

Chemical stability

- Chemical stability implies:

The lack of any decomposition in the chemical moiety that is incorporated in the formulation as the drug, preservatives or any other excipients.

This decomposition may influence the physical and chemical stability of the drug

- **Factors**
- **Temperature • pH • Buffers • Ionic strength • Dielectric constant of solvent • Oxygen • Light • Polymorphism • Moisture & Humidity • Excipients**

Chemical Stability Of Pharmaceuticals

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**Alok K. Kulshreshtha, Onkar N.
Singh, G. Michael Wall**



Chemical Stability Of Pharmaceuticals Chemical Stability Of Pharmaceuticals:

Chemical Stability of Pharmaceuticals Kenneth A. Connors, Gordon L. Amidon, Valentino J. Stella, 1986-10-13 Provides a sound theoretical basis for understanding chemical kinetics and its uses in studying drug stability Treats the calculations approximations and estimates that are useful to the pharmacist in professional practice and presents a collection of selected drug stability data from the pharmaceutical literature This Handbook makes accessible to the pharmacist much of the information necessary to make pharmaceutical decisions about drug stability Changes in this edition include thorough revision of the chapter on oxidation addition of a new chapter on solid state stability and a tripling of the number of stability monographs All monographs figures have been redrawn most of them from published data and all sources are cited

Factors Affecting Chemical Stability of Pharmaceuticals Jung-Chung Lee, 1984 Stability of Drugs and Dosage Forms Sumie Yoshioka, Valentino J. Stella, 2000-12-31 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 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 Developing Solid Oral Dosage Forms Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lirong Liu, William Porter, 2009-03-10 Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms It covers essential principles of physical pharmacy biopharmaceutics and industrial pharmacy as well as various aspects of state of the art techniques and approaches in pharmaceutical sciences and technologies along with examples and or case studies in product development The objective of this book is to offer updated or current knowledge and skills required for rational oral product design and development The specific goals are to provide readers with Basics of modern theories of physical pharmacy biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation formulation process design characterization and scale up in pharmaceutical sciences and technologies New developments challenges trends

opportunities intellectual property issues and regulations in solid product development The first book ever that provides comprehensive and in depth coverage of what is required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market including the most updated science and technologies practice applications regulation intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well established authors co authors of diverse background knowledge skills and experience from industry academia and regulatory agencies 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 Annual Reports in Medicinal Chemistry, 2008-12-17 Annual Reports in Medicinal Chemistry provides timely and critical reviews of important topics in medicinal chemistry together with an emphasis on emerging topics in the biological sciences which are expected to provide the basis for entirely new future therapies Covers findings related to cardiovascular inflammation and pulmonary diseases Examines issues in oncology from mTor inhibitors to drug targets Incorporates up to date information on drug design and discovery including delivery to market **Pharmaceutical Calculations** Howard C. Ansel, Shelly J. Prince, 2004 This handbook is intended to be used as a tool that can be quickly accessed and employed in the in the student setting as a lab reference and in the pharmacy practice Designed as a concise reference and resource it will provide easily accessible definitions pharmacy applications insight on working with tricky calculations and realistic function example calculation With its convenient size and easy to navigate outline structure this handbook should provide great value to both the student and pharmacist Pharmaceutical Suspensions Alok K. Kulshreshtha, Onkar N. Singh, G. Michael Wall, 2009-11-05 The suspension dosage form has long been used for poorly soluble active ingredients for various therapeutic indications Development of stable suspensions over the shelf life of the drug product continues to be a challenge on many fronts A good understanding of the fundamentals of disperse systems is essential in the development of a suitable pharmaceutical

suspension The development of a suspension dosage form follows a very complicated path The selection of the proper excipients surfactants viscosity imparting agents etc is important The particle size distribution in the finished drug product dosage form is a critical parameter that significantly impacts the bioavailability and pharmacokinetics of the product Appropriate analytical methodologies and instruments chromatographs viscometers particle size analyzers etc must be utilized to properly characterize the suspension formulation The development process continues with a successful scale up of the manufacturing process Regulatory agencies around the world require clinical trials to establish the safety and efficacy of the drug product All of this development work should culminate into a regulatory filing in accordance with the regulatory guidelines Pharmaceutical Suspensions From Formulation Development to Manufacturing in its organization follows the development approach used widely in the pharmaceutical industry The primary focus of this book is on the classical dispersion system poorly soluble active pharmaceutical ingredients suspended in a suitable vehicle Handbook of Pharmaceutical Manufacturing Formulations Sarfaraz K. Niazi, 2004-04-27 The third volume in the six volume Handbook of Pharmaceutical Manufacturing Formulations this book covers liquid drugs which include formulations of non sterile drugs administered by any route in the form of solutions monomeric and multimeric suspensions powder and liquid drops extracts elixirs tinctures paints sprays colloids emulsions

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