

Test for particulate contamination

The FDA has asked intravenous and infusion medical device manufacturers to provide data regarding particulates to evaluate the potential effects the use of their device may have on patients. When a medical device is deployed or exposed to a patient, particles may be released and lodge in their vascular capillary system.

Whether these particles are harmful to patients is determined by their size, shape, composition, and where and to what degree they cause an occlusion. The source of these particulates may be the manufacturing process, the environment, the product packaging or the device itself.

SAXOCON has the tools and laboratory set up to provide you with comprehensive data to document whether your device is within acceptable particulate limits, including:

- Class N2 clean workspaces
- Filtration units
- Microscopes for analysing filters
- Inspection of device surface integrity using SEM.

Why choose us?

SAXOCON analytical services for test for particulate contamination give you access to:

- Extensive expertise in the measurement and characterisation of materials and surfaces
- A multidisciplinary team of highly skilled scientists and experts
- We are ISO 13485-certified and work with GLP-based standards

Delivery

SAXOCON generates and compiles all physical characterisation data needed to support the biological evaluation of your product.