Tableting Specification Manual

This multi-authored handbook is a unique cross-industry resource for formulators and compounders, and an invaluable reference for the producers of formulated commodities and industrial minerals. Monographs on each of the common functional industrial mineralsùasbestos, barite, calcium carbonate, diatomite, feldspar, gypsum, hormite, kaolin, mica, nepheline syenite, perlite, pyrophyllite, silica, smectite, talc, vermiculite, wollastonite, and zeoliteùinclude an overview of natural and commercial varieties, market size, and application areas. These are supported by descriptions of mineral structures and the wedding of minerals and chemicals through mineral surface modification. This orientation to the minerals and their uses forms the foundation for chapters where they are presented in the context of the overall technology of various consuming industries. Each of these industry-specific presentations covers both the chemical and mineral raw materials used by the formulator, how these are combined, and relevant test methods. These chapters serve a dual purpose. Each clarifies for technologists the function and value of the mineral constituents of their products. Equally important, they provide a primer on the technology of industries other than their own, so that raw material, formulation, processing and testing considerations can be compared and contrasted. The book concludes with a formulary demonstrating how specific mineral and chemical ingredients are actually compounded in major application areas, and technical data on scores of commercial mineral products.

Part I: Process design -- Introduction to design -- Process flowsheet development -- Utilities and energy efficient design -- Process simulation -- Instrumentation and process control --

Materials of construction -- Capital cost estimating -- Estimating revenues and production costs -- Economic evaluation of projects -- Safety and loss prevention -- General site considerations -- Optimization in design -- Part II: Plant design -- Equipment selection, specification and design -- Design of pressure vessels -- Design of reactors and mixers -- Separation of fluids -- Separation columns (distillation, absorption and extraction) -- Specification and design of solids-handling equipment -- Heat transfer equipment -- Transport and storage of fluids.

While FDA regulations, cGMP, GLP, GCP, and the industry standard ISO 9000 require that documentation be established and followed, they do not provide guidelines on how to produce that documentation. Pharmaceutical Equipment Validation gives details on how to demonstrate compliance, what data to use, and how to produce the appropriate documentation. This book's user-friendly diagrams and other clear graphics illustrate key ideas throughout each protocol, offering a bird's-eye view of what is coming next-and they quickly guide you through the equipment validation. The author provides a thorough understanding of how to prepare, test, and complete equipment qualification protocols. He also explains how to perform qualification testing and whether to test the equipment for a worst case scenario. No other book deals exclusively with the key issues of equipment qualification and process validation for pharmaceutical process equipment-and provides instructions on how to achieve it. With pragmatic approach, this book includes 38 useful protocol templates, already completed, that provide instant answers to most protocol writing and testing questions. These templates cover specific equipment types, such, and provide accurate, industry acceptable equipment qualification protocols. Step-by-step, they show how to qualify each piece of equipment, and they provide a check for

readers own protocols.

As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct efficient and successful bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence, and advances in the analytical technology used to detect drug and metabolite levels have made

When a pharmaceutical company decides to build a Quality System, it has to face the fact that there aren't any guideline that define exactly how such a system has to be built. With terms such as quality system, quality assurance, and quality management used interchangeably, even defining the system's objectives is a problem. This book provides a pr

Edited by one of the leading experts in the field, this handbook emphasizes why solid-state issues are important, which approaches should be taken to avoid problems and exploit the opportunities offered by solid state properties in the pharmaceutical and agricultural industries. With its practical approach, this is at once a guideline for development chemists just entering the field as well as a high-quality source of reference material for specialists in the pharmaceutical and chemical industry, structural chemists, physicochemists, crystallographers, inorganic chemists, and patent departments.

