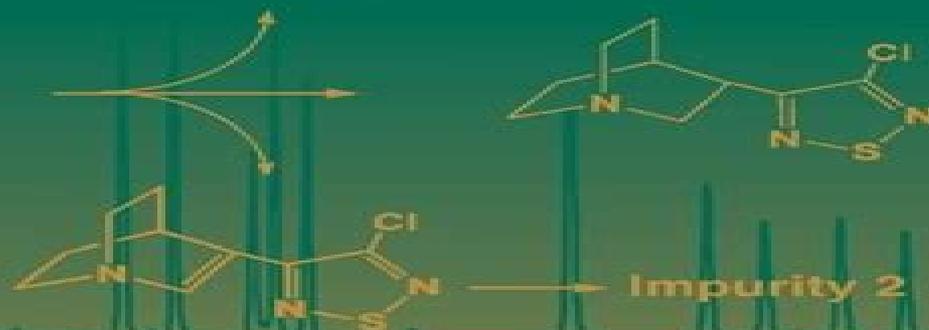


# HANDBOOK OF ISOLATION AND CHARACTERIZATION OF IMPURITIES IN PHARMACEUTICALS

Edited by  
Satinder Ahuja  
Karen Mills Alsante



VOLUME 5

Series Editor **Satinder Ahuja**



**SEPARATION SCIENCE AND TECHNOLOGY**

**Handbook Of Isolation And Characterization Of  
Impurities In Pharmaceuticals Volume 5 Separation  
Science And Technology**

**Roman Wölfel**



## **Handbook Of Isolation And Characterization Of Impurities In Pharmaceuticals Volume 5 Separation Science And Technology:**

**Handbook of Isolation and Characterization of Impurities in Pharmaceuticals** Satinder Ahuja, Karen Mills Alsante, 2003-06-26 The United States Food and Drug Administration FDA and other regulatory bodies around the world require that impurities in drug substance and drug product levels recommended by the International Conference on Harmonisation ICH be isolated and characterized Identifying process related impurities and degradation products also helps us to understand the production of impurities and assists in defining degradation mechanisms When this process is performed at an early stage there is ample time to address various aspects of drug development to prevent or control the production of impurities and degradation products well before the regulatory filing and thus assure production of a high quality drug product This book therefore has been designed to meet the need for a reference text on the complex process of isolation and characterization of process related synthesis and formulation impurities and degradation products to meet critical regulatory requirements Its objective is to provide guidance on isolating and characterizing impurities of pharmaceuticals such as drug candidates drug substances and drug products The book outlines impurity identification processes and will be a key resource document for impurity analysis isolation synthesis and characterization Provides valuable information on isolation and characterization of impurities Gives a regulatory perspective on the subject Describes various considerations involved in meeting regulatory requirements Discusses various sources of impurities and degradation products

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