A LEADER IN EXTRACTABLES AND LEACHABLES 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

West employs current techniques and technology, including the Triple Quadrupole Mass Spectrometer, to enable trace analysis of a wide range of extractables and leachables in challenging modern drug matrices. This is bolstered by the use of high-resolution accurate mass chromatography so that no compounds are left as unknown.

We offer the following off-the-shelf extractables packages for selected West 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.

Contact West's analytical services team today to design a program to meet your E&L testing requirements. Westanalyticalservices.com

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