Following the well-received first edition, the Drug Abuse Handbook, Second Edition is a thorough compendium of the knowledge of the pharmacological, medical, and legal aspects of drugs. The book examines criminalistics, pathology, pharmacokinetics, neurochemistry, treatment, as well as drugs and drug testing in the workplace and in sports, and the ethical, legal, and practical issues involved. Dr. Karch gathers contributions from 80 leading experts in their respective fields to update and revise this second edition with more than 40 percent new material. New topics include

genetic testing in drug death investigation, the neurochemistry of nicotine and designer amphetamines, genetic doping in sports, and the implications of the Daubert ruling on the admissibility of scientific evidence in federal court. Packed with the latest information in an easily accessible format, the book includes tables of all Scheduled Drugs, methods of Drug Quantitative Analysis, and a glossary of forensic toxicology terms. Vivid pictures and diagrams illustrate the pathological effects of drugs and the chemical make-up and breakdown of abused drugs. It includes more than 6000 references to the best sources in medicine, pharmacology, and the law. This book addresses specific problems in drug testing, drug-related medical emergencies, and the physical, neurochemical, and sociological phenomenon of addiction. With unparalleled detail and the highest level of authoritative information, The Drug Abuse Handbook, Second Edition is the definitive resource for drug related issues.

It is always hard to set manufacturing systems to produce large quantities of standardized parts. Controlling these mass production lines needs deep knowledge, hard experience, and the required related tools as well. The use of modern methods and techniques to produce a large quantity of products within productive manufacturing processes provides improvements in manufacturing costs and product quality. In order to serve these purposes, this book aims to reflect on the advanced manufacturing systems of different alloys in production with related components and automation technologies. Additionally, it focuses on mass production processes designed according to Industry 4.0 considering different kinds of quality and

improvement works in mass production systems for high productive and sustainable manufacturing. This book may be interesting to researchers, industrial employees, or any other partners who work for better quality manufacturing at any stage of the mass production processes.

The FAO/WHO Manual on development and use of FAO and WHO specifications for pesticides contains general principles and methodologies of the work undertaken by JMPS, is the continuous evaluation of new scientific developments and guidance documents. The Manual gives the historical background of the operation of the JMPS and describes the purpose of the work. The Manual is also used by countries as a guidance document in setting pesticide specifications. This 3rd revision of the Manual contains n ew methodologies/principles developed in recent 5 years and incorporates the current working principles applied by the JMPS.

A practical summary of the technical and technological as well as nutritional and physiological properties attained through the targeted selection of raw materials and the corresponding production processes. The two authors come from the world's leading gelatine company and adopt here an international approach, enabling their knowledge to be transferred between the various application areas on a global scale. Following an introduction to and the history of gelatine, the text surveys the global industry and current trends, before going on to analyze the basic physical, chemical and technological properties of gelatine. Manufacturing,

including quality and safety and the processing of powder, instant gelatine and hydrolysate are dealt with next, prior to an in-depth review of applications in beverages and foodstuffs, pharmaceuticals, health and osteoarthritis, among others. The whole is rounded off by future visions and a useful glossary. Aimed at all gelatine users, heads and technicians in production and quality control, product developers, students of food science and pharmacy as well as marketing experts within the industry and patent lawyers.

This book represents the invited presentations and some of the posters presented at the conference entitled "In Vitro-In Vivo Relationship (IVIVR) Workshop" held in Sep tember, 1996. The workshop was organized by the IVIVR Cooperative Working Group which has drawn together scientists from a number of organizations and institutions, both academic and industrial. In addition to Elan Corporation, which is a drug delivery com pany specializing in the development of ER (Extended Release) dosage forms, the IVIVR Cooperative Working Group consists of collaborators from the University of Maryland at Baltimore, University College Dublin, Trinity College Dublin, and the University of Not tingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. lain Cumming, Elan Corporation Dr. John Devane, Elan Corporation Dr. Adrian Dunne, University College Dublin Dr. Stuart Madden, Elan Corporation Dr. Colin Melia, University of Nottingham Mr. Tom O'Hara, Elan Corporation Dr. Deborah Piscitelli, University of Maryland at Baltimore Dr. Araz Raoof, Elan Corporation

Mr. Paul Stark, Elan Corporation Dr. David Young, University of Maryland at Baltimore The purpose of the workshop was to discuss new concepts and methods in the devel opment of in vitro-in vivo relationships for ER products. The original idea went back ap proximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development.

