Genotoxic Impurities. Strategies for Identification and Control

Description:

A one-stop reference to genotoxic impurities in pharmaceuticals

This volume examines the full range of issues the pharmaceutical industry faces when seeking to ensure control over the levels of genotoxic impurities in pharmaceuticals. It offers comprehensive practical guidance on how to both assess and control genotoxic impurities (GIs) through all phases of drug development.

Featuring contributed chapters by experts from both the quality assurance and toxicology fields, Genotoxic Impurities covers all topics from the ground up, using real-world examples and case studies to help readers meet the challenges of regulatory compliance. Other important features include:

A detailed review of current regulatory guidelines relating to GIs, including discussion of their implications and the thinking behind their development

A thorough evaluation of the threshold of toxicological concern (TTC) concept, along with an examination of the emerging evidence supporting the existence of thresholds even for DNA-reactive mutagens.

Step-by-step instructions, including both analytical and safety strategies, on how to evaluate risks posed by GIs

Discussion of the risks posed by GIs from other sources, i.e., dietary exposure and the endogenous production of genotoxins.

Specific advice on chromatographic strategy and other key analytical techniques, including the innovative use of NMR

The first comprehensive resource of its kind, Genotoxic Impurities is an indispensable reference for researchers and professionals in the pharmaceutical industry. It is also useful for regulatory professionals who need to interpret the regulatory guidelines covering GIs.

Contents:

Foreword.

Preface.

Section I: Development of GI Guidelines and the TTC Concept.


Chapter 2. Development of the Threshold of Toxicological Concern Concept (TTC) and its Relationship to Duration of Exposure (A. Brigo and L. Muller).

Section 2: Evaluation of Genotoxic Risk from a Pre-clinical Perspective.

Chapter 3. Genetic Toxicity Testing to Qualify Alerting Impurities (M. O. Donovan).


Section 3. Perspective on Risk Posed by Genotoxic Impurities.


Chapter 12. Strategic Approaches to the Chromatographic Analysis of Genotoxic Impurities (Frank David, Karine Jacq, Gerd Canhoenacker and Pat Sandra).


Chapter 15. Aspects to Consider when Devising a Strategy to Understand if Low Level API/DP Degradants have the Potential for Genotoxicity (Alan P. McKeown and Andrew Teasdale).

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