

What is an Active Pharmaceutical Ingredient (API)?



Active Pharmaceutical Ingredients Api Surrogate

A Gutmann



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Manufacturing of Quality Oral Drug Products Sam A. Hout, 2022-06-27 This book provides an understanding of what is required to engineer and manufacture drug products It bridges established concepts and provides for a new outlook by concentrating and creating new linkages in the implementation of manufacturing quality assurance and business practices related to drug manufacturing and healthcare products This book fills a gap by providing a connection between drug production and regulated applications It focuses on drug manufacturing quality techniques in oral solid dosage and capsule filling including equipment and critical systems to control production and the finished products The book offers a correlation between design strategies and a step by step process to ensure the reliability safety and efficacy of healthcare products Fundamentals of techniques quality by design risk assessment and management are covered along with a scientific method approach to continuous improvement in the usage of computerized manufacturing and dependence on information technology and control operations through data and metrics Manufacturing and Quality Assurance of Oral Pharmaceutical Products Processing and Safe Handling of Active Pharmaceutical Ingredients API is of interest to professionals and engineers in the fields of manufacturing engineering quality assurance reliability business management process and continuous improvement life cycle management healthcare products manufacturing pharmaceutical processing and computerized manufacturing

Case Studies in Bayesian Methods for Biopharmaceutical CMC Paul Faya, Tony Pourmohamad, 2022-12-15 The subject of this book is applied Bayesian methods for chemistry manufacturing and control CMC studies in the biopharmaceutical industry The book has multiple authors from industry and academia each contributing a case study chapter The collection of case studies covers a broad array of CMC topics including stability analysis analytical method development specification setting process development and optimization process control experimental design dissolution testing and comparability studies The analysis of each case study includes a presentation of code and reproducible output This book is written with an academic level aimed at practicing nonclinical biostatisticians most of whom have graduate degrees in statistics First book of its kind focusing strictly on CMC Bayesian case studies Case studies with code and output Representation from several companies across the industry as well as academia Authors are leading and well known Bayesian statisticians in the CMC field Accompanying website with code for reproducibility Reflective of real life industry applications problems

Handbook of Pharmaceutical Manufacturing Formulations Sarfaraz K. Niazi, 2016-04-19 The fourth volume in the series covers the techniques and technologies involved in the preparation of semisolid products such as ointments creams gels suppositories and special topical dosage forms Drug manufacturers need a thorough understanding of the specific requirements that regulatory agencies impose on the formulation and efficacy deter

Continuous Manufacturing of Pharmaceuticals Peter Kleinebudde, Johannes Khinast, Jukka Rantanen, 2024-10-28 A comprehensive look at existing technologies and processes for continuous manufacturing of pharmaceuticals As rising costs outpace new

drug development the pharmaceutical industry has come under intense pressure to improve the efficiency of its manufacturing processes Continuous process manufacturing provides a proven solution Among its many benefits are minimized waste energy consumption and raw material use the accelerated introduction of new drugs the use of smaller production facilities with lower building and capital costs the ability to monitor drug quality on a continuous basis and enhanced process reliability and flexibility Continuous Manufacturing of Pharmaceuticals prepares professionals to take advantage of that exciting new approach to improving drug manufacturing efficiency This book covers key aspects of the continuous manufacturing of pharmaceuticals The first part provides an overview of key chemical engineering principles and the current regulatory environment The second covers existing technologies for manufacturing both small molecule based products and protein peptide products The following section is devoted to process analytical tools for continuously operating manufacturing environments The final two sections treat the integration of several individual parts of processing into fully operating continuous process systems and summarize state of art approaches for innovative new manufacturing principles Brings together the essential know how for anyone working in drug manufacturing as well as chemical food and pharmaceutical scientists working on continuous processing Covers chemical engineering principles regulatory aspects primary and secondary manufacturing process analytical technology and quality by design Contains contributions from researchers in leading pharmaceutical companies the FDA and academic institutions Offers an extremely well informed look at the most promising future approaches to continuous manufacturing of innovative pharmaceutical products Timely comprehensive and authoritative Continuous Manufacturing of Pharmaceuticals is an important professional resource for researchers in industry and academe working in the fields of pharmaceuticals development and manufacturing 29th European Symposium on Computer Aided Chemical Engineering Anton A. Kiss, Edwin Zondervan, Richard Lakerveld, Leyla Özkan, 2019-06-28 The 29th European Symposium on Computer Aided Process Engineering contains the papers presented at the 29th European Symposium of Computer Aided Process Engineering ESCAPE event held in Eindhoven The Netherlands from June 16 19 2019 It is a valuable resource for chemical engineers chemical process engineers researchers in industry and academia students and consultants for chemical industries Presents findings and discussions from the 29th European Symposium of Computer Aided Process Engineering ESCAPE event **The United States pharmacopeia**, 2012

