

KIM HUYNH-BA  
Editor

# Handbook of Stability Testing in Pharmaceutical Development

REGULATIONS, METHODOLOGIES,  
AND BEST PRACTICES

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 Springer

# Handbook Of Stability Testing In Pharmaceutical Development Regulations Methodologies And Best Practices

**Hany El-Shemy**



## **Handbook Of Stability Testing In Pharmaceutical Development Regulations Methodologies And Best Practices:**

**Handbook of Stability Testing in Pharmaceutical Development** Kim Huynh-Ba, 2008-11-16 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 Pharmaceutical Stability Testing to Support Global Markets Kim Huynh-Ba, 2009-12-04 The International Conference of Harmonization ICH has worked on harmonizing 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 **Accelerated Predictive Stability (APS)** Fenghe Qiu, Garry Scrivens, 2018-05-14 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 Pharmaceutical Stress Testing Steven W. Baertschi, Karen M. Alsante, Robert A. Reed, 2016-04-19 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

**Specification of Drug Substances and Products** Christopher M. Riley, K. Lien Nguyen, 2024-09-22 Specification of Drug Substances and Drug Products is a fully comprehensive reference on Specification Setting for Pharmaceuticals There have been several recent developments in the ICH Guidelines which were not captured in previous editions notably the new guideline on Development of Analytical Procedure and the revisions to the validation guidelines and the specification guidelines This edition contains chapters discussing the unique requirements for the universal critical quality attributes as well as the specific tests required to characterize and control different types of products ranging in complexity from small molecules in immediate release oral dosage forms to complex products such as drug antibody conjugates and mRNA based products This substantially expanded revision of the 2nd edition will serve as practical comprehensive reference for scientists managers educators and consultants involved in the development and regulation of pharmaceutical products Presents critical assessment potential impact and application of the recent revisions to ICH guidelines on method validation Q2 as well as the latest guideline on Analytical Method Development Q14 and the special regional requirements in non ICH regions Addresses comprehensive treatment of the development and validation of analytical methodologies used in the analysis control and specification of a variety of different types of dosage forms ranging from traditional oral solid dosage forms to proteins nRNA based drugs vaccines and gene therapy This book will also address drug device combination products such as digital drug delivery systems transdermal systems and inhalation products Presents detailed treatment of latest statistical approaches including new approaches to the treatment of validation data method specification setting and shelf life prediction based on stability data

**Handbook of Modern Pharmaceutical Analysis** Satinder Ahuja, Stephen Scypinski, 2010-11-11

Handbook of Modern Pharmaceutical Analysis Second Edition synthesizes the complex research and recent changes in the field while covering the techniques and technology required for today s laboratories The work integrates strategy case studies methodologies and implications of new regulatory structures providing complete coverage of quality assurance from the point of discovery to the point of use Treats pharmaceutical analysis PA as an integral partner to the drug development process rather than as a service to it Covers method development validation selection testing modeling and simulation studies combined with advanced exploration of assays impurity testing biomolecules and chiral separations Features detailed coverage of QA ethics and regulatory guidance quality by design good manufacturing practice as well as high tech methodologies and technologies from lab on a chip to LC MS LC NMR and LC NMR MS

**Drug Stability and Chemical Kinetics** Muhammad Sajid Hamid Akash, Kanwal Rehman, 2020-11-01 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

Pharmaceutical Inhalation Aerosol Technology, Third Edition Anthony J. Hickey, Sandro R. da Rocha, 2019-03-26 This fully revised and updated third edition of Pharmaceutical Inhalation Aerosol Technology encompasses the scientific and technical foundation for the rationale design componentry assembly and quality performance metrics of therapeutic inhalers in their delivery of pharmaceutical aerosols to treat symptoms or the underlying causes of disease It focuses on the importance of pharmaceutical engineering as a foundational element of all inhaler products and their application to pulmonary drug delivery The expanded scope considers previously unaddressed aspects of pharmaceutical inhalation aerosol technology and the patient interface by including aerosol delivery lung deposition and clearance that are used as measures of effective dose delivery Key Features Provides a thoroughly revised and expanded reference with authoritative discussions on the physiologic pharmacologic metabolic molecular cellular and physicochemical factors influencing the efficacy and utilization of pharmaceutical aerosols Emphasizes the importance of pharmaceutical engineering as a foundational element of all inhaler products and their application to pulmonary drug delivery Addresses the physics chemistry and engineering principles while establishing disease relevance Expands the technology focus of the original volumes to address the title more directly Offers an impressive breadth of coverage as well as an international flavour from outstanding editors and contributors

**Quality Control and Regulatory Aspects for Biologicals** Gauri Misra, 2024-04-22 This book serves as a comprehensive guide on quality control and regulatory aspects for biological products It covers a wide range of topics including regulatory requirements quality control strategies analytical methods and risk management It delves into the advantages and limitations of in vivo tests and discusses alternative methods that can be employed The book explores the use of animal based testing methods in quality control and examines viable alternatives Key Features Reviews various scientific and regulatory aspects involved in the quality control of biologicals Provides an overview of the roles of various national and international regulatory bodies and accreditation agencies Presents advanced analytical methods innovative technologies and the integration of molecular diagnostics in quality control processes Explores the use of animal based testing methods in quality control as well as their alternatives Discusses guidelines and methodologies involved in the development of biological products Overall this book is an important reference source for various professionals in the pharmaceutical industry including researchers scientists quality control personnel and regulatory affairs professionals

