Medistri.SA

Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.


# Extractables & Leachable's (E&L) Testing for Pharmaceuticals - Medistri

🚀 **Extractables & Leachable's (E&L) Testing for Pharmaceuticals**

Assessing the purity of a final product is a key task when releasing pharmaceutical products on the market.

Historically, it was limited to impurities that were created during the production process and the  degradation of the pharmaceutical product. But currently, it is essential to assess the diffusion of mobile compounds from the materials used for the manufacturing process and storage of pharmaceutical product. he USFDA & the EMA are bringing awareness to how different production systems, drug delivery systems, and container-closure systems interact with the finished pharmaceutical product.

The objective of Extractable's & Leachable's Testing for Pharmaceutical products is to determine and evaluate any toxicological concerns that may result from such interactions.

Extractables and leachables (E&L) studies are now a crucial component of product release.

The FDA states that: "Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality or purity of the drug beyond the official or established requirements." (From the US FDA, Code of Federal Regulations, 21CFR211.94)

👉 The FDA defines Extractable's as "Organic and inorganic chemical species that can be released from the surfaces of components used in the manufacture and storage of drug products under laboratory conditions (accelerated or exaggerated temperatures, solvents or surface exposure)."

👉 The FDA defined Leachable's as "Organic and inorganic chemical species that can be released from the surfaces of components used in the manufacture and storage of drug products under conditions of normal use."

How it works:

✅ Our laboratory begins learning everything there is to know about your packaging & manufacturing system in order to provide a thorough picture of all potential sources of leachables. Our team can anticipate and identify possible sources of risk linked with leachable impurities through strategic screening tests thanks to our experience in method development for a controlled extractables research and our extensive understanding of leachable substances and regulations.

Medistri's Laboratory provides GMP-compliant leachables method validation for use in GMP stability testing and storage programs and are able to support a variety of closure or drug delivery systems - including:
- Pre-filled Syringes,
- Pharmaceutical Vials
- Large Volume Parenteral Products,
- Orally inhaled and nasal drug products (OINDP),
- Single-use and disposable medical equipment
- Printed packaging
- Secondary packaging migration behaviour
- Medical Devices (ISO 10993-19)
- Drug Deliver Systems

🎯 To learn more about Medistri's Extractables & Leachable's (E&L) Testing for Pharmaceuticals, visit on our website at www.medistri.swiss or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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