Guidelines On Stability Testing Of Cosmetic Products

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Guidelines On Stability Testing Of Cosmetic Products ***2021-02-27***

LAWRENCE SKINNER

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

Guidelines on Stability Testing of Cosmetic Products

CRC Press

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.

Development and Validation of Analytical Methods

OECD Publishing

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).

Stability Testing of Drug Products OECD Publishing

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 ...

IDMA-APA Guideline Elsevier

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.

Methods for Stability Testing of Pharmaceuticals John Wiley & Sons

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

Drug Stability and Chemical Kinetics CRC Press

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 ...

Stability Testing of New Drug Substances and Products John Wiley & Sons

High pressure liquid chromatography–frequently called high performance liquid chromatography (HPLC or, LC) is the premier analytical technique in pharmaceutical analysis and is predominantly used in the pharmaceutical industry. Written by selected experts in their respective fields, the Handbook of Pharmaceutical Analysis by HPLC Volume 6, provides a complete yet concise

reference guide for utilizing the versatility of HPLC in drug development and quality control. Highlighting novel approaches in HPLC and the latest developments in hyphenated techniques, the book captures the essence of major pharmaceutical applications (assays, stability testing, impurity testing, dissolution testing, cleaning validation, high-throughput screening). A complete reference guide to HPLC Describes best practices in HPLC and offers 'tricks of the trade' in HPLC operation and method development Reviews key HPLC pharmaceutical applications and highlights currents trends in HPLC ancillary techniques, sample preparations, and data handling **scientif. criteria, guidelines and official state requirements in Europe, Japan and USA** Springer 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

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

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.

Pharmaceutical, Biotechnology, and Medical Device Regulations and Guidance Concise Reference Routledge 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) *An Implementation Guide* Elsevier The International Conference of Harmonization (ICH) has worked on harnizing 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.

Regulations, Methodologies, and Best Practices

Humana

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.

Fundamentals and Pharmaceutical Industry Practices

International Publishers Service, Incorporated

Handbook of Stability Testing in Pharmaceutical DevelopmentRegulations, Methodologies, and Best PracticesSpringer Science & Business Media

Stability of Drugs and Dosage Forms

Academic Press

Packaging, Products, Testing, Stability, Cosmetics

Pharmaceutical Stability Testing to Support Global Markets

Academic Press

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.

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

The second edition of Pharmaceutical Stress Testing: Predicting Drug Degradation provides a practical and scientific guide to designing, executing and interpreting stress testing studies for drug

substance and drug product. This is the only guide available to tackle this subject in-depth. The Second Edition expands coverage from chemical stability into the physical aspects of stress testing, and incorporates the concept of Quality by Design into the stress testing construct / framework. It has been revised and expanded to include chapters on large molecules, such as proteins and antibodies, and it outlines the changes in stress testing that have emerged in recent years. Key features include: A renowned Editorial team and contributions from all major drug companies, reflecting a wealth of experience. 10 new chapters, including Stress Testing and its relationship to the assessment of potential genotoxic degradants, combination drug therapies, proteins, oligonucleotides, physical changes and alternative dosage forms such as liposomal formulations Updated methodologies for predicting drug stability and degradation pathways Best practice models to follow An expanded Frequently Asked Questions section This is an essential reference book for Pharmaceutical Scientists and those working in Quality Assurance and Drug Development (analytical sciences, formulations, chemical process, project management).

Springer
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

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

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.

OECD Guidelines for the Testing of

Chemicals, Section 1 Test No. 113: Screening Test for Thermal Stability and Stability in Air Springer Science & Business Media
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.