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NITROSAMINES

Nitrosamine impurities became a focus for the pharmaceutical industry in July 2018 after a recall was announced for Sartans due to the presence of the carcinogenic impurity, N-nitrosodimethylamine (NDMA). There has since been an increase of Nitrosamine contamination observed within other drug substances and drug product batches.

It is imperative that manufacturers understand the possible source of nitrosamine formation in their manufacturing process and implement proper controls to reduce the possibility of the contamination risk.

- **Step 1: Risk Assessment**
  - Evaluation of their medicinal products containing chemically synthesized APIs.
- **Step 2: Confirmatory Testing**
  - Use validated and sensitive methods
- **Step 3: Changes to the Marketing Authorization**
  - Introduce any required changes, such as an amendment of the manufacturing process or changes to product specifications.

The analysis of nitrosamines can be challenging. Ultra-low levels of these impurities must be quantified in diverse and complex matrices. The developed methods then need to be validated to conform to GMP requirements.

- **Eurofins** has experience with nitrosamine testing, including validating methods for sartans and ranitidine, as well as screening test methods.
- **Eurofins** has a network of laboratories with vast capacity at multiple sites globally.
- All Eurofins BPT laboratories perform this testing under GMP requirements.

Our laboratories specialize in method development and validation for highly sensitive and specific methods to help face the challenges of low detection levels, difficult matrices and identification of unknown impurities during the pharmaceutical method development process.

Eurofins BPT Toronto can assist you with testing for Nitrosamine impurities at our GMP compliant facility to alleviate the demands for compliance. Our validated analytical methods target the specific sensitivities of the following Nitrosamine impurities: NDMA, NDEA, NEIPA, NDIPA, NDBA and NMBA, which may be found in Sartans, Ranitidine, Metformin, and chemically synthesized active pharmaceutical ingredients.

Our Eurofins BPT Toronto consulting team can advise on risk analysis including product risk assessment, evaluation of the drug product composition, and evaluation of the manufacturing process.

Eurofins BioPharma Product Testing Toronto, Inc.
1111 Flint Rd., Unit 36, North York, Toronto
M3J 3C7- Ontario - Canada
1-866-610-5576
CA01_customerservice@eurofins.com
www.eurofins.ca