

Extractables and Leachables Testing



Ofichem offers extractables and leachables (E&L) testing in accordance with the recommendations of a number of global organisations, including the FDA, EMEA, USP, ICH, PQRI, BPSA and BPOG.

Our E&L testing capabilities include a wide range of analytical techniques designed to identify and test all possible additives and impurities, which could migrate from packaging to the drug product, potentially affecting drug efficacy and patient safety.

At Ofichem we offer:

- Fully compliant E&L testing during new product development and following changes to packaging materials and manufacturing equipment
- Custom testing strategies according to individual project requirements and compliance goals
- A range of analytical testing techniques, such as HS-SPME-GC-MS, GC-MS, UPLC-UV-HRMS/MS and ICP-MS
- E&L testing of possible additives including plasticisers, lubricants, pigments, stabilisers, antioxidants, UV-filters, monomers and slip agents
- Dedicated testing team and state of-the-art instrumentation
- E&L testing of all types of leachable substances including volatile, semi-volatile, non-volatile and elemental
- Testing and analysis beyond the regulatory requirements to offer a deeper understanding of the risks associated with any identified leachable substances
- Preliminary toxicological assessment of all observed extractables and leachables.

