

Watch On Demand Webinar: Impurity Profiling Knowledge Accelerator

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Nitrosamine Impurities Quantification using LC-MS/MS and Challenges in Quality Control Laboratories Date: 28th April 2020 Time: 11:30 AM (Indian Standard Time)



Synopsis:

The recent nitrosamine impurity crisis has firmly put the spotlight on genotoxic impurities (GTIs). Regulatory agencies, including US FDA and European Medicines Agency (EMA), have issued guidelines on allowable limits of genotoxic impurities in pharmaceutical products. These limits are to ensure product safety, not just for the ones frequently highlighted because of nitrosamines, but for all potentially contaminated drugs and processes in a company's portfolio of active pharmaceutical ingredients (APIs).

In this knowledge accelerator, our presenter were focusing on below summarized topics

• Dr. BM Rao (Head - EM QA, ASAT & CQC, Dr. Reddy's Laboratories Limited) had discussed about current challenges in quality control laboratories, best practices and next generation solutions in the pharmaceutical ecosystem

 Dr. Anoop Kumar (Business Manager, SCIEX India) had discussed the rapid, sensitive and robust qualitative and quantitative analysis of genotoxic nitrosamines in Sartan products using SCIEX LC-MS/MS instrumentation to surpass current and future limits set by regulatory agencies
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