**Analytical Testing for the Pharmaceutical GMP Laboratory** Kim Huynh-Ba, 2022-04-19 Provides practical guidance on pharmaceutical analysis written by leading experts with extensive industry experience Analytical Testing for the Pharmaceutical GMP Laboratory

presents a thorough overview of the pharmaceutical regulations working processes and drug development best practices used to maintain the quality and integrity of medicines With a focus on smaller molecular weight drug substances and products the book provides the knowledge necessary for establishing the pharmaceutical laboratory to support Quality Systems while maintaining compliance with Good Manufacturing Practices GMP regulations Concise yet comprehensive chapters contain up to date coverage of drug regulations pharmaceutical analysis methodologies control strategies testing development and validation method transfer electronic data documentation and more Each chapter includes a table of contents definitions of acronyms a reference list and ample tables and figures Addressing the principal activities and regulatory challenges of analytical testing in the development and manufacturing of pharmaceutical drug products this authoritative resource Describes the structure roles core guidelines and GMP regulations of the FDA and ICH Covers the common analytical technologies used in pharmaceutical laboratories including examples of analytical techniques used for the release and stability testing of drugs Examines control strategies established from quality systems supported by real world case studies Explains the use of dissolution testing for products such as extended release capsules aerosols and inhalers Discusses good documentation and data reporting practices stability programs and the Laboratory Information Management System LIMS to maintain compliance Includes calculations application examples and illustrations to assist readers in day to day laboratory operations Contains practical information and templates to structure internal processes or common Standard Operating Procedures SOPs Analytical Testing for the Pharmaceutical GMP Laboratory is a must have reference for both early career and experienced pharmaceutical scientists analytical chemists pharmacists and quality control professionals It is also both a resource for GMP laboratory training programs and an excellent textbook for undergraduate and graduate courses of analytical chemistry in pharmaceutical sciences or regulatory compliance programs

**Introduction to Pharmaceutical Technology Development** Yaser Dahman, 2025-02-24 Introduction to Pharmaceutical Technology Development Journey from Lab to Shelf of Commercial Pharmaceutical Drugs is a complete reference and learning resource for those working in pharmaceuticals or aspiring to join the industry The book provides a comprehensive view into all aspects of drug discovery approval and production Using examples of well known drugs and their journeys from lab to market the book provides a comprehensive overview of all steps involved in bringing new drugs including biologics to the shelves Topics covered include Drug Discovery Pharmaceutical Formulations of Different Dose Form Analytical Testing and Development Unit Operations and Design for Major Equipment Basics of Analytics and Process Validations and Protocols DQ IQ OQ PQ in FDA Regulated Industries This book provides graduate students from several areas with a solid foundation of the Pharmaceutic industry across key stages on new drug lifecycle Provides readers with introductory information on the developments in pharmaceutical technology Includes complete coverage of equipment and unit operations relevant across the production cycle of drugs Illustrates the path to commercialization through studies on the journey of several common

commercially available formulated medications

***Nonclinical Statistics for Pharmaceutical and Biotechnology Industries*** Lanju Zhang, 2016-01-13 This book serves as a reference text for regulatory industry and academic statisticians and also a handy manual for entry level Statisticians Additionally it aims to stimulate academic interest in the field of Nonclinical Statistics and promote this as an important discipline in its own right This text brings together for the first time in a single volume a comprehensive survey of methods important to the nonclinical science areas within the pharmaceutical and biotechnology industries Specifically the Discovery and Translational sciences the Safety Toxicology sciences and the Chemistry Manufacturing and Controls sciences Drug discovery and development is a long and costly process Most decisions in the drug development process are made with incomplete information The data is rife with uncertainties and hence risky by nature This is therefore the purview of Statistics As such this book aims to introduce readers to important statistical thinking and its application in these nonclinical areas The chapters provide as appropriate a scientific background to the topic relevant regulatory guidance current statistical practice and further research directions

***Sterile Drug Products*** Michael J. Akers, 2016-04-19 Sterile Drug Products Formulation Packaging Manufacturing and Quality teaches the basic principles of the development and manufacture of high quality sterile dosage forms The author has 38 years of experience in the development and manufacture of sterile dosage forms including solutions suspensions ophthalmics and freeze dried products This book is based on the courses he has delivered for over three decades to over 3000 participants and is intended to remain relevant for the indefinite future even as new technologies and new applications of old technologies become common This is an ideal reference book for those working directly and indirectly with sterile dosage forms be it product development formulation package process analytical manufacturing quality control quality assurance regulatory purchasing or project management This book is also intended as an educational resource for the pharmaceutical and biopharmaceutical industry and pharmacy schools providing basic knowledge and principles in four main areas of parenteral science and technology Product development including formulation packaging and process development Manufacturing including basic teaching on all the primary unit operations involved in preparation of sterile products and the underlying importance of contamination control Quality and regulatory including the application of good manufacturing practice regulations aseptic processing guidelines and unique quality control testing methods for the sterile dosage form Clinical aspects including administration potential hazards and biopharmaceutics of sterile products in a clinical setting

