Extractables & Leachables (E&L) Analysis

Delivering accurate results in accordance with regulatory guidelines

The complex chemical cross-talk between pharmaceutical compounds and their packing materials is the current focus of regulatory authorities. With the development of a variety of packaging technology and formulation conditions, extractables and leachables (E&L) study results are at the forefront of evaluating the efficacy of drug products. To ensure quality products, the Wipro pharma lab can guide pharmaceutical enterprises to design E&L studies containing comprehensive and quality data that meets USFDA guidelines.

Accurate and precise testing services that provide trustworthy results in compliance with industry standards.

Key Takeaways

E&L study designs that meet the latest regulatory guidelines and recommendations as per FDA warning letters

Sample preparations in line with the Product Quality Research Institute (PQRI) and United States Pharmacopeia (USP) recommendations

Data interpretations from well-qualified and experienced scientists

Toxicological information provided by experienced toxicologists

Wipro-developed validated methods on TOC, FTIR, RI/FLD, LC-MS APCI/ESI, GC-FID/MS-HS, ICPMS/ICPOES, IC, and UV

Key Benefits

- Background checks through read-across, evaluating vendor-supplied details and exploring in-house databases
- Extractable studies built on our in-house-developed and validated methods utilizing orthogonal detections and nontargeted/targeted compound analysis
- Leachables studies that include stability studies, correlation studies, quantitation, and nontargeted and targeted compound analysis
- Toxicological assessment reports that include a qualification threshold and a toxicological risk assessment from an expert toxicologist
- Well-designed studies offering complete data that meets regulatory requirements, preventing delays in reanalysis

Our E&L studies are carried out in line with guidelines from the PQRI, the Extractables and Leachables Safety Information Exchange (ELSIE), and the BioPhorum Operations Group, as well as with applicable USP recommendations.

Key Takeaways

Wipro's E&L analysis studies examine the following factors:

Extraction: Our extraction testing focuses on solvent types, strength, pH, and polarity, followed by other affecting factors such as concentration factor, volume, loss of compounds, and control blanks.

Packaging: Our interpretation of extractable data includes detail component evaluation, its known toxicological effects, and migration studies.

Leachables: The factors taken into consideration correlate with controlled extractable, targeted, and nontargeted analysis, as well as real-time (long and intermediate) and accelerated condition studies.

Method development: This analysis involves an exploration of various chemistries of column, gradient, and mobile-phase conditions, especially in standardizing nontargeted methods, followed by method validation as per ICH guidelines.

Method validation: Following method development, method validation is carried out as per ICH guidelines on multiple instruments, such as TOC, FTIR, RI/FLD, LC-MS APCI/ESI, GC-FID/MS-HS, ICPMS/ICPOES, IC, and UV.

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Wipro Limited (NYSE: WIT, BSE: 507685, NSE: WIPRO) is a leading global information technology, consulting and business process services company. We harness the power of cognitive computing, hyper-automation, robotics, cloud, analytics and emerging technologies to help our clients adapt to the digital world and make them successful. A company recognized globally for its comprehensive portfolio of services, strong commitment to sustainability and good corporate citizenship, we have over 200,000 dedicated employees serving clients across six continents. Together, we discover ideas and connect the dots to build a better and a bold new future.

For more information,
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