

Extractables & Leachables Analysis

On the leading **EDGE** of extractables and leachables understanding and analysis

Ensuring that a drug product reaches the market safely and effectively means selecting primary containment and delivery that does not significantly interact with the drug itself. Such interactions can result in contamination of the drug product that can diminish efficacy or potentially cause harm to patients.

West has the scientific knowledge and experience to design and execute extractable and leachable (E&L) studies and to interpret the results. Our dedicated E&L group includes industry recognized experts who can provide customers with meaningful E&L information and help customers navigate through the challenging regulatory landscape.

We perform customized, cGMP studies that follow the most current regulatory requirements and guidances, including USP <1663> and USP <1664> and partner with our clients on:

- Extractable, simulation and migration studies
- Leachables method development and validation
- Leachables stability testing and storage
- Extractable Risk Assessment using our E₂L™ assessment
- Toxicology support
- Method development and validation for leachables

Instrumentation such as the Triple Quadrupole Inductively Coupled Plasma Mass Spectrometer offers unparalleled performance for the removal of polyatomic interferences, allowing for trace analysis in the most demanding matrices. The ion mobility Q-ToF allows for separation and selectivity by combining chromatography, ion mobility and mass spectrometry. We offer the following off-the-shelf extractable packages for selected elastomer formulations:

- VeriSure™ Report
- Extractables Data Report
- Material Characterization
- Theoretical Material Extractables

By partnering with West, customers receive sound, scientific results that can help determine the proper primary containment and delivery – reducing risk and helping to ensure your drug product reaches the market and the patients who need it.

For more information visit WestAnalyticalServices.com

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