



# stability studies in pharmaceutical development

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## Agenda



### Overview of stability studies during drug product Lifecycle

- Stability considerations during early development
- Review ICH and WHO stability guidelines
- Stability requirements to support registration
- Post approval stability

# Stability Studies In Pharmaceutical Development Catalent

**Kim Huynh-Ba**



## **Stability Studies In Pharmaceutical Development Catalent:**

**Early Drug Development, 2 Volume Set** Fabrizio Giordanetto,2018-12-10 This one stop reference systematically covers key aspects in early drug development that are directly relevant to the discovery phase and are required for first in human studies Its broad scope brings together critical knowledge from many disciplines ranging from process technology to pharmacology to intellectual property issues After introducing the overall early development workflow the critical steps of early drug development are described in a sequential and enabling order the availability of the drug substance and that of the drug product the prediction of pharmacokinetics and dynamics as well as that of drug safety The final section focuses on intellectual property aspects during early clinical development The emphasis throughout is on recent case studies to exemplify salient points resulting in an abundance of practice oriented information that is usually not available from other sources Aimed at medicinal chemists in industry as well as academia this invaluable reference enables readers to understand and navigate the challenges in developing clinical candidate molecules that can be successfully used in phase one clinical trials

**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

**Protein Formulation and Delivery** Eugene J. McNally,Eugene McNally,Jayne E. Hastedt,2007-10-26 This title is intended to assist pharmaceutical scientists in the development of stable protein formulations during the early stages of the product development process providing a comprehensive review of mechanisms and causes of protein instability in formulation development coverage of accelerated stability testing methods and relevant analytical

**Integrated Pharmaceutics** Antoine Al-Achi,Mali Ram Gupta,William Craig Stagner,2022-09-07 This work is an examination of all aspects of the science in developing effective dosage form for drug delivery Pharmaceutics refers to the subfield of pharmaceutical sciences that develops drug delivery products or devices to optimize the drug s performance once administered This multidisciplinary field draws on physical chemistry organic chemistry and biophysics to generate and refine these crucial elements of medical care Moreover incorporating such disparate dimensions of drug product design as material properties and legal regulation bridges the gap between effective chemicals and viable medical treatments Integrated Pharmaceutics provides a comprehensive introduction to the creation and manufacture of effective dosage forms for drug delivery It presents its subject following the principles of physical pharmacy product design and drug regulations This tripartite structure allows readers to move from theory to practice beginning from a firm foundation of physical pharmacy principles including drug solubility and stability estimation rheology and interfacial properties From there it proceeds to discussions of drug product design and of harmonizing pharmaceutical design with the regulatory regimens and technological standards of the United States European Union and Japan Readers of the second edition of Integrated Pharmaceutics will also find A glossary

defining key terms extensive informative appendices and a list of references leading to the primary literature in the field for each chapter Earlier chapters are expanded with additional new chapters including one entitled Biotechnology Products Supplementary instructor guide with questions and solutions available online for registered professors Updated regulatory guidelines including quality by design design space analysis process analytical technology polymorphism characterization blend sample uniformity and stability protocols Integrated Pharmaceuticals is a useful textbook for graduate students in pharmaceutical sciences drug formulation and design and biomedical engineering In addition professionals in the pharmaceutical industry including regulatory bodies will find it a helpful reference guide 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 **Liposomes in Drug Delivery** Sophia G. Antimisiaris,2024-04-10 Liposomes in Drug Delivery What Where How and When to Deliver is a concise well structured reference covering all the important issues related to the potential of this technology Organized to provide practical information to researchers from any discipline with a particular therapeutic or bio active substance to deliver this book helps readers understand if liposomes can be of benefit for their particular need what is the best type of liposome to use according to what needs to be delivered where when to deliver it and how to design prepare characterize investigate optimize liposome properties for a particular application The book is structured in Four parts The first covers in a concise but in depth way what liposomes are which are the liposome types advantages disadvantages and what is their stability characterization methods in vitro stability and in vivo fate after different administration methods routes The second part focuses on the different mechanisms for liposomal drug delivery Methodologies technologies for manipulation of liposome structure properties in order to design liposomes for particular delivery applications Specific roadmaps for liposome design are discussed including components to incorporate in liposomes

for specific types of encapsulated molecules or specific routes of administration The third part covers liposome applications for drug delivery It focuses on specific delivery considerations for particular diseases Finally the fourth part covers methods of liposome fabrication Focuses on key information What Where How and When to deliver needed for drug delivery researchers Covers all aspects of liposomes in drug delivery in one single volume Guides researchers through the decision process on whether and what liposomes are most applicable to their particular interest

