CORMICA®

SCAN ME

Case Study: Solving Cytotoxicity Challenges with an Absorbent Medical Device

Challenge

A medical device manufacturer approached Cormica, during their biological risk assessment phase. Their device is a novel, absorbent material intended for limited patient contact, presented a common but critical challenge: insufficient extract volume during **cytotoxicity testing** using the extraction (elution) method. This posed a serious risk of invalid or inconclusive test results, potentially delaying regulatory submissions.

Cytotoxicity testing is a core requirement under **ISO 10993-5**, forming part of the broader **Biological Evaluation Report (BER**) process for medical devices. It evaluates whether a device releases any toxic components that can affect mammalian cell viability. The testing involves:

- Extracting the device in cell culture medium
- Exposing cells to the extract
- Grading cell reactivity (0–4 scale)

In this case, the device's absorbent nature meant it would retain significant amounts of the extraction medium, leaving too little volume for reliable testing.

Cormica's Approach

Key Actions Taken:

- Performed an absorbency trial to determine the volume of media absorbed by the sample.
- Calculated and adjusted the total extraction medium volume accordingly to ensure sufficient extract remained post-incubation.
- Proceeded with cytotoxicity testing using the adjusted extraction ratio and validated protocol.

Outcome & Client Benefit

Thanks to the customised approach, the client received:

- Valid cytotoxicity results despite the challenging sample properties
- No delays in their regulatory submission timeline
- Confidence that testing complied fully with ISO 10993-5 and 12, supporting their global regulatory goals (including EU MDR and FDA)

Whether you're working with absorbent, irregular, or high-risk materials, our team has the expertise to help you achieve compliant, validated results. Contact us today to discuss your next biological evaluation.

Why Cormica

We combine scientific excellence with regulatory insight to deliver robust, compliant, and timely results. Our **ISO 10993 biocompatibility testing** offering includes:

- Cytotoxicity, Sensitisation, Irritation, and Systemic Toxicity testing
- Biological Evaluation Plans (BEPs) and Reports (BERs)
- Integrated testing with Analytical Chemistry, Microbiology, and Physical Testing
- GMP, GLP, and ISO 17025 accreditations
- Facilities in the UK, EU, and US to support international submissions

CORMICA®

Global specialists in pharmaceutical, medical device & combination product testing

Learn more about Cormica's Cytotoxicity Testing
https://www.cormica.com/services/microbiology-testing/cytotoxicity-testing/