nano-manufacturing, and biomedical manufacturing are also covered in this handbook. The handbook will help prepare readers for future exploration of manufacturing research as well as practical engineering applications.

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Developing Solid Oral Dosage Forms Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lirong Liu, William Porter, 2009-03-10 Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with: Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design, characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges, trends, opportunities, intellectual property issues and regulations in solid product development The first book (ever) that provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice, applications, regulation, intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies

Handbook of Modern Pharmaceutical Analysis Satinder Ahuja, Stephen Scypinski, 2010-11-11 Handbook of Modern Pharmaceutical Analysis, Second Edition, synthesizes the complex research and recent changes in the field, while covering the techniques and technology required for today's laboratories. The work integrates strategy, case studies, methodologies, and implications of new regulatory structures, providing complete coverage of quality assurance from the point of discovery to the point of use. Treats pharmaceutical analysis (PA) as an integral partner to the drug development process rather than as a service to it Covers method development, validation, selection, testing, modeling, and simulation studies combined with advanced exploration of assays, impurity testing, biomolecules, and chiral separations Features detailed coverage of QA, ethics, and regulatory guidance (quality by design, good manufacturing practice), as well as high-tech methodologies and technologies from lab-on-a-chip to LC-MS, LC-NMR, and LC-NMR-MS

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 into the physical aspects of stress testing, and incorporates the concept of Quality by Design into the stress testing construct / framework. It has been revised and expanded to include chapters on large molecules, such as proteins and antibodies, and it outlines the changes in stress testing that have emerged in recent years. Key features include: A renowned Editorial team and contributions from all major drug companies, reflecting a wealth of experience. 10 new chapters, including Stress Testing and its relationship to the assessment of potential genotoxic degradants, combination drug therapies, proteins, oligonucleotides, physical changes and alternative dosage forms such as liposomal formulations Updated methodologies for predicting drug stability and degradation pathways Best practice models to follow An expanded Frequently Asked Questions section This is an essential reference book for Pharmaceutical Scientists and those working in Quality Assurance and Drug Development (analytical sciences, formulations, chemical process, project management).

Basque Legends; With an Essay on the Basque Language Wentworth Webster,2022-11-21 Basque Legends by Wentworth Webster is a collection of marvelous mythological tales from Biscay, Spain. Contents: I.—Legends of the Tartaro 1 The Tartaro 4 M.

d'Abbadie's Version 4 Variations of above 5 Errua, the Madman 6 Variations of above 10 The Three Brothers, the Cruel Master, and the Tartaro 11 The Tartaro and Petit Perroquet 16 II.—The Heren-Suge.—The Seven-Headed Serpent 20 The Grateful Tartaro and the Heren-Suge 22 Variation of above.

Missing Karin Alvtegen, 2010-08-31 Can murder and mercy go hand in hand? In The Grand Hotel, a homeless woman charms a businessman into paying for dinner and a room. When his dead body is discovered the following morning she becomes the prime suspect. When a second person is killed in similar circumstances, Sybilla, having left her comfortable middle-class upbringing for the anonymity of the streets, becomes the most wanted person in Sweden . . . Missing is a gripping, multi-faceted thriller; more than a murder-hunt, it is also something more profound : an individual's journey to self-awareness and hope.

Modern Pharmaceutics Gilbert S. Banker, Juergen Siepmann, Christopher Rhodes, 2002-05-24 Completely revised and expanded throughout. Presents a comprehensive integrated, sequenced approach to drug dosage formulation, design, and evaluation. Indentifies the pharmacodynamic and physicochemical factors influencing drug action through various routes of administration.

<u>Pharmaceutical Capsules</u> Fridrun Podczeck, Brian E. Jones, 2004 Updated and expanded second edition covers all aspects of capsule technology, including history, standards, methods and equipment used in manufacture, filling, printing, weighing, cleaning and inspecting of both hard and soft capsules.

Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals Feroz Jameel, Susan Hershenson, 2010-07-13 A real-world guide to the production and manufacturing of biopharmaceuticals While much has been written about the science of biopharmaceuticals, there is a need for practical, up-to-date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products. This book helps fill the gap in the field, examining all areas of biopharmaceuticals manufacturing, from development and formulation to production and packaging. Written by a group of experts from industry and academia, the book focuses on real-world methods for maintaining product integrity throughout the commercialization process, clearly explaining the fundamentals and essential pathways for all development stages. Coverage includes: Research and early development phase-appropriate approaches for ensuring product stability Development of commercially viable formulations for liquid and lyophilized dosage forms Optimal storage, packaging, and shipping methods Case studies relating to therapeutic monoclonal antibodies, recombinant proteins, and plasma fractions Useful analysis of successful and failed products Formulation and Process Development Strategies for Manufacturing Biopharma-ceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries, for government and regulatory agencies, and for anyone with an interest in the latest developments in the field.

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