



ARTICLE

A STRATEGIC APPROACH FOR NITROSAMINE SCREENING IN DRUG PRODUCTS

Abstract

As a result of concerns regarding the potential of nitrosamine impurity contamination in some medicines, regulatory agencies have requested that Marketing Authorisation Holders (MAH) conduct risk assessments to determine the potential for nitrosamine contamination. If the risk assessment indicates a potential for contamination, screening products for the presence of nitrosamine impurities becomes critical.

In this article our expert Ashleigh Wake, describes a strategy for screening nitrosamines that delivers clear and accurate results and avoids false positives, by applying both LC-MS/MS and HRMS techniques.

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