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 limits for impurities is a crucial aspect in pharmaceutical development to ensure the quality and safety of the product. 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
- Categorisation and classification of organic impurities according to ICH Q3A, Q3B, and Q3C
- Establishing PDE based on the methods and principles in ICH Q3C
- Establishing PDE and control of 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 in state-of-the-art safety assessment of pharmaceutical products according to international standards and regulatory guidelines
- Best in class experience in using computer models for prediction of toxicological effects, i.e. (Q)SAR models
- 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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