eurofins | BioPharma Product Testing



Extractables and Leachables Testing

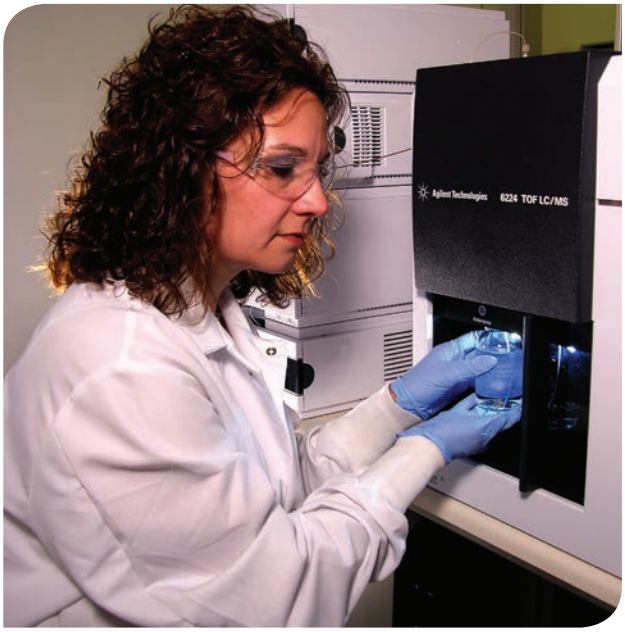
During the drug development process, it is important to evaluate the potential for various chemicals to migrate from container closure or manufacturing systems into pharmaceuticals and biologics. Regulatory agencies require extractables and leachables testing to identify any risks of product adulteration.

Whether you are evaluating container closure systems, delivery devices, single-use systems or manufacturing equipment, Eurofins BioPharma Product Testing offers a broad range of services to support extractables and leachables testing. With more than 50 scientists and 12 years of experience testing bottles, caps, stoppers, tubing, filters, syringes, bioprocess bags and packaging, and hundreds of controlled extraction studies completed along with associated leachables work, we have established a variety of extraction and testing options to meet your extractables and leachables needs.

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 simulation studies to evaluate the probable occurence of extractable compounds in the presence of product matrix. We can use our extensive experience to sucessfully develop and validate fully GMP-compliant methods to monitor leachables in your drug product or intermediates.

Why Choose Eurofins BioPharma Product Testing?

- We have the ability to write GMP-compliant protocols to direct extractables and leachables testing or to define conditions for stability studies.
- Our extractables and leachables studies include a report detailing the results of the study, including mass spectra of tentatively identified peaks; comparison spectra from commercially available and in-house databases; and interpretation of results.
- Our proprietary spectral database, Eurofins Extractables Index (EEI), contains reference spectra for over 1,500 non-volatile compounds (including common plasticizers, anti-oxidants, stabilizers, elastomers, lubricants and accelerants) that we use to identify extractable compounds detected by LC/MS.



- We work with our clients to design a study that provides them with meaningful extractables data and we assist them in performing a risk assessment of their product configuration or manufacturing chain, recommending testing options that are up to current industry standards and expectations.
- We offer toxicological evaluations on extractables data at our sister company, Eurofins Biolab Milan.

Our Approach

Our extractables studies can be designed per guidances such as USP <1663> and <1664>, as well as FDA/CDER/CBER and EMEA, PQRI, BPSA and BPOG documents.

Extraction Techniques

- Reflux
- Soxhlet
- Sonication
- Incubation in controlled temperature conditions
- Agitation in controlled temperature conditions

Analysis Techniques

We have established the following methodology to analyze extraction solutions by LC/MS, GC/MS, LC/UV and ICP-OES:

- Semi-quantitative screening for both volatile and semi-volatile organic compounds



  - Use of GC/MS instrumentation with direct injection sample introduction and electron impact ionization.
  - Use of GC/MS instrumentation with headspace sample introduction and electron impact ionization.
  - For extractables compounds detected by GC/MS analysis, we utilize the NIST98K, Wiley 2010, NIST2011 and Wiley7 databases to assist in identification.

- Semi-quantitative screening for non-volatile organic compounds
  - Analysis using LC/MS TOF (electrospray and atmospheric pressure chemical ionization) and LC/UV/Vis.

- Semi-quantitative analysis for metals
  - Evaluation of samples for 30 metals

- Gravimetric determination of extractables
- TOC
- pH
- Conductivity

Instrumentation

- Agilent LC/MS TOF and QTOF
- Agilent/Waters HPLC/UHPLC – including UV/Vis, RI, Fluorescence, ELSD, CAD, and Conductivity detectors
- Agilent GC/MS – both headspace and direct injection sample introduction
- Agilent GC/FID/TCD – both headspace and direct injection sample introduction
- Agilent ICP/MS
- Thermo Scientific iCAP ICP-OES
- Perkin Elmer ICP-OES