Until now, books addressing Halal issues have focused on helping Muslim consumers decide what to eat and what to avoid among products currently on the marketplace. There was no resource that the food industry could refer to that provided the guidelines necessary to meet the Halal requirements of Muslim consumers in the U.S. and abroad. Halal

3D printing is forecast to revolutionise the pharmaceutical sector, changing the face of medicine development, manufacture and use. Potential applications range from pre-clinical drug development and dosage form design through to the fabrication of functionalised implants and regenerative medicine. Within clinical pharmacy practice, printing technologies may finally lead to the concept of personalised medicines becoming a reality. This volume aims to be the definitive resource for anyone thinking of developing or using 3D printing technologies in the pharmaceutical sector, with a strong focus on the translation of printing technologies to a clinical setting. This text brings together leading experts to provide extensive information on an array of 3D printing techniques, reviewing the current printing technologies in the pharmaceutical manufacturing supply

chain, in particular, highlighting the state-of-the-art applications in medicine and discussing modern drug product manufacture from a regulatory perspective. This book is a highly valuable resource for a range of demographics, including academic researchers and the pharmaceutical industry, providing a comprehensive inventory detailing the current and future applications of 3D printing in pharmaceuticals. Abdul W. Basit is Professor of Pharmaceutics at the UCL School of Pharmacy, University College London. Abdul's research sits at the interface between pharmaceutical science and gastroenterology, forging links between basic science and clinical outcomes. He leads a large and multidisciplinary research group, and the goal of his work is to further the understanding of gastrointestinal physiology by fundamental research. So far, this knowledge has been translated into the design of new technologies and improved disease treatments, many of which are currently in late-stage clinical trials. He has published over 350 papers, book chapters and abstracts and delivered more than 250 invited research presentations. Abdul is also a serial entrepreneur and has filed 25 patents and founded 3 pharmaceutical companies (Kuecept, Intract Pharma, FabRx). Abdul is a frequent speaker at international conferences, serves as a consultant to many pharmaceutical companies and is on the advisory boards of scientific journals, healthcare organisations and charitable bodies. He is the European Editor of the International Journal of Pharmaceutics. Abdul was the recipient of the Young Investigator Award in Pharmaceutics and Pharmaceutical Technology from

the American Association of Pharmaceutical Scientists (AAPS) and is the only non-North American scientist to receive this award. He was also the recipient of the Academy of Pharmaceutical Sciences (APS) award. Simon Gaisford holds a Chair in Pharmaceutics and is Head of the Department of Pharmaceutics at the UCL School of Pharmacy, University College London. He has published 110 papers, 8 book chapters and 4 authored books. His research is focused on novel technologies for manufacturing medicines, particularly using ink-jet printing and 3D printing, and he is an expert in the physico-chemical characterisation of compounds and formulations with thermal methods and calorimetry.

Pharmaceutical Dosage Forms: Capsules covers the development, composition, and manufacture of capsules. Despite the important role that capsules play in drug delivery and product development, few comprehensive texts on the science and technology of capsules have been available for the research and academic environments. This text addresses this gap, discussing how capsules provide unique capabilities and options for dosage form design and formulation.

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines;

Guidelines on Good Manufacturing Practices (GMP) for heating, ventilation and air-conditioning systems (HVAC) illustrative part; Guidance on GMP for Validation, including the general main text, analytical procedure validation, validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report and recommended for implementation.

