SAXOCON
Co-owned by Technical University of Denmark DTU

# Nitrosamine impurities

Nitrosamine compounds are highly toxic. Some are considered carcinogenic at much lower levels than the currently established ICH M7 thresholds for toxicological concern (TTC). Nitrosamine residuals can arise from several sources, including starting materials, intermediates, and degradation products. According to a European Medicinal Agency (EMA) review under Article 5(3) of Regulation (EC) No 726/2004, all marketing authorisation holders in the EU are required to evaluate, and potentially test for, the presence of nitrosamines in drug substances used in medical products. In addition to the EU requirements, the US Food and Drug Agency (FDA) also recommends conducting risk assessments and, potentially, testing final drug product batches for the presence of nitrosamine impurities.

SAXOCON provides you with everything you need to fulfil the regulatory expectations of the EMA and the FDA, including:

- Supporting the risk evaluation (step 1 in EMA/409815/2020) with an assessment of impact for supply chain information not made available to the pharma manufacturer
- Characterisation of carcinogenic potency based on literature data, structural activity relationships, and/or read-across methods
- Test strategies according to EMA and FDA requirements, including review of protocols and monitoring of studies
- Establishing health-based limits such as a compound-specific TTC

## Why choose us?

SAXOCON services for the manufacture of pharmaceutical products give you access to:

- Extensive experience with state-of-the-art safety assessment of pharmaceutical products according to international standards and regulatory guidelines
- Best-in-class experience with using computer models (QSAR) for predicting toxicological effects
- Smart, cost-effective test strategies to ensure regulatory compliance

## Delivery

SAXOCON compiles a toxicological risk assessment report necessary for fulfilling EMA and FDA requirements.

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