

1. Record Nr.	UNINA9910831035503321
Titolo	Mutagenic impurities : strategies for identification and control / / edited by Andrew Teasdale
Pubbl/distr/stampa	Hoboken, New Jersey : , : John Wiley & Sons, Incorporated, , [2022] ©2022
ISBN	1-119-55126-9 1-119-55125-0 1-119-55124-2
Descrizione fisica	1 online resource (547 pages)
Disciplina	576.542
Soggetti	Drugs - Testing Mutagenicity testing
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Historical perspective on the development of the EMEA Guideline and subsequent ICH M7 Guideline -- ICH M7 -assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk -- Control strategies for mutagenic impurities -- Use of structure-activity relationship (SAR) evaluation as a critical tool in the evaluation of the genotoxic potential of impurities -- Evolution of quantitative structure-activity relationships ((Q)SAR) for mutagenicity -- Toxicity testing to understand the mutagenicity of pharmaceutical impurities -- Compound- and class-specific limits for common impurities in pharmaceuticals -- Genotoxic threshold mechanisms and points of departure -- Mutagenic impurities - assessment of fate and control options -- N-nitrosamines -- Conditions potentially leading to the formation of mutagenic impurities -- Strategic approaches to the chromatographic analysis of mutagenic impurities -- Analysis of mutagenic impurities by nuclear magnetic resonance (NMR) spectroscopy -- Addressing the complex problem of degradation-derived mutagenic impurities in drug substances and products.
Sommario/riassunto	"This book examines mutagenic impurities and their impact on the

pharmaceutical industry, following the adoption of the ICH M7 guideline, while focusing on mutagenic impurities from both a toxicological and analytical perspective. The book serves as a primary reference point for anyone faced with addressing the issue of mutagenic impurities, providing readers with a definitive narrative of the guidelines and actual practical solutions to allow them to develop effective control measures"--
