Guidelines On Stability Testing Of Cosmetic Products

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.

The basis for selection of the dosage form. Specialized dose dispensing equipment. Formulation of drug dosage forms for animals. Formulations of drugs for administration via feed or drinking water. Stability studies of veterinary formulations. Regulatory clearance.

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.

Methods for Stability Testing of Pharmaceuticals

ICH Quality Guidelines

Drug Stability and Chemical Kinetics

Formulation of Veterinary Dosage Forms
Canadian Good Manufacturing Practices

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 ...

Drug products are complex mixtures of drugs and excipients and, as such, their chemical and physical stability kinetics are complex. This book discusses the stability of these dosage forms with preformulation studies through to the studies on the final products. The book is intended for graduate students, researchers and professionals in the field of Pharmaceutics and Pharmaceutical Chemistry.

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).
International Stability Testing
An Implementation Guide
The GCC Guidelines on Stability Testing of Pharmaceutical Products
The Fundamentals of Stability Testing
Pharmaceutical Photostability and Stabilization Technology

The aim of these studies is to demonstrate the time period for which stability has been shown in representative commodities from crops. Freezer storage stability studies should include sufficient starting material and should have a sufficiently high ...
Packaging, Products, Testing, Stability, Cosmetics
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.

OECD Guidelines for the Testing of Chemicals, Section 3 Test No. 318: Dispersion Stability of Nanomaterials in Simulated Environmental Media

Drug Stability for Pharmaceutical Scientists

Troubleshooting Finite-Element Modeling with Abaqus

Essential Chemistry for Formulators of Semisolid and Liquid Dosages

Accelerated Predictive Stability (APS)

This book gives Abaqus users who make use of finite-element models in academic or practitioner-based research the in-depth program knowledge that allows them to debug a structural analysis model. The book provides many methods and guidelines for different analysis types and modes, that will help readers to solve problems that can arise with Abaqus if a structural model fails to converge to a solution. The use of Abaqus affords a general checklist approach to debugging analysis models, which can also be applied to structural analysis. The author uses step-by-step methods and detailed explanations of special features in order to identify the solutions to a

variety of problems with finite-element models. The book promotes: • a diagnostic mode of thinking concerning error messages; • better material definition and the writing of user material subroutines; • work with the Abaqus mesher and best practice in doing so; • the writing of user element subroutines and contact features with convergence issues; and • consideration of hardware and software issues and a Windows HPC cluster solution. The methods and information provided facilitate job diagnostics and help to obtain converged solutions for finite-element models regarding structural component assemblies in static or dynamic analysis. The troubleshooting advice ensures that these solutions are both high-quality and cost-effective according to practical experience. The book offers an in-depth guide for students learning about Abaqus, as each problem and solution are complemented by examples and straightforward explanations. It is also useful for academics and structural engineers wishing to debug Abaqus models on the basis of error and warning messages that arise during finite-element modelling processing.

A needed resource for pharmaceutical scientists and cosmetic chemists, Essential Chemistry for Formulators of Semisolid and Liquid Dosages provides insight into the basic chemistry of mixing different phases and test methods for the stability study of nonsolid formulations. The book

covers foundational surface/colloid chemistry, which forms the necessary background for making emulsions, suspensions, solutions, and nano drug delivery systems, and the chemistry of mixing, which is critical for further formulation of drug delivery systems into semisolid (gels, creams, lotions, and ointments) or liquid final dosages. Expanding on these foundational principles, this useful guide explores stability testing methods, such as particle size, rheological/viscosity, microscopy, and chemical, and closes with a valuable discussion of regulatory issues. Essential Chemistry for Formulators of Semisolid and Liquid Dosages offers scientists and students the foundation and practical guidance to make and analyze semisolid and liquid formulations. Unique coverage of the underlying chemistry that makes possible stable dosages Quality content written by experienced experts from the drug development industry Valuable information for academic and industrial scientists developing topical and liquid dosage formulations for pharmaceutical as well as skin care and cosmetic products

This book comprehensively reviews drug stability and chemical kinetics: how external factors can influence the stability of drugs, and the reaction rates that trigger these effects. Explaining the important theoretical concepts of drug stability and chemical kinetics, and providing numerous examples in the form of illustrations, tables and

calculations, the book helps readers gain a better understanding of the rates of reactions, order of reactions, types of degradation and how to prevent it, as well as types of stability studies. It also offers insights into the importance of the rate at which the drug is degraded and/or decomposed under various external and internal conditions, including temperature, pH, humidity and light. This book is intended for researchers, PhD students and scientists working in the field of pharmacy, pharmacology, pharmaceutical chemistry, medicinal chemistry and biopharmaceutics.

