SAXOCON
Co-owned by Technical University of Denmark DTU

Safety evaluation of impurities

Residuals of starting materials, intermediates, and degradation products can give rise to impurities in drug substances and drug products. Establishing impurities limits is a critical aspect of pharmaceutical development to help ensure product quality and safety.

SAXOCON provides you with everything you need to establish and document Permitted Daily Exposure (PDE) in accordance with regulatory requirements, including:

- ICH M7 classification of mutagenic impurities using (Q)SAR and read-across methods
- The categorisation of organic impurities according to ICH Q3A, Q3B, and Q3C
- Establishing a PDE based on the methods and principles in ICH Q3C
- Controlling elemental impurities in accordance with ICH Q3D, European, and US Pharmacopoeias

Why choose us?

SAXOCON services for pharmaceutical development 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 computational toxicology, including (Q)SAR modelling and read-across methods
- Smart, cost-effective test strategies that bring your products to market in a timely manner

Delivery

SAXOCON compiles all necessary documentation for your New Drug Application file to fulfil ICH Q3A, Q3B, Q3C, Q3D, and M7 requirements.

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