



## EXTRACTABLES AND LEACHABLES TESTING

One of the most important factors involved in guaranteeing maintenance of the intrinsic characteristics of a pharmaceutical product, an active substance, or a health care product is undoubtedly the primary packaging. This makes it necessary to carry out complete studies on packaging and its components in order to be able to guarantee product suitability.

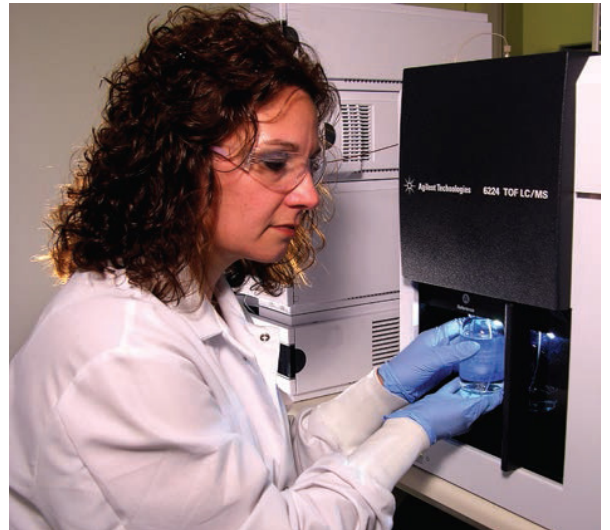
Eurofins professionals have an extensive knowledge of the behavior of packaging materials (glass, elastomer materials, polymeric materials, metals, etc.), and can prepare protocols for specific studies to evaluate the suitability of the materials used, the final packaging chosen, and the interaction between packaging and contents.

Whether you are evaluating container closure systems or manufacturing equipment, Eurofins offers a broad range of services to support extractables and leachables testing. With more than 10 years of experience testing bottles, caps, stoppers, tubing, filters and bioprocess bags, we have established a variety of extraction and testing options to meet your extractables and leachables needs.

We offer extraction techniques to generate an extractable profile needed to best match the intended use of the components being evaluated. And with extensive expertise in developing, validating and providing testing support for impurities, we can provide you with directed method development and full GMP-compliant validation of methods to monitor the presence of leachables in your drug product.

### Why Choose Eurofins?

- For extractable compounds detected by GC/MS analysis, we compare with databases to assist in identification.
- We have established methodology to analyze extraction solutions by LC/MS, GC/MS, LC/UV and ICP-OES.
- We have the ability to write GMP-compliant protocols to direct extractables and leachables testing or define conditions for stability studies.
- We have established methodology to perform the toxicological evaluation of the extractables found in order to focus on the possible relevant leachables.
- Our extractable and leachable studies include a report detailing all of the results of the study and interpretation of results.



### Extraction and Analysis Options Available

#### Extraction techniques available

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

#### Analysis techniques available

- Semi-quantitative analysis of ions by Indirect UV
  - Utilizing LC analysis with a mobile phase that has absorbance in the visible range. Ions are then detected as a negative response by UV.
- Semi-quantitative screening for semi-volatile organic compounds
  - Use of GC/MS instrumentation with direct injection sample introduction.
- Semi-quantitative screening for non-volatile organic compounds
  - Analysis using either LC/MS ion trap or LC/MS TOF and LC/UV/Vis
- Semi-quantitative analysis of metals
  - Evaluation of samples by using ICP

