Syngene

Putting Science to Work

Nitrosamine impurity testing Center of Excellence

For risk assessment, development, and validation of Nitrosamine impurities in Drug Substances and Drug Products

Syngene offers a state-of-the-art facility to cater to the needs of Nitrosamine impurity testing. The facility supports testing requirements for small molecule APIs, key sourcing materials (KSM), and intermediates. Its internationally accredited Analytical labs and highly skilled scientists ensure all the data generated complies with regulatory requirements.

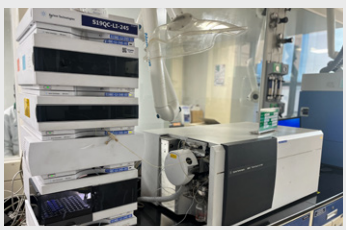
Key Features

- Diverse experience in risk assessment, method development, method validation, and testing of Nitrosamine impurities in drug products, drug substances, KSM, and intermediates
- All methods developed and validated according to USP General Chapter <1469> in line with current scientific and regulatory approaches. This ensures appropriate control over Nitrosamine impurities in APIs and drug formulations
- Availability of skilled workforce, including those with expertise in Nitrosamine impurity testing Availability of sophisticated instruments such as LC-MS/MS, GC-MS/MS, and HRMS to quantify impurities at the ppb level as per regulatory requirements
- All testing conducted in cGMP labs audited by multiple regulatory agencies

Capabilities & Highlights

- Dedicated area for Nitrosamine and Azido impurity testing
- Characterization of Nitrosamine and Azido impurities
- All methods as per Regulatory requirements
- Risk assessment report based on the root of synthesis
- Faster turnaround on method development and validation analysis



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