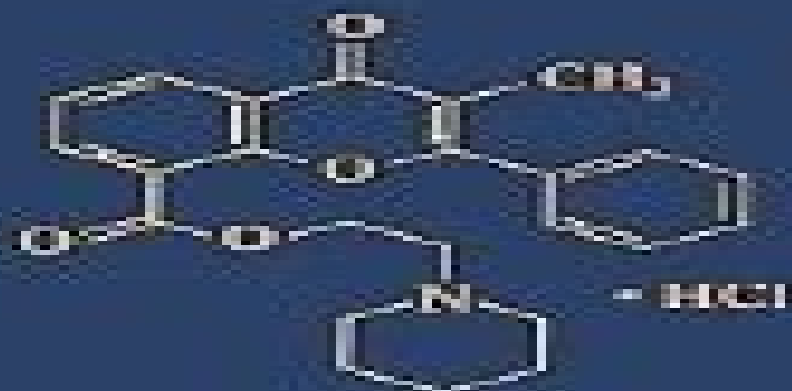


Analytical Profiles of Drug Substances and Excipients

VOLUME 28



Edited by
Harry G. Brittain

Analytical Pro Of Drug Substances And Excipients

Harry G. Brittain



Analytical Pro Of Drug Substances And Excipients:

Analytical Profiles of Drug Substances and Excipients Harry G. Brittain, 2002-12-19 Although the official compendia define a drug substance as to identity purity strength and quality they normally do not provide other physical or chemical data nor do they list methods of synthesis or pathways of physical or biological degradation and metabolism Such information is scattered throughout the scientific literature and the files of pharmaceutical laboratories *Analytical Profiles of Drug Substances and Excipients* brings the latest information together in one source Represents a very important contribution to the practice of pharmaceutical analysis Presents an excellent overview of physical chemical and biomedical properties of some regularly prescribed drugs Each volume in the series contains a cumulative index *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 *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 *Modern Pharmaceutical Analytical Techniques* Mr. Rohit Manglik, 2024-07-04 EduGorilla Publication is a trusted name in the education sector committed to empowering learners with high quality study materials and resources Specializing in competitive exams and academic support EduGorilla provides comprehensive and well structured content tailored to meet the needs of students across various

streams and levels Handbook of Pharmaceutical Manufacturing Formulations Sarfaraz K. Niazi,2016-04-19 Providing methodologies that can serve as a reference point for new formulations the second volume covers uncompressed solids which include formulations of powders capsules powders ready for reconstitution and other similar products Highlights from Uncompressed Solid Products Volume Two include the fundamental issues of good manufacturing **Profiles of Drug Substances, Excipients and Related Methodology** Harry G. Brittain,2004-12-28 Whilst following in the footsteps of previous volumes by presenting comprehensive reviews of drug substances and additional materials this title also heralds a significant expansion of the scope of the series Traditional contributions will now also be augmented by publication of critical review chapters that summarize information related to the characterization of drug substances and excipients This change is required to better meet the needs of the pharmaceutical community and to allow the development of a timely vehicle for publishing review materials on this topic The scope of the Profiles series will encompass review articles and database compilations that fall within one of the following six broad categories Physical profiles of drug substances and excipients Analytical profiles of drug substances and excipients Drug metabolism and pharmacokinetic profiles of drug substances and excipients Methodology related to the characterization of drug substances and excipients Methods of chemical synthesis and Reviews of the uses and applications for individual drug substances classes of drug substances or excipients Presents comprehensive reviews covering all aspects of drug development and formulation of drugs Now encompassing critical review chapters Meets the information needs of the drug development community **Handbook of Modern Pharmaceutical Analysis** Satinder Ahuja,Stephen Scypinski,2001 This book describes the role modern pharmaceutical analysis plays in the development of new drugs Detailed information is provided as to how the quality of drug products is assured from the point of discovery until the patient uses the drug Coverage includes state of the art topics such as analytics for combinatorial chemistry and high throughput screening formulation development stability studies international regulatory aspects and documentation and future technologies that are likely to impact the field Emphasis is placed on current easy to follow methods that readers can apply in their laboratories No book has effectively replaced the very popular text Pharmaceutical Analysis that was edited in the 1960s by Tak Higuchi This book will fill that gap with an up to date treatment that is both handy and authoritative Essential Chemistry for Formulators of Semisolid and Liquid Dosages Vitthal S. Kulkarni,Charles Shaw,2015-10-15 A needed resource for pharmaceutical scientists and cosmetic chemists Essential Chemistry for Formulators of Semisolid and Liquid Dosages provides insight into the basic chemistry of mixing different phases and test methods for the stability study of nonsolid formulations The book covers foundational surface colloid chemistry which forms the necessary background for making emulsions suspensions solutions and nano drug delivery systems and the chemistry of mixing which is critical for further formulation of drug delivery systems into semisolid gels creams lotions and ointments or liquid final dosages Expanding on these foundational principles this useful guide explores stability testing methods such as

particle size rheological viscosity microscopy and chemical and closes with a valuable discussion of regulatory issues

Essential Chemistry for Formulators of Semisolid and Liquid Dosages offers scientists and students the foundation and practical guidance to make and analyze semisolid and liquid formulations Unique coverage of the underlying chemistry that makes possible stable dosages Quality content written by experienced experts from the drug development industry Valuable information for academic and industrial scientists developing topical and liquid dosage formulations for pharmaceutical as well as skin care and cosmetic products

Analysis of Cannabis ,2020-08-27 Analysis of Cannabis Volume 91 contains a wide variety of information on the analysis of cannabis and hemp including cannabinoids terpenes volatile solvents and metals Specific chapters in this new release include the Comprehensive Analytical Testing of Cannabis and Hemp Machine Learning Methods for Inferring Chemotype Profiles in Cannabis Sativa Recent Analytical Methodologies and Strategic Pharmacological Applications of Cannabinoids Analysis of Cannabinoids in Plants Marijuana Products and Biological Tissues LC based UV and MS Analysis of Cannabinoids Testing Cannabis Samples for Heavy Metal Contamination using Microwave Assisted Digestion and ICP MS Techniques Applications of GC MS Techniques for Cannabis Analysis and much more Contains diverse state of the art methodologies for the analyses of cannabinoids and terpenes in a variety of matrices Analyzes different cannabis and hemp based products Provides the expertise of leading contributors from an international board of authors

Modern Methods of Pharmaceutical Analysis, Second Edition, Volume II Roger E. Schirmer,2024-11-01 This book reviews several of the newer methods that find wide application in pharmaceutical analysis as well as several older methods of unique importance The principle of each technique is discussed with emphasis on factors that directly affect its proper application to analytical problems

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