Guideline On Stability Testing For Applications For

This Test Guideline describes methods for determining storage stability of a substance with respect to heat and air. Two methods are applicable to homogeneous solid and liquid substances and to mixtures of these: the accelerated storage test and the ...

This test guideline describes a test procedure to gain information on dispersion stability of manufactured nanomaterials in simulated environmental media. The main purpose of this guideline is to assess the ability of a nanomaterial to attain a colloidal dispersion and to conserve this ...

WHO's international guidelines, written and physical standards developed under the aegis of this Expert Committee for more than 60 years are designed to serve all Member States, international organizations, United Nations agencies, regional and interregional harmonization efforts, and underpin important initiatives, including the prequalification of medicines, the Roll Back Malaria Programme, Stop TB, essential medicines and medicines for children. The Forty-seventh WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted 26 new monographs and general texts for inclusion in The International Pharmacopoeia,/I>. The specifications under development are internationally applicable test methodologies for anti-infective, antimalarial, antituberculosis, contraceptives and antiretroviral medicines, as well as medicines for children. In addition, the following four written standards were adopted in the area of quality assurance and are now available for implementation : * Release procedure for International Chemical Reference Substances (update); * WHO guideline on quality risk management (new) * WHO guideline on variations to a prequalified product (update) *

Collaborative procedure between the WHO Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products (new).

Providing the guidance needed for formulation, handling, and quality control of photolabile drugs, Photostability of Drugs and Drug Formulations, Second Edition explores the significance of new information on drug photoreactivity in a pharmaceutical context. Completely revised and updated, with chapter authors drawn from an international panel of experts, the book supplies the background necessary for planning standardized photochemical stability studies as a part of drug development and formulation work. It contains comprehensive coverage of the physical and chemical aspects of drug photoreactivity, formulation, stability testing, and drug design/discovery in one resource. The contents have been reorganized to focus on the standardization of photostability testing of drug substances and products, in vitro photoreactivity screening of drugs, and various aspects of the formulation of photoreactive substances. The information on in vitro screening of drug photoreactivity is of great relevance for scientists who are developing and validating a set of testing protocols to address photosafety. Discussing kinetic and chemical aspects of drug photodecomposition as well as the practical problems frequently encountered in photochemical stability testing, this book helps you design a test protocol and interpret the results. Features Assists non-experts in this field design a test protocol and interpret the results Covers in vitro and in vivo aspects of interactions between drugs and light Explores the kinetic and chemical aspects of drug photodecomposition Discusses the problems frequently encountered in photochemical stability testing Provides guidance on how to address photosafety assessments and labeling

requirements of potentially photoreactive drugs Highlights the practical implications of drug photodecomposition from a pharmaceutical viewpoint Offers specific guidance in photostability testing and screening of drug photoreactivity

The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the

book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of

assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

The GCC Guidelines on Stability Testing of Pharmaceutical ProductsGCC Guidelines on Stability Testing of Active Pharmaceutical Ingredients (APLs) and Finished Pharmaceutical Products (FPPs)Handbook of Stability Testing in Pharmaceutical DevelopmentRegulations, Methodologies, and Best PracticesSpringer

This report discusses the monographs on antiretrovirals proposed for inclusion in The International Pharmacopoeia and specifications for radiopharmaceuticals, quality specifications for antituberculosis drugs and the revision of the monograph on artemisinin derivatives, as well as quality control of reference materials, good manufacturing practices, inspection, distribution and trade, and other aspects of quality assurance of pharmaceuticals, and regulatory issues. Several annexes include an amendment togood manufacturing practices: main principles regarding the requirement for the sampling of starting materials, guidelines on good manufacturing practices regarding water for pharmaceutical

use, guidelines on the sampling of pharmaceutical products, and draft guidelines for registration of fixed-dose combination medicinal products.

Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. • Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies • Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines • Uses case studies to help readers understand and apply ICH guidelines • Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines • Includes coverage of stability testing, analytical method validation, impurities, biotechnology drugs and products, and good manufacturing practice (GMP)

This detailed volume collects numerous methods and protocols related to different aspects of stability programs that are followed in pharmaceutical development laboratories. Implementation of a successful stability program, vital in preventing product failures and recalls, requires critical and logical thinking that goes beyond the regular documented protocols and methods, so the experiences of the book's internationally-based expert

contributors fill the chapters with practical guidance. As a volume in the Methods in Pharmacology and Toxicology series, this book presents the kind of real-world advice that is essential for advancing laboratory research. Authoritative and thorough, Methods for Stability Testing of Pharmaceuticals serves as a valuable addition to the existing armamentarium of resources available to stability testing personnel in research and industry.