**Nanotechnology and Antivirus Nanomaterials for Combating COVID-19** Jen-Tsung Chen, 2025-12-19 Nanotechnology and Antivirus Nanomaterials for Combating COVID 19 Strategies against SARS CoV 2 Variants in the Post pandemic Era explores the state of the art and advancements in nanotechnology to fight SARS CoV 2 and its variants Providing a comprehensive overview the chapters cover the molecular mechanisms of viral infection and advanced tools for diagnosis prevention treatments drug development and vaccine creation offering valuable insights into managing COVID 19 The book also includes discussions on potential challenges and future research directions This book is a valuable resource for researchers scientists and professionals seeking a deeper understanding of nanotechnology s applications for preventing diagnosing and managing COVID 19 Highlights cutting edge tools and recent applications of nanotechnology in the fight against SARS CoV 2 Outlines the latest accomplishments in COVID 19 management through nanomaterial based strategies Presents up to date insights into the role of nanotechnology in the development of COVID 19 vaccines

*Parenteral Medications, Fourth Edition* Sandeep Nema, John D. Ludwig, 2019-07-19 Parenteral Medications is an authoritative comprehensive reference work on the formulation and manufacturing of parenteral dosage forms effectively balancing theoretical considerations with practical aspects of their development Previously published as a three volume set all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration Key Features Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation processing manufacturing parenteral technology including advanced delivery and cell therapies The book is divided into seven sections Section 1 Parenteral Drug Administration and Delivery Devices Section 2 Formulation Design and Development Section 3 Specialized Drug Delivery Systems Section 4 Primary Packaging and Container Closure Integrity Section 5 Facility Design and Environmental Control Section 6 Sterilization and Pharmaceutical Processing Section 7 Quality Testing and Regulatory Requirements

*Drug Delivery* Anya Hillery, Kinam Park, 2016-09-15 This book provides a comprehensive introduction to advanced drug delivery and targeting covering their principles current applications and

potential future developments This edition has been updated to reflect significant trends and cutting edge advances that have occurred since the first edition was published All the original chapters have been retained but the material therein has been updated Eight new chapters have been added that deal with entirely new technologies and approaches Features Offers a comprehensive introduction to the fundamental concepts and underlying scientific principles of drug delivery and targeting Presents an in depth analysis of the opportunities and obstacles afforded by the application of nanotechnologies for drug delivery and targeting Includes a revised and expanded section on the major epithelial routes of drug delivery currently under investigation Describes the most recent emerging and innovative technologies of drug delivery Provides real life examples of the clinical translation of drug delivery technologies through the use of case studies Discusses the pertinent regulatory hurdles and safety issues of drug delivery and targeting systems crucial considerations in order to achieve licensing approval for these new technologies

*Spray Drying of Vaccines* Cordin Arpagaus,2023-04-03 This book addresses the stabilization of vaccine powders by spray drying and provides an overview of the current state of the art on a laboratory and industrial scale The book aims to familiarize readers with the advances in vaccine spray drying technology to understand its application potential better In particular the book addresses the design of aseptic spray dryers parameters affecting the spray drying process sterile powder processing cleaning procedures and powder filling In addition different drying technologies for the production of dry powder vaccines are compared to discuss the unique capabilities of spray drying as a particle technology for vaccines Special attention is given to research studies on spray dried vaccines published over the past 30 years with key findings from laboratory research to clinical trials Potential applications of spray dried vaccines and routes of administration are presented in detail Finally an outlook is given on how close the aseptic spray drying of vaccines is to the market and the challenges that need to be overcome to be commercially successful The book s target audience is academics researchers vaccine developers industry experts students and possibly funders including government agencies who are active in the field In addition the book is a reference source for those involved in the vaccine formulation and biopharmaceutical processing industry

Methods for Stability Testing of Pharmaceuticals Sanjay Bajaj,Saranjit Singh,2019-06-08 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

**Pharmaceutical Stability & Stability Testing: Theoretical and Practical Aspects** Prof. Abdrhman Mahmoud

Gamil, 2025-08-16 Being foreword by Professor Abubakr O Nur University of Khartoum this book combines the theoretical background of dosage form degradation and stability problems together with practical procedures to perform various types of stability studies It describes the probable physical changes the chemical kinetics of degradation reactions that may take place and the microbiological spoilage It considers the influence of different factors on the stability of pharmaceuticals and their impact on the shelf life with emphasis on the effect of temperature taking in account the concept of the mean kinetic temperature and its calculation The international regulatory guidelines together with the dosage form requirements and specifications and how to estimate or predict the shelf life with practical examples This book is a valuable guide to students where they can find model question and answers researchers and professionals of industrial pharmacy