Applied Biopharmaceutics & Pharmacokinetics, Seventh Edition Leon Shargel, Andrew B. C. Yu, 2015-11-22 The landmark textbook on the theoretical and practical applications of biopharmaceutics and pharmacokinetics now fully updated Explains how to detect clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them Helps you critically evaluate biopharmaceutic studies involving drug product equivalency and unequivalency Chapters have been revised to reflect the latest clinical perspectives on drug performance bioavailability bioequivalence pharmacokinetics pharmacodynamics and drug therapy The field s leading text for more than three decades Applied Biopharmaceutics

Pharmacokinetics gets you up to speed on the basics of the discipline like no other resource Practical problems and clinical examples with discussions are integrated within each chapter to help you apply principles to patient care and drug consultation situations In addition outstanding pedagogy including chapter objectives chapter summaries and FAQs plus additional application questions identify and focus on key concepts Written by authors who have both academic and clinical experience Applied Biopharmaceutics Pharmacokinetics shows you how to use raw data and formulate the pharmacokinetic models and parameters that best describe the process of drug absorption distribution and elimination The book also helps you work with pharmacokinetic and biopharmaceutic parameters to design and evaluate dosage regimens of drugs In the seventh edition of this must have interactive learning tool most of the chapters are updated to reflect our current understanding of complex issues associated with safe and efficacious drug therapy *Chemical Week ,2007 Technical Report Series ,2006* Dispersion and Dissolution Kinetics of API Particles in Pharmaceutical Hot Melt Extrusion Wang Zhan,2014 Pharmaceutical Hot Melt Extrusion HME is essentially a special case of polymer compounding The elementary steps involved in traditional plastics melt processing are handling of particulates melting dispersive and distributive mixing devolatilization and stripping and finally pressurization and pumping However for pharmaceutical HME the dissolution of the API Active Pharmaceutical Ingredient is an additional and very important elementary step along with the melting of the polymeric excipient that precedes it and mixing which accelerates the dissolution process A major concern in pharmaceutical HME is the thermal degradation of the API To avoid overexposure of API to heat while ensuring complete dissolution of the API in the production of solid solution the dissolution kinetics of the API must be known This work employs a non dissolving surrogate material in an attempt to deconvolute the phenomena of distribution dispersion and dissolution of the API inside a molten polymeric matrix using a Brabender batch mixer in order to determine the dissolution kinetics of the API

Structural Characterizations of Protein Antigens for The Next-Generation Vaccines Against Anthrax and Plague ,2004

Two recombinant protein antigens called rPA and F1 V are recommended by the U S Army as active pharmaceutical ingredients API for the next generation vaccines to protect the warfighter against aerosolized anthrax and plague Separate candidate vaccines containing purified antigen bound to aluminum hydroxide adjuvant in phosphate buffered saline PBS have been tested at the research level and each has satisfied requirements for advancement to product development These criteria included demonstrations of direct and surrogate efficacy in respective animal disease models preliminary assessment of product safety by testing acute toxicity and API stability demonstration of an in vitro correlate of protection for development as a potency test and proposed baseline methods from which to develop a robust manufacturing process and assays for testing product purity quality strength and stability USAMRIID scientists provided the discovery and concept research in this regard for both candidate vaccines and have been performing ongoing supportive basic research to further the eventual translation of each into a viable product In looking forward one of many U S Food and Drug Administration FDA

requirements for eventual human use of these vaccines is documentation of progressive studies that increase understanding of the chemical and biophysical properties of the API Each of these two protein antigens exhibited unexpected physical features early in research that required further definition This paper summarizes our characterizations of observed heterogeneity within these pure vaccine proteins in primary structure for the rPA antigen and in quaternary structure for the F1 V antigen This work also illustrates the value of extending technology base research beyond the stages of discovery and proof of concept so as to better support the creation of medical biological products that will protect the warfighter against biological threats

Predictive in Vitro Dissolution Tools Emmanuel Scheubel,2010 Dissolution has emerged as a key method during development of medicines and for quality control of marketed products At the early stage of development dissolution guides the selection of toxicology and first test in man formulations At later stages of development dissolution tests are performed to compare prototype formulations the robustness of the manufacturing process to indicate stability and to assure safe release and reproductibility of the products to the market However despite they wide use in pharmaceutical development several challenges still exist In particular there is a lack of thorough identification and understanding of the critical quality attributes that control dissolution of Active Pharmaceutical Ingredient and Drug Product Dissolution exhibits clearly a higher predictability if it can be extrapolated directly to in vivo behavior The present work focuses on the optimization of the existing and alternative dissolution techniques to lay a foundation for Quality by Design QbD principles In Vitro In Vivo Correlation IVIVC and In Vitro In Vivo Relationship IVIVR The dissolution applied on API and on different formulations types Immediate release and extended release form during the different development phases as well as for generic has been explored Simple and cost effective dissolution methods were shown to be potential surrogate for in vivo performance and serve as well for strong quality control method The future perspectives and central role of dissolution testing are presented and discussed

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