SAXOCON
Co-owned by Technical University of Denmark DTU

Technically Unavoidable Particles (TUP)

Technically Unavoidable Particles (TUP) are ubiquitous in the raw materials used in pharmaceutical production facilities. Good Manufacturing Practice (GMP) and proper risk management of product quality require identifying the impact of TUPs on product safety. SAXOCON follows the framework defined in ICH Q9 and the IPEC Technically Unavoidable Particle Profile (TUPP) Guide released in 2024.

A predefined service level agreement (SLA) with SAXOCON provides a fast-track process with everything you need to analyse and evaluate the impact of TUPs, including:

- The optimal stacking of activities that ensures a 2–3-week lead time from discovery to a completed toxicological risk assessment
- SAXOCON's expertise and laboratory capabilities to quickly and accurately identify the root cause of any findings
- Expert advice in sampling and risk mitigation
- A toxicological risk assessment

Why choose us?

SAXOCON's services for the manufacture of pharmaceutical products provide access to:

- Our extensive experience with state-of-the-art safety assessments of pharmaceutical products according to international standards and regulatory guidelines
- A multidisciplinary team of highly skilled scientists and experts
- Extensive expertise in measuring and characterising materials, including nanomaterials

Delivery

SAXOCON compiles all necessary results and documents them in a toxicological risk statement.

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