Providing Sterilisation & Laboratory Services for the world's most innovative healthcare companies.

From the Blog

An Overview of Cleaning Validation & Cleanliness Testing for Medical Devices

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Medical device manufacturers face increasing demands for fast product release, regulatory compliance, and cost control. At Medistri, we offer one of the most competitive and efficient laboratory services in the Swiss market, enabling you to accelerate time-to-market while maintaining the highest quality standards.

Why Cleanliness Testing Matters for Medical Devices
During manufacturing, medical devices come into contact with a wide range of processing aids - lubricants, cleaning agents, passivation chemicals, solvents, and more. Residues from these materials can adhere to surfaces, accumulate in complex geometries, or penetrate polymers, potentially impacting patient safety and regulatory compliance.

With the growing demands of the EU Medical Device Regulation (MDR), ISO standards, and international authorities, manufacturers must provide robust, scientifically valid evidence that their devices are clean and safe for patient use. At Medistri, we support you with a comprehensive suite of cleanliness and cleaning validation tests, covering every critical risk.

Our Cleanliness Testing Services - Your Competitive Advantage
Medistri's laboratory offers a broad menu of validated test methods, all with industry-leading turnaround times and competitive pricing:

- **Total Organic Carbon (TOC):** Sensitive detection of organic residues, including oils, surfactants, and residual process chemicals.
- **Hydrocarbon Testing (HCT):** Quantifies a broad range of organic residues not captured by TOC alone, using C10-C40 analysis.
- **Particle Testing:** Rapid measurement and sizing of particulate contaminants, essential for critical devices.
- **Cytotoxicity Testing:** Direct assessment of biological safety, compliant with ISO 10993-5, using both qualitative and quantitative methods.
- **Metals Analysis (ICP):** Fast detection of trace metals, supporting risk assessment for passivation residues or metallic debris.
- **FTIR Spectroscopy:** Identification of unknown organic contaminants or polymeric residues—results delivered quickly for your decision-making.
- **Residual Solvent Testing:** Quantitative analysis of residual solvents, with reliable, rapid reporting.

Validated Recovery and Method Performance:
To ensure that our results are meaningful and reliable, Medistri conducts **full method validation - including recovery studies - for key cleanliness assays such as TOC, HCT, and particle testing.** Our team carefully evaluates extraction efficiency and recovery on your actual device surfaces, providing you with robust evidence that our methods accurately detect and quantify residues - even in the most challenging geometries or material types. This approach ensures your data is defensible for regulatory authorities and risk assessments.

Ready to Gain a Competitive Edge?
Contact Medistri today to discuss your cleaning validation, routine cleanliness testing, or custom analytical requirements.
Let us show you how our unmatched combination of expertise, speed, and value can support your success.

Need a custom solution or accelerated timeline?
Our team routinely develops and validates custom analytical methods - and can expedite testing to meet your project's deadlines.

From Process Qualification (OQ/PQ) to Routine Batch Release
Whether you're qualifying a new cleaning process, validating an update, or conducting routine batch release, Medistri provides:

- **OQ/PQ support:** Expert guidance, protocol development, and worst-case challenge testing.
- **Contamination studies**: Controlled testing to demonstrate cleaning efficiency.
- **Routine monitoring**: Cost-effective, reliable, and rapid results for ongoing control.
- **Custom method development & validation**: Including recovery studies to demonstrate real-world method performance on your specific device.

Why Choose Medistri?

- **Highly competitive pricing** for all standard and advanced analyses.
- **Fastest possible turnaround times** - keep your project moving.
- **No compromise on quality**: ISO 17025 accredited, compliant with ISO 19227, ISO 10993, and USP guidelines.
- **Full method validation with recovery studies** for TOC, HCT, and particle assays.
- **Personalized support** from initial consultation to final report.

Learn more about our Laboratory. To ensure your products meet the highest quality and safety standards, contact our dedicated team at contact@medistri.com.

— The Medistri Team

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