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A Novel Usp Apparatus 4 Based Release Testing Method For

**Christopher M. Riley, Thomas W.
Rosanske, George L. Reid**



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Poorly Soluble Drugs Gregory K. Webster, Robert G. Bell, J. Derek Jackson, 2017-01-06 This book is the first text to provide a comprehensive assessment of the application of fundamental principles of dissolution and drug release testing to poorly soluble compounds and formulations. Such drug products are, vis-à-vis their physical and chemical properties, inherently incompatible with aqueous dissolution. However, dissolution methods are required for product development and selection, as well as for the fulfillment of regulatory obligations with respect to biopharmaceutical assessment and product quality understanding. The percentage of poorly soluble drugs defined in classes 2 and 4 of the Biopharmaceutics Classification System (BCS) has significantly increased in the modern pharmaceutical development pipeline. This book provides a thorough exposition of general method development strategies for such drugs, including instrumentation and media selection, the use of compendial and non-compendial techniques in product development, and phase-appropriate approaches to dissolution development. Emerging topics in the field of dissolution are also discussed, including biorelevant and biphasic dissolution, the use of enzymes in dissolution testing, dissolution of suspensions, and drug release of non-oral products. Of particular interest to the industrial pharmaceutical professional, a brief overview of the formulation and solubilization techniques employed in the development of BCS class 2 and 4 drugs to overcome solubility challenges is provided and is complemented by a collection of chapters that survey the approaches and considerations in developing dissolution methodologies for enabling drug delivery technologies, including nanosuspensions, lipid-based formulations, and stabilized amorphous drug formulations.

Natural and Synthetic Biomedical Polymers Sangamesh G. Kumbar, Cato Laurencin, Meng Deng, 2014-01-21 Polymers are important and attractive biomaterials for researchers and clinical applications due to the ease of tailoring their chemical, physical, and biological properties for target devices. Due to this versatility, they are rapidly replacing other classes of biomaterials, such as ceramics or metals. As a result, the demand for biomedical polymers has grown exponentially and supports a diverse and highly monetized research community. Currently worth 1.2bn in 2009, up from 650m in 2000, biomedical polymers are expected to achieve a CAGR of 9.8% until 2015, supporting a current research community of approximately 28,000. Summarizing the main advances in biopolymer development of the last decades, this work systematically covers both the physical science and biomedical engineering of the multidisciplinary field. Coverage extends across synthesis, characterization, design, consideration, and biomedical applications. The work supports scientists researching the formulation of novel polymers with desirable physical, chemical, biological, biomechanical, and degradation properties for specific targeted biomedical applications. Combines chemistry, biology, and engineering for expert and appropriate integration of design and engineering of polymeric biomaterials. Physical, chemical, biological, biomechanical, and degradation properties alongside currently deployed clinical applications of specific biomaterials, aids use as single source reference on field 15 case studies, provides in-depth analysis of currently used polymeric biomaterials, aiding design considerations for the future.

Long Acting Injections and Implants Jeremy C. Wright, Diane J. Burgess, 2012-01-29 Long acting injections and implants improve therapy enhance patient compliance improve dosing convenience and are the most appropriate formulation choice for drugs that undergo extensive first pass metabolism or that exhibit poor oral bioavailability An intriguing variety of technologies have been developed to provide long acting injections and implants Many considerations need to go into the design of these systems in order to translate a concept from the lab bench to actual therapy for a patient This book surveys and summarizes the field Topics covered in Long Acting Injections and Implants include the historical development of the field drugs diseases and clinical applications for long acting injections and implants anatomy and physiology for these systems specific injectable technologies including lipophilic solutions aqueous suspensions microspheres liposomes in situ forming depots and self assembling lipid formulations specific implantable technologies including osmotic implants drug eluting stents and microfabricated systems peptide protein and vaccine delivery sterilization drug release testing and regulatory aspects of long acting injections and implants This volume provides essential information for experienced development professionals but was also written to be useful for scientists just beginning work in the field and for others who need an understanding of long acting injections and implants This book will also be ideal as a graduate textbook

Specification of Drug Substances and Products Christopher M. Riley, Thomas W. Rosanske, George L. Reid, 2020-07-23 Specification of Drug Substances and Products Development and Validation of Analytical Methods Second Edition presents a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products with an emphasis on phase appropriate development validation of analytical methods and their application in practice This thoroughly revised second edition covers topics not covered or not substantially covered in the first edition including method development and validation in the clinical phase method transfer process analytical technology analytical life cycle management special challenges with generic drugs genotoxic impurities topical products nasal sprays and inhalation products and biotechnology products The book's authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines and or subject matter experts in the industry academia and in government laboratories Presents a critical assessment of the application of ICH guidelines on method validation and specification setting Written by subject matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis control and specification of new drug substances and products Covers the latest statistical approaches including analytical quality by design in the development of specifications method validation and shelf life prediction

Development of In Vitro Release Testing Methods for Modified Release Parenterals and Correlation with In Vivo Performance Upkar Bhardwaj, 2009

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