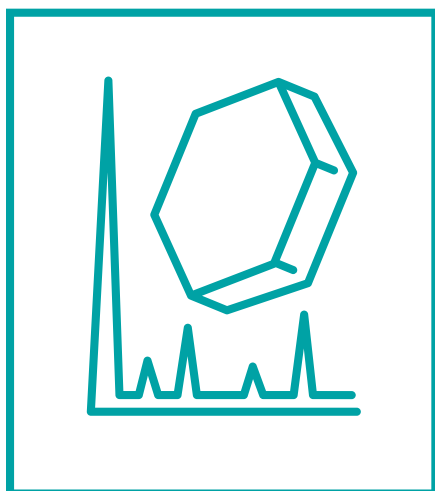




WE'VE GOT EXTRACTABLES AND LEACHABLES TESTING DOWN TO AN EXACT SCIENCE



Analytical and Solid State Services

Speed product development and improve the quality of your compound with solid state chemistry and analytical testing services.



Complex Science. Expert Solutions.

EXTRACTABLES AND LEACHABLES TESTING

Extractables and Leachables (E&L) evaluations have become increasingly more vital to successful product development and regulatory submissions. Recently, many E&L related guidelines/standards have been revised to better address patient safety in the pharma/biotech and medical device industries. These heightened requirements necessitate manufacturers to seek out experts able to navigate this complex regulatory landscape for medical device evaluations and container qualification pertaining to final fill, intermediate storage and manufacturing systems including single use systems.

Our E&L studies are based on the recommendations of the Product Quality Research Institute Extractables and Leachables Working Group to the FDA, as well as on USP <1663>, USP <1664>, USP <661>, the recommendations of the Bio-Process Systems Alliance (BPSA) Extractables and Leachables Subcommittee, ISO 10993: Part 18 and more. At AMRI, we can develop and validate a variety of analytical methods for the routine analysis of material extractables and leachables according to ICH guidelines and in full compliance with cGMP requirements.

AMRI offers toxicological risk assessment services to evaluate adverse risks to patients' health by assessing the leachates of a system against information on in-vitro tests, animal studies, computational methods and predictive means. The information obtained allows our clients to mitigate risk during product development, and demonstrate safety in regulatory documentation. If the chemical profile assessed poses a risk concern, the need to perform additional testing can be evaluated.

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Extractable and Leachable Services

- Development of a tailored extractable and leachable study design for container closure system, single use system, and medical devices
- Controlled extraction studies
- Extractables profiling and identification
- Simulation study
- Leachables studies on drug product over shelf life and/or accelerated conditions
- Extractables and leachables method development, validation and routine testing
- Trace organic analysis
- Toxicology Risk Assessments (TRA)

Extractables and Leachables Instrumentation

- HPLC-MS, UPLC-MS, HPLC-MS/MS, HPLC-high resolution MS, & LC-HRAM
- HPLC-UV/CAD/ELSD, UPLC-UV/CAD/ELSD
- HS-GC-MS, GC-MS, GC-FID, GC-ECD
- ICP-OES, ICP-MS, IC
- FTIR, NMR, TOC & NVR
- TGA, DSC



AMRI is a global contract research and manufacturing organization that has been working with the life sciences industry to improve patient outcomes and quality of life for more than 25 years.

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