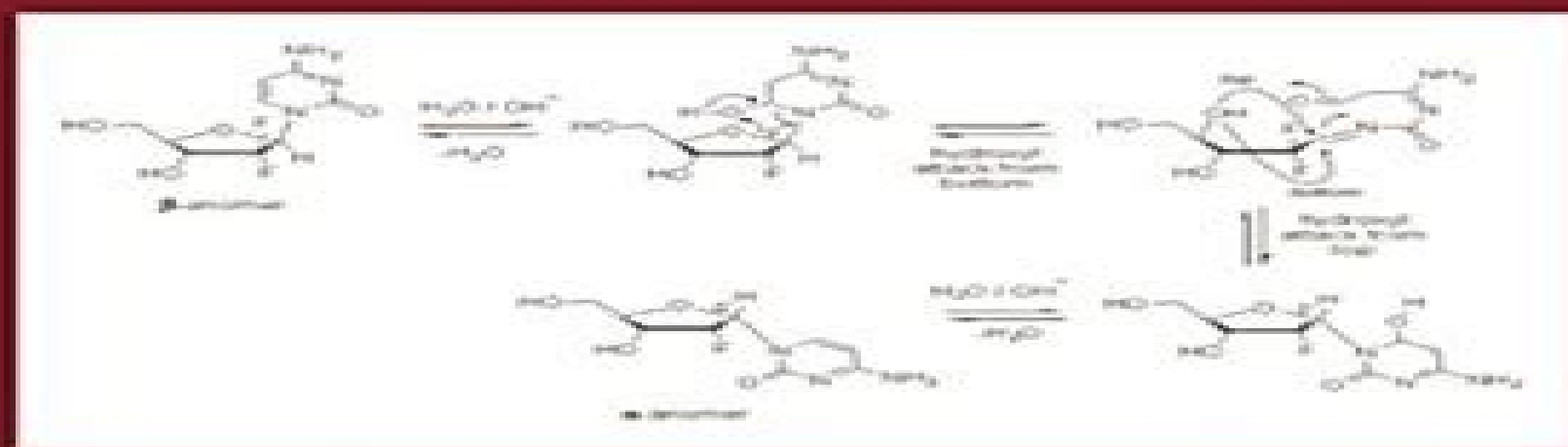


Pharmaceutical Stress Testing

Predicting Drug Degradation



edited by
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Pharmaceutical Stress Testing

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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

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Pharmaceutical Industry Practices on Genotoxic Impurities Heewon Lee, 2014-08-29 A great deal of confusion and uncertainty over genotoxic impurity identification assessment and control exists in the pharmaceutical industry today *Pharmaceutical Industry Practices on Genotoxic Impurities* strives to facilitate scientific and

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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 **Handbook of Pharmaceutical Analysis by HPLC** Satinder

Ahuja, Michael Dong, 2005-02-09 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 current trends in HPLC ancillary techniques sample preparations and data handling *HPLC for Pharmaceutical Scientists* Yuri V. Kazakevich, Rosario LoBrutto, 2006-12-13 *HPLC for Pharmaceutical Scientists* is an excellent book for both novice and experienced pharmaceutical chemists who regularly use HPLC as an analytical tool to solve challenging problems in the pharmaceutical industry It provides a unified approach to HPLC with an equal and balanced treatment of the theory

and practice of HPLC in the pharmaceutical industry In depth discussion of retention processes modern HPLC separation theory properties of stationary phases and columns are well blended with the practical aspects of fast and effective method development and method validation Practical and pragmatic approaches and actual examples of effective development of selective and rugged HPLC methods from a physico chemical point of view are provided This book elucidates the role of HPLC throughout the entire drug development process from drug candidate inception to marketed drug product and gives detailed specifics of HPLC application in each stage of drug development The latest advancements and trends in hyphenated and specialized HPLC techniques LC MS LC NMR Preparative HPLC High temperature HPLC high pressure liquid chromatography are also discussed

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

Mutagenic Impurities Andrew Teasdale, 2022-02-01 Learn to implement effective control measures for mutagenic impurities in pharmaceutical development In *Mutagenic Impurities Strategies for Identification and Control* distinguished chemist Andrew Teasdale delivers a thorough examination of mutagenic impurities and their impact on the pharmaceutical industry The book incorporates the adoption of the ICH M7 guideline and focuses on mutagenic impurities from both a toxicological and analytical perspective The editor has created a primary reference for any professional or student studying or working with mutagenic impurities and offers readers a definitive narrative of applicable guidelines and practical tested solutions It demonstrates the development of effective control measures including chapters on the purge tool for risk assessment The book incorporates a discussion of N Nitrosamines which was arguably the largest mutagenic impurity issue ever faced by the pharmaceutical industry resulting in the recall of Zantac and similar drugs resulting from N Nitrosamine contamination Readers will also benefit from the inclusion of A thorough introduction to the development of regulatory guidelines for mutagenic and genotoxic impurities including a historical perspective on the development of the EMEA guidelines and the ICH M7 guideline An exploration of in silico assessment of mutagenicity including use of structure activity relationship evaluation as a tool in the evaluation of the genotoxic potential of impurities A discussion of a toxicological perspective on mutagenic impurities including the assessment of mutagenicity and examining the mutagenic and carcinogenic potential of common synthetic reagents Perfect

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problems related to pharmaceutical research **Quality Control of Herbal Medicines and Related Areas** Yukihiro Shoyama, 2011-11-04 The authors of this thematic issue provide a comprehensive summary of most recent knowledge and references on quality control in wide fields Quality control is essential for natural products like natural medicine and related food products In this issue fifteen chapters have been included discussing in detail various aspects of quality control It will certainly prove useful not only for phytochemical researchers but also many scientists working in numerous fields Much effort has been invested by the contributors to share current information Without their efforts and input Quality Control of Herbal Medicine and Related Areas could not exist *Specification of Drug Substances and Products* Christopher M. Riley, Thomas W. Rosanske, George L. Reid, 2020-07-23 *Specification of Drug Substances and Products Development and Validation of Analytical Methods* Second Edition presents a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products with an emphasis on phase appropriate development validation of analytical methods and their application in practice This thoroughly revised second edition covers topics not covered or not substantially covered in the first edition including method development and validation in the clinical phase method transfer process analytical technology analytical life cycle management special challenges with generic drugs genotoxic impurities topical products nasal sprays and inhalation products and biotechnology products The book's authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines and or subject matter experts in the industry academia and in government laboratories Presents a critical assessment of the application of ICH guidelines on method validation and specification setting Written by subject matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis control and specification of new drug substances and products Covers the latest statistical approaches including analytical quality by design in the development of specifications method validation and shelf life prediction

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