Extractables & Leachables (E&L) testing

E&L testing includes analytical techniques designed to identify and test a wide range of additives and impurities, which could migrate from packaging to the drug product, potentially affecting drug efficacy and patient safety. Recipharm offers extractables and leachable testing in accordance with the guidelines and recommendations of a number of global organisations, including the FDA, EMEA, USP, PQRI, BPSA and BPOG.

Our solution

- 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
- Dedicated testing team and state-of-the-art instrumentation
- A range of analytical testing techniques, such as HSSPME-GC-MS, GC-MS, UPLC-UV-HRMS/MS with orbitrap and ICP-MS
- Extraction techniques including Sohlet, reflux, micro-wave, incubation under controlled temperature with agitation and immersion
- E&L testing of possible additives including plasticisers, lubricants, pigments, stabilisers, antioxidants, UV filters, monomers and slip agents
- E&L testing of all types of leachable substances including volatile, semi-volatile, non-volatile and elemental
- Detailed protocol based on scientific background to direct the conditions of extractables and leachable testing
- Reports with detailed information, relevant chromatograms and summary table approved by quality assurance team
- Testing and analysis beyond the regulatory requirements to offer a deeper understanding of the risks associated with any identified leachable substance
- Evaluation of safe and sustainable pharmaceutical & bio-pharmaceutical container closure systems
- Assessment of critical component interaction with drug product by gathering MOC information
- Proposal of experimental design on proposed CCS
- Risk assessment and mitigation
- Conduct simulated and real-time leachables studies to evaluate the presence of leachable compounds in the drug product

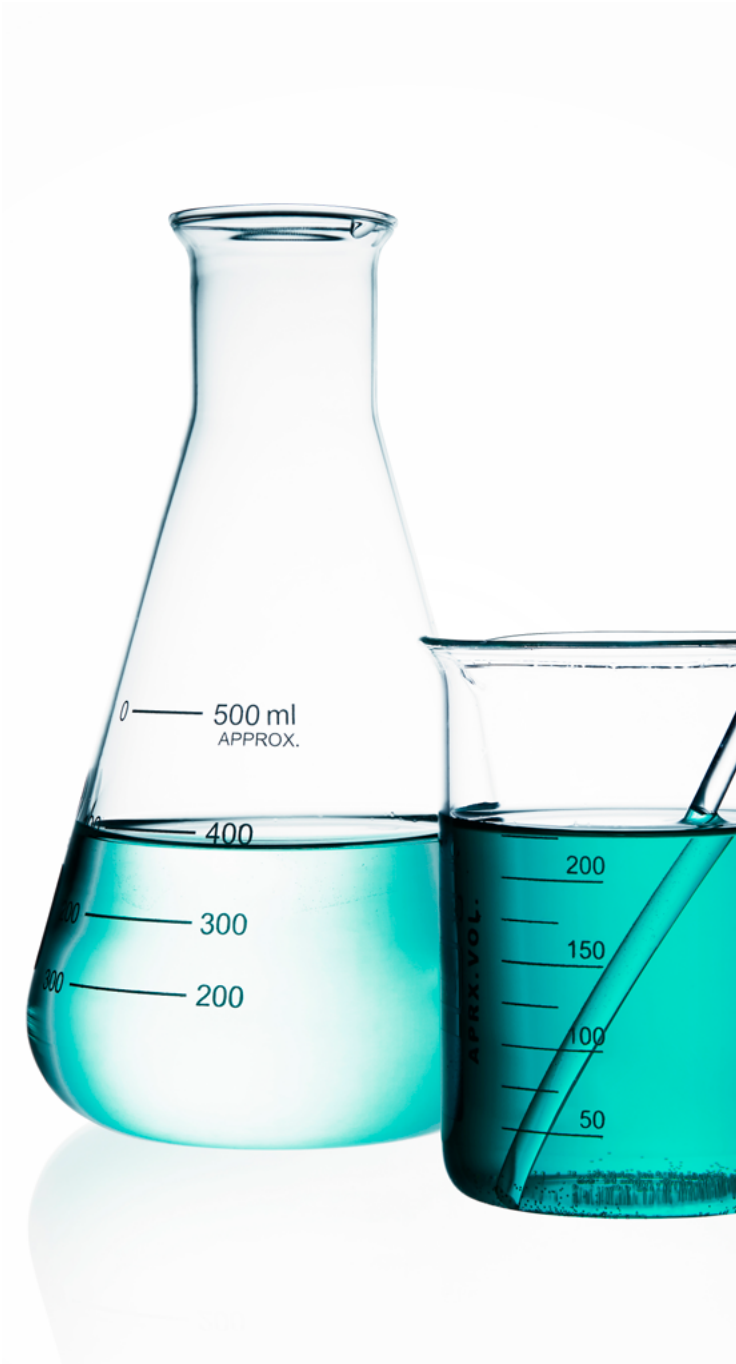
Testing programs – high-risk dosage forms

- **Inhalation** – MDIs, DPIs and breath actuated meter dose inhalers, nasal sprays and aerosols
- **Injection** – pre-filled syringes, sterile dry power injectables, small- and large-volume parenterals
- **Ophthalmic** – solutions and suspensions
- **Transdermal** – patches and dermal drug delivery devices

Assessment of 1, 2 and 3 packing material

Screening on selection of CCS

Stability testing throughout product shelf life



E&L – experiment approach

- Perform extractions to support targeted and non-targeted screening
- Adjust temperature and time of extraction to mimic real-time exposure of drug product
- Design of experiments to support extractable, simulation and leachable testing
- Report of observations with TOX risk assessment

Evaluation	Technique
VOC	HS-GCMS
SVOC	GC-MS
NVOC	LC-HRMS/LC-MSMS
Element estimation	ICP-MS/OES
Ionic species	IC

About us

Established in 1995, Recipharm's manufacturing, fill & finish, and delivery-device services encompass a wide variety of drug dosage forms and modalities. Recipharm is an industry leading CDMO with over 30 facilities and 9,000 employees globally – supporting companies that are developing small molecules, biologics, and drug-device combinations. The company operates development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US.

Introducing ReciBioPharm, Recipharm's biologics business combining the capabilities of recently acquired CDMOs Arranta Bio, GenIbet and Vibalogics. Our expanded biologics drug development and manufacturing services encompass technologies based on live viruses and viral vectors, live-microbial biopharmaceutical products, recombinant proteins, nucleic acid-based mRNA and plasmid DNA production.

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