Who Expert Committee on Specifications for Pharmaceutical Preparations

Stability Testing of New Drug Substances and Products: Drugs Directorate Guidelines

With Application in Structural Engineering Analysis

Drugs Directorate Guidelines : ICH Harmonised Tripartite Guideline

Stability Guidelines for Testing Pharmaceutical Products

Based on a training course developed by Dr. Joseph T. Piechocki and other experts in this field whose contributions appear in this book for two International Meetings on the Photostability of Drugs and Drug Products, this text clarifies the guidelines set by the International Conference on Harmonization (ICH) and provides a comprehensive background

Handbook of Stability Testing in Pharmaceutical DevelopmentRegulations, Methodologies, and Best

PracticesSpringer Science & Business Media
Drug Stability for Pharmaceutical Scientists is a clear and easy-to-follow guide on drug degradation in pharmaceutical formulation. This book features valuable content on both aqueous and solid drug solutions, the stability of proteins and peptides, acid-base catalyzed and solvent catalyzed reactions, how drug formulation can influence drug stability, the influence of external factors on reaction rates and much more. Full of examples of real-life formulation problems and step-by-step calculations, this book is the ideal resource for graduate students, as well as scientists in the pharmaceutical and related industries. Illustrates important theoretical concepts with numerous examples, figures, calculations, learning problems and questions for self-study and retention of material Provides answers and explanations to test your knowledge Enables you to better understand key concepts such as rate and order of reaction, reaction equilibrium, complex reaction mechanisms and more Includes an in-depth discussion of both aqueous and solid drug solutions and contains the latest international regulatory requirements on drug stability
Forty-seventh Report
Guidelines on Stability Testing of Cosmetic Products
OECD Guidelines for the Testing of Chemicals / Section 5: Other Test Guidelines Test No 506: Stability of Pesticide Residues in Stored Commodities
Food and Beverage Stability and Shelf Life
Cosmetics. Guidelines on the Stability Testing of Cosmetic Products

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.

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)

"The greater our knowledge increases, the more our ignorance unfolds. " U. S. President John F. Kennedy, speech, Rice University, September 12, 1962 My primary purpose for writing this book was much more than to provide another information source on Chemistry, Manufacturing & Controls (CMC) that would rapidly become out of date. My primary purpose was to provide insight and practical suggestions into a common sense business approach to manage the CMC regulatory compliance requirements for biopharmaceuticals. Such a common sense business approach would need (1) to be applicable for all types of biopharmaceutical products both present and future, (2) to address the needs of a biopharmaceutical manufacturer from the beginning to the end of the clinical development stages and including post market approval, and (3) to be adaptable to the constantly changing CMC regulatory compliance requirements and guidance. Trying to accomplish this task was a humbling experience for this author! In Chapter

1, the CMC regulatory process is explained, the breadth of products included under the umbrella ofbiopharmaceuticals are identified, and the track record for the pharmaceutical and biopharmaceutical industry in meeting CMC regulatory compliance is discussed. In Chapter 2, while there are many CMC commonalities between biopharmaceuticals and chemically-synthesized pharmaceuticals, the significant differences in the way the regulatory agencies handle them are examined and the reasons for why such differences are necessary is discussed. Also, the importance of CMC FDA is stressed.

