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Control of genotoxic impurities (GTIs) in APIs

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Most pharmaceutical products are manufactured a naturally occurring product. These occurring products are applying a total synthesis approach or by modifying. In both cases, a wide range of reactive reagents are used. Therefore, it is natural that low levels of such reagents or side products are present in the natural active pharmaceutical ingredient (API) or drug product as impurities. Pharmaceutical regulatory agencies such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have raised concerns regarding the presence of genotoxic impurities (GTIs) in APIs that could impact negatively on human health. Compounds categorized as GTIs include a broad range of unrelated chemicals with very different structures and from very different chemical families. Such impurities may have unwanted toxicities, including genotoxicity and carcinogenicity. The risk for patient's health caused by the presence of small molecules as impurities in APIs has become an increasing concern of pharmaceutical companies, regulatory authorities, patients, and doctors alike. To ensure compliance with the required low GTI concentrations, a significant effort during development is necessary. The quantity of genotoxic impurities in drug products is strictly controlled by regulatory authorities that have set limits to ensure patient safety.

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