SAXOCON
Co-owned by Technical University of Denmark DTU

Assure Safe Primary Packaging

Containers and other primary packaging systems for drug products must be designed, tested, and documented to not alter the safety or quality of the finished product.

SAXOCON provides you with everything you need to establish and document compliance with regulatory requirements for primary packaging, including:

- The selection and characterisation of construction materials
- A risk analysis according to ICH, EMA, and FDA guidelines
- Extractable and leachable test strategies according to European and US Pharmacopoeia
- A review of protocols and the monitoring of extractable and leachable studies
- A toxicological risk assessment of results

Why choose us?

SAXOCON services for pharmaceutical development give you access to:

- Extensive experience with state-of-the-art safety assessments of pharmaceutical products in accordance with international standards and regulatory guidelines
- A multidisciplinary team of highly skilled toxicologists, material scientists, and supply chain professionals
- Safety evaluations based on proprietary information obtained from our worldwide network of materials suppliers
- Smart, cost-effective test strategies that bring your products to market in a timely manner

Delivery

SAXOCON compiles all necessary documentation to ensure your New Drug Application file meets ICH Q8, FDA, and EMA requirements.

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