Design and Manufacture of Pharmaceutical Tablets offers real world solutions and outcomes of formulation and processing challenges of pharmaceutical tablets. This book includes numerous practical examples related to actual formulations that have been validated and marketed and covers important data in the areas of stability, dissolution, bioavailibity and processing. It provides important background and theoretical information on design and manufacturing and includes a full section dedicated to design experimental methodology and statistics. In addition, this book offers a a general discussion of excipients used in proper tablet design along with practical examples related to excipients. Drug development scientists in industry and academia, as well as students in the pharmaceutical sciences will greatly benefit from the practical knowledge

and case examples provided throughout this book. Incorporates important mathematical models and computational applications Includes unique content on central composite design and augmented simplex lattice Provides background on important design principles with emphasis on quality-based design (QBD) of pharmaceutical dosage forms

Pharmaceutics is one of the most diverse subject areas in all of pharmaceutical science. In brief, it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms or medicines. An understanding of pharmaceutics is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely, effectively and conveniently to the patient. Now in its fourth edition, this best-selling textbook in pharmaceutics has been brought completely up to date to reflect the rapid advances in delivery methodologies by eye and injection, advances in drug formulations and delivery methods for special groups (such as children and the elderly), nanomedicine, and pharmacognosy. At the same time the editors have striven to maintain the accessibility of the text for students of pharmacy, preserving the balance between being a suitably pitched introductory text and a clear reflection of the state of the art. provides a logical, comprehensive account of drug design and manufacture includes the science of formulation and drug delivery designed and written for newcomers to the design of dosage forms New to this edition New editor: Kevin Taylor, Professor of Clinical Pharmaceutics, School of

Pharmacy, University of London. Twenty-two new contributors. Six new chapters covering parenteral and ocular delivery; design and administration of medicines for the children and elderly; the latest in plant medicines; nanotechnology and nanomedicines, and the delivery of biopharmaceuticals. Thoroughly revised and updated throughout.

The only reference on U.S. manufacturing specifications for tablets and tablet tooling. Also adopted by International tablet tooling manufacturers as industry standards, this manual is the complete guide to the design of and specifications for tablet tooling, the design of tablets, and the appropriate compression forces for various types of tooling. Also provided are detailed explanations and supporting illustrations for inspection and maintenance of tooling. Two troubleshooting charts identify common tablet production problems and their remedies. Extensively revised and updated, the sixth edition is the most comprehensive reference and training resource available on tablet tooling.

This book is about the chemical properties of starch. The book is a rich compendium driven by the desire to address the unmet needs of biomedical scientists to respond adequately to the controversy on the chemical properties and attendant reactivity of starch. It is a collective endeavor by a group of editors and authors with a wealth of experience and expertise on starch to aggregate the influence of qualitative and quantitative morphological, chemical, and genetic properties of starch on its functionalities, use, applications, and health benefits. The chemical properties of starch are conferred

by the presence, amount and/or quality of amylose and amylopectin molecules, granule structure, and the nature and amounts of the lipid and protein molecules. The implication of this is comprehensively dealt with in this book.

This volume gathers the proceedings of the International Conference on Medical and Biological Engineering, which was held from 16 to 18 May 2019 in Banja Luka, Bosnia and Herzegovina. Focusing on the goal to 'Share the Vision', it highlights the latest findings, innovative solutions and emerging challenges in the field of Biomedical Engineering. The book covers a wide range of topics, including: biomedical signal processing, medical physics, biomedical imaging and radiation protection, biosensors and bioinstrumentation, bio-micro/nano technologies, biomaterials, biomechanics, robotics and minimally invasive surgery, and cardiovascular, respiratory and endocrine systems engineering. Further topics include bioinformatics and computational biology, clinical engineering and health technology assessment, health informatics, e-health and telemedicine, artificial intelligence and machine learning in healthcare, as well as pharmaceutical and genetic engineering. Given its scope, the book provides academic researchers, clinical researchers and professionals alike with a timely reference guide to measures for improving the quality of life and healthcare.

The Tableting Specification Manual covers every facet of tablet manufacturing: tooling and tablet design, tooling steels, maximum compression forces, tooling inspection and maintenance, and troubleshooting of tablet and tool

production problems. This reference helps users increase tablet quality and production rate, extend tooling life, prevent damage to presses, and avoid costly work stoppages.

