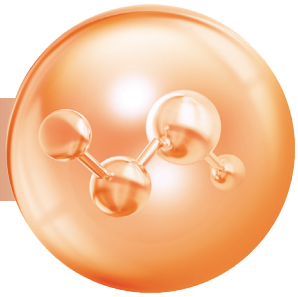
AMRI®
Albany Molecular Research Inc.

AMRI Extractable and Leachable Testing



The determination of extractables and leachables in bio/pharmaceutical products is an important measure in drug product development because any materials that come into contact with your device or product has the potential to be a contaminant. To ensure your drug product is safe from contamination, we offer a comprehensive extractable and leachable (E&L) testing service.

Our E&L studies are based on the recommendations of the Product Quality Research Institute's (PQRI) Extractables and Leachables Working Group to the FDA, USP <1663>, USP <1664>, and the recommendations of Bio-Process Systems Alliance (BPSA) Extractables and Leachables subcommittee. 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.

EXTRACTABLE AND LEACHABLE SERVICES

- Development of a Tailored Extractable and Leachable Study Design for Container Closure System and Single-Use System
- Controlled Extraction Studies
- Extractable Profiling and Identification
- Simulation Study
- Leachable Studies on Drug Product over Shelf Life and/or Accelerated Stability Program
- Extractable and Leachable Method Development, Validation, and Routine Testing
- Trace Organic Analysis

EXTRACTABLE AND LEACHABLE INSTRUMENTATION

AMRI uses state-of-the-art instrumentation to produce high-quality data and submission-ready results. Our instrumentation ranges from general analytical equipment to specialty systems like GC-MS and LC-MS.

- HPLC-MS, UPLC-MS, HPLC-MS/MS, HPLC-High Resolution MS
- HPLC-UV/CAD/ELSD, UPLC-UV/CAD/ELSD
- HS-GC-MS, GC-MS, GC-FID, GC-ECD
- ICP-OES, ICP-MS, IC
- FTIR, NMR
- TGA, DSC