Tableting Specification Manual Free

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

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.

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.
In recent years there has been an explosion of interest in the production of nanoscale fibres for drug delivery and tissue engineering. Nanofibres in Drug Delivery aims to outline to new researchers in the field the utility of nanofibres in drug delivery, and to explain to them how to prepare fibres in the laboratory. The book begins with a brief discussion of the main concepts in pharmaceutical science. The authors then introduce the key techniques that can be used for fibre production and explain briefly the theory behind them. They discuss the experimental implementation of fibre production, starting with the simplest possible set-up and then moving on to consider more complex arrangements. As they do so, they offer advice from their own experience of fibre production, and use examples from current literature to show how each particular type of fibre can be applied to drug delivery. They also consider how fibre production could be moved beyond the research laboratory into industry, discussing regulatory and scale-up aspects.
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.
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-

Conducting tablet-based field data collection with CSPro is a joint initiative of the Asian Development Bank and the Food and Agriculture Organization of the United Nations to support national statistics offices and line ministries to develop human capacities to conduct tablet-based field data collections for official statistics in the Asia and Pacific region for more robust, accurate and timely data.

The adoption of tablet-based data collection methods, also referred to as Computer-assisted Personal Interviewing, is part of an overarching development in official statistics to adopt new cost-effective technologies to move from traditional pen-and-paper questionnaires to more cost-efficient, high quality and timely methods using electronic devices. This Handbook seeks to support this transition by providing step-by-step instruction and guidance to develop, test and run Computer Assisted Personal Interviewing field data collection using one of the free software's currently available on the market – CSPro.

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

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

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.

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.

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.

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.

This book is the definitive work on the theory and practice of pharmaceutical tablet and pellet coating. It describes both the practical and theoretical aspects of tablet coating, including the equipment and methods used in laboratory development, scale-up and production systems, More...as well as automation and validation. This book also discusses the problems of conforming to world-wide regulations, and the hazards of environmental pollution.

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.

The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients.

Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form, an

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.

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.

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 edited volume brings together the expertise of numerous specialists on the topic of particles – their physical, chemical, pharmacological and toxicological characteristics – when they are a component of pharmaceutical products and formulations. The book discusses in detail properties such as the composition, size, shape, surface properties and porosity of particles with respect to how they impact the formulations and products in which they are used and the effective delivery of pharmaceutical active ingredients. It considers all dosage forms of pharmaceuticals involving particles, from powders to tablets, creams to ointments, and solutions to dry-powder inhalers, also including the latest nanomedicine products. Further, it discusses examples of particle toxicity, as well as the important subject of pharmaceutical industry regulations, guidelines and legislation. The book is of interest to researchers and practitioners who work on testing and developing pharmaceutical dosage and delivery systems.

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.

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.

Since the earliest dosage forms to modern drug delivery systems, came a great development and growth of knowledge with respect to drug delivery. Strategies to Modify the Drug Release from Pharmaceutical Systems will address principles, systems, applications and advances in the field.It will be principally a textbook and a reference source of strategies to modify the drug release. Moreover, the characterization, mathematical and physicochemical models, applications and the systems will be discussed. Addresses the principles, systems, applications and advances in the field of drug delivery Highlights the mathematical and physicochemical principles related to strategies Discusses drug release and its possible modifications

This volume offers a comprehensive guide on the theory and practice of amorphous solid dispersions (ASD) for handling challenges associated with poorly soluble drugs. In twenty-three inclusive chapters, the book examines thermodynamics and kinetics of the amorphous state and amorphous solid dispersions, ASD technologies, excipients for stabilizing amorphous solid dispersions such as polymers, and ASD manufacturing technologies, including spray drying, hot melt extrusion, fluid bed layering and solvent-controlled micro-precipitation technology (MBP). Each technology is illustrated by specific case studies. In addition, dedicated sections cover analytical tools and technologies for characterization of amorphous solid dispersions, the prediction of long-term stability, and the development of suitable dissolution methods and regulatory aspects. The book also highlights future technologies on the horizon, such as supercritical fluid processing, mesoporous silica, KinetiSol®, and the use of non-salt-forming organic acids and amino acids for the stabilization of amorphous systems. Amorphous Solid Dispersions: Theory and Practice is a valuable reference to pharmaceutical scientists interested in developing bioavailable and therapeutically effective formulations of poorly soluble molecules in order to advance these technologies and develop better medicines for the future.

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.

First multi-year cumulation covers six years: 1965-70.

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 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.

A collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances, excipients and dosage forms intended to serve as source material for reference by any WHO member state.

Completely updated and enlarged to three volumes (originally published as two volumes), the Second Edition of Pharmaceutical Dosage Forms: Parenteral Medications examines every important aspect of sterile drug products. This volume (3) offers comprehensive coverage of medical devices, quality assurance and regulatory issues.;This in-depth reference and text: discusses regulatory requirements in record-keeping based on the US Food and Drug Administration's (FDA) Current Good Manufacturing Practices; places special emphasis on methods of detecting, counting and sizing particles; offers new perspectives on contemporary validation concepts and how they affect the validation process; explains current FDA enforcement activities, the voluntary compliance policy, select court cases, and how these relate to parenterals; provides recent materials on the use of audits as a means of verifying the efficacy of manufacturing control systems; highlights new US regulations for medical devices; and examines quality assurance, including new information on biological control tests for medical device materials.;With the contributions of leading experts, volume 3 of Pharmaceutical Dosage Forms: Parenteral Medications is intended as a day-to-day reference for pharmacists, medical device manufacturers, quality control and regulatory personnel, chemists and drug patent and litigation attorneys, as well as a text for upper-level undergraduate, graduate and continuing-education students in the pharmaceutical sciences.

Hot-melt extrusion (HME) - melting a substance and forcing it through an orifice under controlled conditions to form a new material - is an emerging processing technology in the pharmaceutical industry for the preparation of various dosage

forms and drug delivery systems, for example granules and sustained release tablets. Hot-Melt Extrusion: Pharmaceutical Applications covers the main instrumentation, operation principles and theoretical background of HME. It then focuses on HME drug delivery systems, dosage forms and clinical studies (including pharmacokinetics and bioavailability) of HME products. Finally, the book includes some recent and novel HME applications, scale -up considerations and regulatory issues. Topics covered include: principles and die design of single screw extrusion twin screw extrusion techniques and practices in the laboratory and on production scale HME developments for the pharmaceutical industry solubility parameters for prediction of drug/polymer miscibility in HME formulations the influence of plasticizers in HME applications of polymethacrylate polymers in HME HME of ethylcellulose, hypromellose, and polyethylene oxide bioadhesion properties of polymeric films produced by HME taste masking using HME clinical studies, bioavailability and pharmacokinetics of HME products injection moulding and HME processing for pharmaceutical materials laminar dispersive & distributive mixing with dissolution and applications to HME technological considerations related to scale-up of HME processes devices and implant systems by HME an FDA perspective on HME product and process understanding improved process understanding and control of an HME process with near-infrared spectroscopy Hot-Melt Extrusion: Pharmaceutical Applications is an essential multidisciplinary guide to the emerging pharmaceutical uses of this processing technology for researchers in academia and industry working in drug formulation and delivery, pharmaceutical engineering and processing, and polymers and materials science. This is the first book from our brand new series Advances in Pharmaceutical Technology. Find out more about the series here.