**Polymorphism in the Pharmaceutical Industry** Rolf Hilfiker, Markus von Raumer, 2019-01-04 Polymorphism in the Pharmaceutical Industry Solid Form and Drug Development highlights the relevance of polymorphism in modern pharmaceutical chemistry with a focus on quality by design QbD concepts It covers all important issues by way of case studies ranging from properties and crystallization via thermodynamics analytics and theoretical modelling right up to patent issues As such the book underscores the importance of solid state chemistry within chemical and pharmaceutical development It emphasizes why solid state issues are important the approaches needed to avoid problems and the opportunities offered by solid state properties The authors include true polymorphs as well as solvates and hydrates while providing information on physicochemical properties crystallization thermodynamics quantum mechanical modelling and up scaling Important analytical tools to characterize solid state forms and to quantify mixtures are summarized and case studies on solid state development processes in industry are also provided Written by acknowledged experts in the field this is a high quality reference for researchers project managers and quality assurance managers in pharmaceutical agrochemical and fine chemical companies as well as for academics and newcomers to organic solid state chemistry

**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

**International Stability Testing** David J. Mazzo,2020-08-26 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

*Photostability of Drugs and Drug Formulations, Second Edition* Hanne Hjorth Tonnesen,2004-06-29 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

**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 **Innovative Dosage Forms** Yogeshwar Bachhav,2019-12-04 Teaches future and current drug developers the latest innovations in drug formulation design and optimization This highly accessible practice oriented book examines current approaches in the development of drug formulations for preclinical and clinical studies including the use of functional excipients to enhance solubility and stability It covers oral intravenous topical and parenteral administration routes The book also discusses safety aspects of drugs and excipients as well as regulatory issues relevant to formulation **Innovative Dosage Forms Design and Development at Early Stage** starts with a look at the impact of the polymorphic form of drugs on the preformulation and formulation development It then offers readers reliable strategies for the formulation development of poorly soluble drugs The book also studies the role of reactive impurities from the excipients on the formulation shelf life preclinical formulation assessment of new chemical entities and regulatory aspects for formulation design Other chapters cover innovative formulations for special indications including oncology injectables delayed release and depot formulations accessing pharmacokinetics of various dosage forms physical characterization techniques to assess amorphous nature novel formulations for protein oral dosage and more Provides information that is essential for the drug development effort Presents the latest advances in the field and describes in detail innovative formulations such as nanosuspensions micelles and cocrystals Describes current approaches in early pre formulation to achieve the best in vivo results Addresses regulatory and safety aspects which are key considerations for pharmaceutical companies Includes case studies from recent drug development programs to illustrate the practical challenges of preformulation design **Innovative Dosage Forms Design and Development at Early Stage** provides valuable benefits to interdisciplinary drug discovery teams working in industry and academia and will appeal to medicinal chemists pharmaceutical chemists and pharmacologists **Solid State Development and Processing of Pharmaceutical Molecules** Michael Gruss,2021-11-16 Solid State Development and Processing of Pharmaceutical Molecules A guide to the latest industry principles for optimizing the production of solid state active pharmaceutical ingredients Solid State Development and Processing of Pharmaceutical Molecules is an authoritative guide that covers the entire pharmaceutical value chain The authors noted experts on the topic examine the importance of the solid state form of chemical and biological drugs and review the development production quality control formulation and stability of medicines The book explores the most recent trends in the digitization and automation of the pharmaceutical production processes that reflect the need for consistent high quality It also includes information on relevant regulatory and intellectual property considerations This resource is aimed at professionals in the pharmaceutical industry and offers an in depth examination of the commercially relevant issues facing developers producers and distributors of drug substances This important book Provides a guide for the

effective development of solid drug forms Compares different characterization methods for solid state APIs Offers a resource for understanding efficient production methods for solid state forms of chemical and biological drugs Includes information on automation process control and machine learning as an integral part of the development and production workflows Covers in detail the regulatory and quality control aspects of drug development Written for medicinal chemists pharmaceutical industry professionals pharma engineers solid state chemists chemical engineers Solid State Development and Processing of Pharmaceutical Molecules reviews information on the solid state of active pharmaceutical ingredients for their efficient development and production

**Drug Stability for Pharmaceutical Scientists** Thorsteinn Loftsson, 2014-01-25 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

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