***Herbal Bioactives and Food Fortification*** D. Suresh Kumar, 2015-09-25 Recent major shifts in global health care management policy have been instrumental in renewing interest in herbal medicine However literature on the development of products from herbs is often scattered and narrow in scope Herbal Bioactives and Food Fortification Extraction and Formulation provides information on all aspects of the extraction o

***Pulmonary Drug Delivery*** Ali Nokhodchi, Gary P. Martin, 2015-05-18 Drug therapy via inhalation route is at the cutting edge of modern drug delivery research There has been significant progress on the

understanding of drug therapy via inhalation products However there are still problems associated with their formulation design including the interaction between the active pharmaceutical ingredients APIs excipients and devices This book seeks to cover some of the most pertinent issues and challenges of such formulation design associated with industrial production and desirable clinical outcome The chapter topics have been selected with a view to integrating the factors that require consideration in the selection and design of device and formulation components which impact upon patient usability and clinical effectiveness The challenges involved with the delivery of macromolecules by inhalation to both adult and pediatric patients are also covered Written by leading international experts from both academia and industry the book will help readers formulation design scientists researchers and post graduate and specialized undergraduate students develop a deep understanding of key aspects of inhalation formulations as well as detail ongoing challenges and advances associated with their development

**Biocompatibility and Performance of Medical Devices** Jean-Pierre Boutrand,2019-11-21

Biocompatibility and Performance of Medical Devices Second Edition provides an understanding of the biocompatibility and performance tests for ensuring that biomaterials and medical devices are safe and will perform as expected in the biological environment Sections cover key concepts and challenges faced in relation to biocompatibility in medical devices discuss the evaluation and characterization of biocompatibility in medical devices describe preclinical performance studies for bone dental and soft tissue implants and provide information on the regulation of medical devices in the European Union Japan and China The book concludes with a review of histopathology principles for biocompatibility and performance studies Presents diverse insights from experts in government industry and academia Delivers a comprehensive overview of testing and interpreting medical device performance Expanded to include new information including sections on managing extractables accelerating and simplifying medical device development through screening and alternative biocompatibility methods and quality strategies which fasten device access to market

**Handbook of Humanitarian Health Care**

**Logistics** George Mc Guire,2015-10-31

**Martin's Physical Pharmacy and Pharmaceutical Sciences** Patrick J.

Sinko,2023-02-08 Consistently revised and updated for more than 60 years to reflect the most current research and practice Martin's Physical Pharmacy and Pharmaceutical Sciences 8th Edition is the original and most comprehensive text available on the physical chemical and biological principles that underlie pharmacology and the pharmaceutical sciences An ideal resource for PharmD and pharmacy students worldwide teachers researchers or industrial pharmaceutical scientists this 8th Edition has been thoroughly revised enhanced and reorganized to provide readers with a clear consistent learning experience that puts essential principles and concepts in a practical approachable context Updated content reflects the latest developments and perspectives across the full spectrum of physical pharmacy and a new full color design makes it easier than ever to discover distinguish and understand information providing users the most robust support available for applying the elements of biology physics and chemistry in work or study

**Bayesian Methods in Pharmaceutical Research**



Emmanuel Lesaffre, Gianluca Baio, Bruno Boulanger, 2020-04-15 Since the early 2000s there has been increasing interest within the pharmaceutical industry in the application of Bayesian methods at various stages of the research development manufacturing and health economic evaluation of new health care interventions In 2010 the first Applied Bayesian Biostatistics conference was held with the primary objective to stimulate the practical implementation of Bayesian statistics and to promote the added value for accelerating the discovery and the delivery of new cures to patients This book is a synthesis of the conferences and debates providing an overview of Bayesian methods applied to nearly all stages of research and development from early discovery to portfolio management It highlights the value associated with sharing a vision with the regulatory authorities academia and pharmaceutical industry with a view to setting up a common strategy for the appropriate use of Bayesian statistics for the benefit of patients The book covers Theory methods applications and computing Bayesian biostatistics for clinical innovative designs Adding value with Real World Evidence Opportunities for rare orphan diseases and pediatric development Applied Bayesian biostatistics in manufacturing Decision making and Portfolio management Regulatory perspective and public health policies Statisticians and data scientists involved in the research development and approval of new cures will be inspired by the possible applications of Bayesian methods covered in the book The methods applications and computational guidance will enable the reader to apply Bayesian methods in their own pharmaceutical research

*Aromatic and Medicinal Plants* Hany El-Shemy, 2017-03-15 This book covers interesting research topics and the use of natural resources for medical treatments in some severe diseases The most important message is to have native foods which contain high amount of active compounds that can be used as a medicinal plant Most pharmaceutical drugs were discovered from plants and still ongoing research will have to predict such new active compounds as anti diseases I do believe this book will add significant knowledge to medical societies as well as can be used for postgraduate students

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