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Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Analysis of Drug Impurities; Contents; Preface; List of contributors; 1 Organic impurities in drug substance: origin, control, and measurement; 1.1 Introduction; 1.2 Origin of impurities; 1.2.1 Process impurities; 1.2.2 Degradation impurities; 1.2.3 Contamination impurities; 1.2.4 Other impurities; 1.3 Control of drug substance impurities; 1.3.1 Control of residual solvents; 1.3.2 Control of synthetic impurities; 1.3.3 Control of impurities in biological and botanical products; 1.3.4 Purification processes; 1.3.5 Control of impurities from packaging; 1.3.6 Control of contamination impurities 1.3.7 Control of degradants on stability1.4 Measurement of drug substance impurities; 1.4.1 HPLC; 1.4.2 GC; 1.4.3 CE; 1.4.4 General considerations; 1.5 Conclusions; Disclaimer; References; 2 Organic impurities in drug products: origin, control and measurement; 2.1 Introduction; 2.2 Analytical methodology; 2.3 Drug-excipient compatibility experimental design; 2.4 Degradation mechanisms; 2.5 Excipients' role in drug product destabilisation; 2.6 Processing as a

source of moisture; 2.7 Hydrolysis; 2.8 Oxidation; 2.9 Photolysis; 2.10 Impact of processing on photostability
2.11 Miscellaneous reactions2.12 Container-closure systems; References; 3 Stereochemical impurities; 3.1 Introduction; 3.2 Separation techniques: direct resolution; 3.2.1 HPLC using CSPs; 3.2.2 HPLC using chiral mobile-phase additives; 3.2.3 Capillary electrophoresis using chiral selectors; 3.2.4 Supercritical fluid chromatography using chiral stationary phases; 3.2.5 Gas chromatography using chiral stationary phases; 3.3 Separation techniques: indirect resolution; 3.4 Non-separation techniques; 3.4.1 Chiroptical spectroscopy; 3.4.2 Nuclear magnetic resonance spectroscopy; 3.5 Conclusions
AcknowledgementsReferences; 4 Low-level measurement of potent toxins; 4.1 Introduction; 4.2 Classes of genotoxic impurity; 4.2.1 Alkylating agents; 4.2.2 Reactive amines; 4.2.3 Fused tricyclics; 4.2.4 Substituted purines and pyrimidines; 4.2.5 Hydroperoxides; 4.3 The analytical challenge of genetic; 4.4 Gas chromatography; 4.4.1 Sample introduction techniques; 4.4.2 Detectors; 4.5 High-performance liquid chromatography; 4.5.1 Separation modes; 4.5.2 Detection techniques; 4.6 Supercritical fluid chromatography; 4.7 Thin-layer chromatography; 4.8 Sample pre-concentration
4.8.1 Liquid-liquid extraction4.8.2 Solid-phase extraction; 4.8.3 Solid-phase microextraction; 4.8.4 Liquid-phase microextraction; 4.9 Other techniques; 4.9.1 Electrochemical measurements; 4.9.2 Derivatisation methods; 4.10 Adapting analytical methods from fields beyond pharmaceuticalsimpurities analysis; 4.10.1 Antineoplastic agents; 4.10.2 Other fields; 4.11 Validation of trace analytical methods; 4.11.1 Sensitivity; 4.11.2 Specificity; 4.11.3 Accuracy; 4.11.4 Solution stability; 4.11.5 Linearity and precision; 4.12 Conclusions; References; 5 A systematic approach to impurity identification
5.1 Introduction

Sommario/riassunto

A key component of the overall quality of a pharmaceutical is control of impurities, as their presence, even in small amounts, may affect drug safety and efficacy. The identification and quantification of impurities to acceptable standards presents a significant challenge to the analytical chemist. Analytical science is developing rapidly and provides increasing opportunity to identify the structure, and therefore the origin and safety implications of these impurities, and the challenges of their measurement drives the development of modern quantitative methods.Written for both practic