# STABILIZATION AND STABILITY TESTING

PRESENTED BY SHARON VUAYANAND

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**M** Carnoy

Stability Testing in the EC, Japan and the USA Wolfgang Grimm, Kurt Krummen, 1993 **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 quide 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 Pharmaceutical Preformulation and Formulation Mark Gibson, 2016-04-19 Pharmaceutical Preformulation and Formulation A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process as well as the shift from developing small molecules to the growth of biopharmaceuticals The book meets the ne Oral Controlled Release Formulation Design and Drug Delivery Hong Wen, Kinam Park, 2011-01-14 This book describes the theories applications and challenges for different oral controlled release formulations This book differs from most in its focus on oral controlled release formulation design and process development It also covers the related areas like preformulation biopharmaceutics in vitro in vivo correlations IVIVC quality by design Generic Drug Product Development Leon Shargel, Isadore Kanfer, 2013-10-24 In this era of QbD and regulatory issues increased pharmaceutical industry competition success for generic drug companies is dependent on their ability to manufacture therapeutic equivalent drug products in an economical and timely manner while also being cognizant of patent infringement and other legal and regulatory concerns Generic Drug Product Development Solid Oral Dosage Forms Second Edition presents in depth discussions from more than 30 noted specialists describing the development of generic drug products from the raw materials to the development of a therapeutic equivalent drug product to regulatory approval Major topics discussed include Active pharmaceutical ingredients Experimental formulation development including a new section on Quality by Design ObD Scale up Commercial product formulation Quality control and bioequivalence Drug product performance ANDA regulatory process Post approval changes Post marketing surveillance Legislative and patent challenges This second edition also contains a new chapter on the relationship between the FDA and the United States Pharmacopeia and in Chapter 4 using specific examples the application of Quality by Design QbD during formulation development is examined The book is a thorough guide to the development of solid oral generic dosage formulations This textbook is ideal for the pharmaceutical industry graduate programs in pharmaceutical sciences and health professionals working in the area of generic drug development 

<u>Handbook of Preformulation</u> Sarfaraz K. Niazi,2006-09-18 Preformulation studies are the physical chemical and biological studies needed to characterize a drug substance for enabling the proper design of a drug product whereas the effectiveness of a drug product is determined during the formulation studies phase Though the two disciplines overlap in

kaigiroku mokuroku Kokuritsu Kokkai Toshokan (Japan),1997 Statistical Design and Analysis in Pharmaceutical
Science Shein-Chung Chow, Jen-pei Liu,2018-10-03 Offers a comprehensive unified presentation of statistical designs and methods of analysis for all stages of pharmaceutical development emphasizing biopharmaceutical applications and demonstrating statistical techniques with real world examples German Americana Christoph Strupp, Kai
Dreisbach,2007 A comprehensive bibliography of books and scholarship on the United States produced in German speaking countries from 1956 2005 Index of Conference Proceedings British Library. Document Supply Centre, 1993

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