This fully revised edition of Handbook of Pharmaceutical Granulation Technology covers the rapid advances in the science of agglomeration, process control, process modelling, scale-up, emerging particle engineering technologies, along with current regulatory changes presented by some of the prominent scientist and subject matter experts around the globe. Learn from more than 50 global subject matter experts who share their years of experience in areas ranging from drug delivery and pharmaceutical technology to advances in nanotechnology. Every pharmaceutical scientist should own a copy of this fourth edition resource. Key Features: 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

10.7.3 State of Control

During the past decades, enormous progress and enhancement of pharmaceutical manufacturing equipment and its use have been made. And while there are support documents, books, articles, and

online resources available on the principles of cleaning and associated processing techniques, none of them provides a single database with convenient, ready-to-

Thoroughly revised edition of the classic text on polymer processing The Second Edition brings the classic text on polymer processing thoroughly up to date with the latest fundamental developments in polymer processing, while retaining the critically acclaimed approach of the First Edition. Readers are provided with the complete panorama of polymer processing, starting with fundamental concepts through the latest current industry practices and future directions. All the chapters have been revised and updated, and four new chapters have been added to introduce the latest developments. Readers familiar with the First Edition will discover a host of new material, including: * Blend and alloy microstructuring * Twin screw-based melting and chaotic mixing mechanisms * Reactive processing * Devolatilization--theory, mechanisms, and industrial practice * Compounding--theory and industrial practice * The increasingly important role of computational fluid mechanics * A systematic approach to machine configuration design The Second Edition expands on the unique approach that distinguishes it from comparative texts. Rather than focus on specific processing methods, the authors assert that polymers have a similar

experience in any processing machine and that these experiences can be described by a set of elementary processing steps that prepare the polymer for any of the shaping methods. On the other hand, the authors do emphasize the unique features of particular polymer processing methods and machines, including the particular elementary step and shaping mechanisms and geometrical solutions. Replete with problem sets and a solutions manual for instructors, this textbook is recommended for undergraduate and graduate students in chemical engineering and polymer and materials engineering and science. It will also prove invaluable for industry professionals as a fundamental polymer processing analysis and synthesis reference.

Spanning every critical element of validation for any pharmaceutical, diagnostic, medical device or equipment, and biotech product, this Second Edition guides readers through each step in the correct execution of validating processes required for non-aseptic and aseptic pharmaceutical production. With 14 exclusive environmental performance evaluati

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Tableting Specification ManualAmer Pharmacists Assn

An internationally acclaimed reference work recognized as one of the most authoritative and comprehensive sources of information on excipients used in pharmaceutical formulation with this new edition providing 340 excipient monographs. Incorporates information on the uses, and chemical and physical properties of excipients systematically collated from a variety of international sources including: pharmacopeias, patents, primary and secondary literature, websites, and manufacturers' data; extensive data provided on the applications, licensing, and safety of excipients; comprehensively cross-referenced and indexed, with many additional excipients described as related substances and an international supplier's directory and detailed information on trade names and specific grades or types of excipients commercially available.

Handbook of Pharmaceutical Wet Granulation: Theory and Practice in a Quality by Design Paradigm offers a single and comprehensive reference dedicated to all aspects of pharmaceutical wet granulation, taking a holistic approach by combining introductory principles with practical solutions. Chapters are written by international experts across industry, academic and regulatory settings, and cover a wide spectrum of relevant and contemporary wet granulation topics, techniques and processes. The books' focus on process analytical technology, quality by design principles, granulation equipment, modeling, scale-up, control and real time release makes it a timely and valuable resource for all those involved in pharmaceutical wet granulation. Discusses fundamentals of theory and current industrial practice in the field of wet granulation, including product and process design and role of material properties in wet granulation Examines the modern evolution of wet granulation through current topics such as established and novel process analytical technologies (PATs), and product development and scale-up paradigms

Written for scientists working within the pharmaceutical industry, as well as academics, regulatory officials and equipment vendors who provide PAT tools and granulation equipment

There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.

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.