Scientific Criteries [sic], Guidelines, Officiel [sic] Requirements in Europe, Japan, and USA

Cosmetics - guidelines on the stability testing of cosmetic products (ISO/TR 18811:2018)

OECD Guidelines for the Testing of Chemicals, Section 1 Test No. 113: Screening Test for Thermal Stability and Stability in Air

Development and Validation of Analytical Methods

New Cosmetic Science

This book discusses the different regulatory pathways for gene therapy (GT) and cell therapy (CT) medicinal products implemented by national and international bodies throughout the world (e.g. North and South America, Europe, and Asia). Each chapter, authored by experts from various regulatory bodies throughout the international community, walks the reader through the applications of nonclinical research to translational clinical research to licensure for these innovative products. More specifically, each chapter offers insights into fundamental considerations that are essential for developers of CT and GT products, in the areas of product manufacturing, pharmacology and toxicology, and clinical trial design, as well as pertinent "must-know" guidelines and regulations. Regulatory Aspects of Gene Therapy and Cell Therapy Products: A Global Perspective is part of the American Society of Gene and Cell Therapy sub-series of the highly successful Advances in Experimental Medicine and Biology series. It is essential reading for graduate students, clinicians, and researchers interested in gene and cell therapy and the regulation of pharmaceuticals. 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

Cosmetic science covers the fields from natural sciences to human and social sciences, and is an important interdisciplinary element in various scientific disciples. New Cosmetic Science is a completely updated comprehensive review of its 35 year old counterpart Cosmetic Science. New Cosmetic Science has been written to give as many people as possible a better understanding of the subject, from scientists and technologists specializing in cosmetic research and manufacturing, to students of cosmetic science, and people with a wide range of interests concerning cosmetics. The relationship between the various disciplines comprising cosmetic science, and cosmetics, is described in Part I. In addition to discussing the safety of cosmetics, the "Usefulness of Cosmetics", rapidly becoming an important theme, is described using

research examples. The latest findings on cosmetic stability are presented, as are databases, books and magazines, increasingly used by cosmetic scientists. Part II deals with cosmetics from a usage viewpoint, including skin care cosmetics, makeup cosmetics, hair care cosmetics, fragrances, body cosmetics, and oral care cosmetics. Oral care cosmetics and body cosmetics are presented with product performance, types, main components, prescriptions and manufacturing methods described for each item. This excellent volume enlightens the reader not only on current cosmetics and usage, but indicates future progress enlarging the beneficial effects of cosmetics. Products with better pharmaceutical properties (cosmeceuticals), working both physically and psychologically, are also highlighted.

Issues and Alternatives

A Global Perspective

Stability of Drugs and Dosage Forms

Statistical Design and Analysis of Stability Studies

The Challenge of CMC Regulatory Compliance for Biopharmaceuticals

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. 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.

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 ...

Stability Testing of New Drug Substances and Products

Stability testing of drug products

GCC Guidelines on Stability Testing of Active Pharmaceutical Ingredients (APLs) and Finished Pharmaceutical Products (FPPs)

Regulations, Methodologies, and Best Practices

Fundamentals and Pharmaceutical Industry Practices

Ensuring that foods and beverages remain stable during the required shelf life is critical to their success in the market place, yet companies experience difficulties in this area. Food and beverage stability and shelf life provides a

comprehensive guide to factors influencing stability, methods of stability and shelf life assessment and the stability and shelf life of major products. Part one describes important food and beverage quality deterioration processes, including microbiological spoilage and physical instability. Chapters in this section also investigate the effects of ingredients, processing and packaging on stability, among other factors. Part two describes methods for stability and shelf life assessment including food storage trials, accelerated testing and shelf life modelling. Part three reviews the stability and shelf life of a wide range of products, including beer, soft drinks, fruit, bread, oils, confectionery products, milk and seafood. With its distinguished editors and international team of expert contributors, Food and beverage stability and shelf life is a valuable reference for professionals involved in quality assurance and product development and researchers focussing on food and beverage stability. A comprehensive guide to factors influencing stability, methods of stability and shelf life assessment and the stability and shelf life of major products Describes important food and beverage quality deterioration processes exploring microbiological spoilage and physical instability Investigate the effects of ingredients, processing and packaging on stability and documents methods for stability and shelf life assessment

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

scientif. criteria, guidelines and official state requirements in Europe, Japan and USA

Pharmaceutical Stability Testing to Support Global Markets

Handbook of Stability Testing in Pharmaceutical Development

Pharmaceutical, Biotechnology, and Medical Device Regulations and Guidance Concise Reference

Regulatory Aspects of Gene Therapy and Cell Therapy Products