

Extractables and Leachables Testing

Extensive Testing That Delivers Unparalleled Results

Impact Analytical (IA) is a full-service contract testing laboratory dedicated to providing comprehensive analytical services for a variety of industries – pharmaceutical, plastics, consumer products, medical devices, packaging, specialty chemical, and more.



Extracting Solutions

The materials used to fabricate container closure systems (CCS), medical devices, and processing equipment are often polymers, such as plastic or elastomers (rubber), as opposed to the traditional metal or glass. The use of polymers in packaging offers much more versatility than traditional glass or metal. The use of polymers in packaging for medical applications does come with risk, however. Polymers and their accompanying additives are prone to degradation over time and in the presence of light, heat, oxygen, and other external influences. The result is a complex formulation that is prone to leaching unwanted chemicals into the drug product formulation or medical device. This risk must be managed.

The experts at Impact Analytical have the experience and resources to perform extractables and leachables studies that mitigate this risk and ensure a safe and compliant product.

Exceptional Polymer Knowledge

Our extensive plastics characterization experience is the backbone of our Extractables & Leachables testing regiment. This knowledge serves as a solid foundation for our experts to quickly and efficiently characterize container closure systems for leachables. We follow Product Quality Research Institute (PQRI) best practices to ensure all studies are thorough and compliant. While a proven testing process is the starting point, each project benefits from our scientific experience and ability to customize methods and develop the best testing solutions.

Extractables & Leachables Process

- Evaluate
 - Initial materials assessment
 - Primary contacting components
 - Secondary contacting components
 - Associated closure and packaging systems
 - > Associated components
- Controlled extraction studies
 - Material extraction
 - Analysis of the extracts
 - > Multiple separation and detection techniques to identify volatiles, semi-volatiles, non-volatiles and inorganics
 - > Establishment of leachables threshold limits
- Leachables method development and validation
 - Leachables testing
 - Correlation establishment
 - Evaluation of leachable profile
 - > Toxicology evaluation
- Ongoing Testing

Testing Technologies

Impact Analytical uses state-of-the-art laboratory equipment to detect, identify, and quantify all extractables and leachables. These instruments include:

- Traditional extraction methodologies – reflux, soxhlet, sonication, agitation
- Headspace GC-MS for volatiles
- GC-MS for volatile and semi-volatile organics
- LC-MS, including exact mass for semi- and non-volatile organics
- ICP-MS for trace metals, inorganics
- Ion chromatography for inorganics



Furthermore, no matter what your study parameters or timeframe, we'll work within those limits to meet your needs.

The People Factor

All Impact Analytical technical staff hold bachelor's, master's, or Ph.D. degrees and are always ready and eager for the next challenge. While IA analysts have specific areas of expertise, they are also cross-trained in several disciplines, which creates a well-rounded, collaborative team dedicated to developing efficient, accurate solutions.

This team of experts offers the following:

- Extensive experience in plastics characterization
- Substantial regulatory compliance experience – ISO 9001:2008, GLP, cGMP, FDA, EPA
- Toxicology evaluation, validation, and methods expertise
- Up-to-date/significant E&L training – PQRI best practices

Impact Analytical analysts are also focused and trained on delivering exceptional customer service. Unlike many testing firms, IA scientists work directly with the customer to identify project goals, develop a plan, and evaluate results.

Put Us to the Test

Impact Analytical will support your product development and registration with thorough, quick, and cost-effective extractables and leachables evaluations.

Choose Impact Analytical, your trusted and experienced analytical testing partner. For more extractables and leachables information, visit our website at www.impactanalytical.com/extractables-leachables.asp.