Part I: Food and Drugs Act - Part A: Administration - Part C: Drugs Division 1 - Division 1A: Establishment Licences - Division 2: Good Manufacturing Practices Part II: Guidance Documents Part III: Annexes to the Current Edition of the Good Manufacturing Practices (GMP) Guidelines Part IV: Questions and Answers Part V: International Conference on Harmonisation (ICH) Guidance Documents - ICH Q1A(R2): Stability Testing of New Drug Substances and Products - ICH Q1B: Stability Testing: Photostability Testing of New Drug Substances and Products - ICH Q1C: Stability Testing for New Dosage Forms - ICH Q2(R1): Validation of Analytical Procedures: Text and Methodology - ICH Q7A: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients - ICH Q9: Quality Risk Management, Part VI: Compliance Policies Part VII: Forms Part VIII: Extensive Index

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.

Accelerated Predictive Stability (APS): Fundamentals and Pharmaceutical Industry Practices provides coverage of both the fundamental principles and pharmaceutical industry applications of the APS approach. Fundamental chapters explain the scientific basis of the APS approach, while case study chapters from many innovative pharmaceutical companies provide a thorough

overview of the current status of APS applications in the pharmaceutical industry. In addition, up-to-date experiences in utilizing APS data for regulatory submissions in many regions and countries highlight the potential of APS in support of registration stability testing for certain regulatory submissions. This book provides high level strategies for the successful implementation of APS in a pharmaceutical company. It offers scientists and regulators a comprehensive resource on how the pharmaceutical industry can enhance their understanding of a product's stability and predict drug expiry more accurately and quickly. Provides a comprehensive, one-stop-shop resource for accelerated predictive stability (APS) Presents the scientific basis of different APS models Includes the applications and utilities of APS that are demonstrated through numerous case studies Covers up-to-date regulatory experience

The US Food and Drug Administration's Report to the Nation in 2004 and 2005 indicated that one of the top reasons for drug recall was that stability data did not support existing expiration dates. Pharmaceutical companies conduct stability studies to characterize the degradation of drug products and to estimate drug shelf life. Illustrating how stability studies play an important role in drug safety and quality assurance, Statistical Design and Analysis of Stability Studies presents the principles and methodologies in the design and analysis of stability studies. After introducing the basic concepts of stability testing, the book focuses on short-term stability studies and reviews several methods for estimating drug expiration dating periods. It then compares some commonly employed study

designs and discusses both fixed and random batch statistical analyses. Following a chapter on the statistical methods for stability analysis under a linear mixed effects model, the book examines stability analyses with discrete responses, multiple components, and frozen drug products. In addition, the author provides statistical methods for dissolution testing and explores current issues and recent developments in stability studies. To ensure the safety of consumers, professionals in the field must carry out stability studies to determine the reliability of drug products during their expiration period. This book provides the material necessary for you to perform stability designs and analyses in pharmaceutical research and development.

Packaging, Products, Testing, Stability, Cosmetics

In this book, recognized industry experts and regulatory inspectors from the world's pharmaceutical manufacturing regions provide stability requirements in all the major markets and discuss all aspects of stability testing and biotechnology. Participants in the ICH debates interpret the ICH guidelines. Other discussions focus on European requirements, the ICH initiatives, the US SUPAC initiative, matrixing and bracketing approaches from the cGMP and FDA perspective, and stability requirements in Japan, Australia, and WHO. Stress programs, testing of preservatives, and physical stability topics are addressed as well as various

protocols and statistical approaches.

This book contains an overview of the scientific and regulatory requirements for stability testing including the draft of the harmonised guideline for the stability testing in the EC, Japan and the USA. Therefore it will be possible to carry out stability testing in the most efficient way. This book may be of interest to scientists in the field of drug development in pharmaceutical industries, responsible for drug registration, responsible for quality control, and at universities.

The International Conference of Harmonization (ICH) has worked on har- nizing the stability regulations in the US, Europe, and Japan since the early 1990s. Even though the Stability Guidelines Q1A (R2) was issued over a decade ago, issues surrounding this arena continue to surface as the principles described in the guideline are applied to different technical concentrations. As a result, the stability community has continued to discuss concerns and find ways of harmonizing regulatory requirements, streamlining practices, improving processes in order to bring safe and effective medical supplies to the patients around the world. In 2007, the American Association of Pharmaceutical Scientists (AAPS) Stability Focus Group organized two workshops – the Stability Workshop and the Degradation Mechanism Workshop. These meetings attracted many industry scientists as well as representatives from several regulatory agencies in the

world to discuss important topics related to pharmaceutical stability practices. Recognizing the importance of documenting these discussions and with the permission of AAPS, I have worked with speakers to assemble a collection of 30 articles from presentations given at these two meetings, mainly the Stability Workshop. I trust that this book will be beneficial to all of you in providing guidance and up-to-date information for building quality stability programs. v Freedom of our mind is Mother of all inventions. This guidance document is intended to address recommendations on the application of bracketing and matrixing to stability studies conducted in accordance with principles outlined in the ICH parent stability guidance document Q1A(R) - Stability Testing of New Drug Substances and Products. A full study design is one in which samples for every combination of all design factors are tested at all time points. A reduced design (e.g., a bracketing or matrixing design) is one in which samples for every factor combination are not all tested at all time points. Specific principles are defined in this guidance document for situations in which bracketing or matrixing can be applied.