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From the Blog

Extractables & Leachables Testing in MedTech and Pharma

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Medical Device and Pharmaceutical companies must ensure their products are safe for use and compliant with international regulations. Extractables and Leachables (E&L) testing plays a key role in this effort, as outlined in standards such as ISO 10993 and the United States Pharmacopeia (USP). At Medistri, we provide comprehensive E&L analyses to support product development, regulatory submissions, and patient safety.

Defining Extractables & Leachables Testing
Extractables are chemicals released from materials under aggressive laboratory conditions, simulating worst-case scenarios.
Leachables are chemicals that migrate from materials into the product under normal conditions, reflecting realistic usage scenarios.

Why E&L Testing Matters
The potential migration of chemicals from materials into drug products or patient tissues can lead to serious consequences, including reduced product efficacy, immune reactions, toxicity, or even product recalls. For example, improper material selection in medical devices, such as an infusion set, could potentially result in leachables causing adverse patient reactions and necessitating costly product recalls. Similarly, insufficient testing of pharmaceutical packaging could lead to contamination of drug products, compromising their stability and safety, with significant financial and reputational consequences for pharmaceutical companies. Comprehensive E&L testing identifies these potential risks before they reach patients, protecting both public health and manufacturer reputation.

E&L in the Context of ISO 10993
ISO 10993-18 outlines chemical characterization requirements for medical device materials, particularly regarding E&L. This includes devices intended for various types of patient contact and exposure durations, ensuring broad applicability across different medical device categories. This standard covers:

- Chemical characterization of materials.
- Identification and quantification of potential chemical contaminants.
- Toxicological risk assessment (TRA) according to ISO 10993-17 to evaluate potential health impacts.
- Biological risk assessments based on chemical exposure.

To support ISO 10993-18 compliance, Medistri uses a broad array of analytical technologies such as GC-MS (including Headspace analysis), LC-MS, ICP-MS, TOC, and Hydrocarbon Testing (C10–C40), ensuring reliable detection of organic and inorganic compounds. Our integrated approach delivers high-quality chemical characterizations to meet regulatory expectations.

Sample Preparation for E&L Extraction

E&L in the Context of USP
The United States Pharmacopeia (USP) provides additional guidelines for pharmaceutical packaging and delivery systems:

- USP <1663> evaluates Extractables under stressed laboratory conditions.
- USP <1664> assesses Leachables under typical storage and usage conditions.
- USP <661> outlines standards for plastic packaging systems and their chemical safety.
- USP <665> addresses standards for polymeric components and systems used in manufacturing pharmaceutical and biopharmaceutical drug products.

Medistri is actively expanding our services to include USP-compliant analyses, demonstrating our commitment to supporting evolving client needs and regulatory demands.

Regulatory Compliance and Accreditation
Medistri's laboratory operates under ISO 17025 accreditation, aligned with ISO 10993-18, ISO 10993-12 and EPA 8260/8270 (modified), ensuring reliability, accuracy, and compliance with international standards.

Medistri's Commitment to Service
By combining expertise in ISO 10993 and developing USP capabilities, Medistri provides tailored laboratory solutions. Our advanced infrastructure and technical knowledge help simplify your regulatory pathway, allowing you to focus on product development and patient safety.

To learn more about Medistri's E&L analysis services, visit our website here or contact our team at contact@medistri.com. Whether you're looking to launch a new product, address regulatory requirements, or enhance material safety, our experts are here to guide you through every step of the process.

— The Medistri Team

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