eurofins | BioPharma Product Testing

Extractables and Leachables Testing

During the drug development process, it is important to evaluate the potential for various chemicals to migrate from container closure systems, manufacturing com ponents or delivery devices into pharmaceuticals and biologics. Regulatory agencies require extractables and leachables (E&L) testing to identify any risks of product adulteration.

Whether you are evaluating pharmaceutical manufacturing equipment (such as single-use systems), container closure systems, delivery devices, or other medical de vices, Eurofins offers a broad range of services to support extractables and leachables testing. With over 3 years of experience and more than 30 scientists dedicated to E&L testing, we conduct hundreds of controlled extraction studies each year, along with the associated leachables stability studies.

We offer a variety of controlled extraction techniques to generate an extractable profile that will best match the intended use of the components being evaluated. In addition, we conduct simulated and real-time leachables studies to evaluate the presence of leachable compounds in the drug product. Our toxicologists can then evaluate the E&L data to determine the impact to patient safety. If needed, we can use our extensive experience to success fully develop and validate fully GMP compliant methods to monitor leachables in your drug product or intermediates.

Why Choose Eurofins BioPharma Product Testing?

Expertise and Experience - With over three years of experience, we're specialists in designing and conducting extractables and leachables (E&L) studies that provide you with meaningful data. We'll work with you to recommend testing options that meet current industry and regulatory standards.

Comprehensive and Compliant Services - We write protocols that are compliant with Good Manufacturing Practices (GMP) to guide your E&L and stability studies. You'll receive a detailed, customizable report with every study that includes instrument parameters, system suitability results, and full data tables.

Advanced Technology - Our proprietary spectral database, the Eurofins Extractables Index (EEi), contains reference spectra for more than 1,500 non-volatile compounds. This allows us to accurately identify extractable compounds found in your samples. If a compound is unknown, our expert analysts and state-of-the-art instruments can perform additional investigative testing to identify it.

Quality and Reliability - All of our E&L methods are qualified to ensure accurate results and meet regulatory expectations. This commitment to quality gives you confidence in the data you receive.

Extraction Techniques

- Reflux
- Soxhlet
- Sonication
- Microwave
- Autoclave
- Incubation at controlled temperature conditions (with agitation or recirculation if needed)

Extraction Techniques

We have established the following semi-quantitative screening methodology to analyze extraction solutions by LC-MS/MS, GC-MS/MS, ICP-MS and IC.

If needed, quantitative methods can be developed for specific compounds.

- Semi-quantitative screening for both volatile and semi-volatile organic compounds
  - Use of GC-MS/MS instrumentation with direct injection sample introduction and electron impact ionization for SVOC.
  - Use of GC-MS/MS instrumentation with head space sample introduction and electron impact ionization for VOC.
  - For extractables compounds detected by GC-MS/MS analysis, we utilize the up-to-date Wiley/ NIST databases to assist in identification.
- Semi-quantitative screening for non-volatile organic compounds
  - Analysis using LC-QTof (in positive and negative mode using electrospray and atmospheric pressure chemical ionization)
  - For extractables compounds detected by LC-QTof analysis, we utilize the Eurofins Extractables Index (containing over 1,500 compounds) to assist in identification.
- Quantitative analysis for metals
  - Evaluation of samples for 34 elemental impurities listed in USP <232> and ICH Q3D using ICP/MS
  - Anions by Ion Chromatography
  - Non-Volatile Residue by Gravimetric Analysis

Toxicological Evaluation

Our team of toxicologists have the capability to evaluate compounds by referring to both toxicological databases and QSAR methods. We are experienced in performing toxicological analyses on medical devices, including den tal and gas pathway devices, as well as pharmaceutical container/closure systems according to standards such as ISO 10993-17 and ISO 18562 and guidance documents from the FDA and PQRI.

Instrumentation

- Agilent LC- QTof (Revident)
- Waters LC- QTof (Xevo G2-XS)
- Shimadzu LC-MS/MS (8060 NX)
- Shimadzu GC-MS/MS (8050 NX)
- Perkin Elmer ICP-MS (Nexion 2000)
- Thermo Scientific Ion Chromatography (DIONEX ICS 6000 DC)

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