

## PHARMACEUTICAL DEVELOPMENT SERVICES

# EXTRACTABLES AND LEACHABLES TESTING

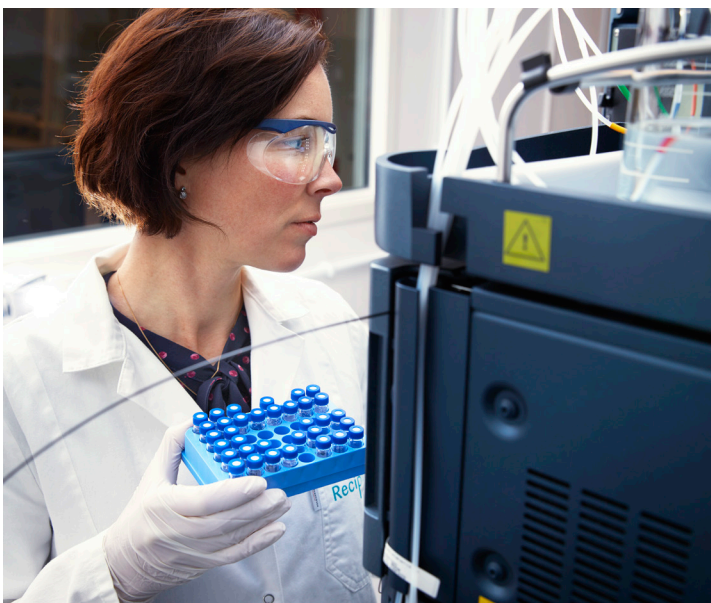
Recipharm offers extractables and leachables (E&L) testing in accordance with the guidelines and recommendations of a number of global organisations, including the FDA, EMEA, USP, PQRI, BPSA and BPOG.

Our E&L testing capabilities include 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.



### At Recipharm 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
- ▶ Dedicated testing team and state-of-the-art instrumentation
- ▶ 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
- ▶ 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



**About Recipharm:** Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and are continuing to grow and expand our offering for our customers. Employing around 6,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 20 years we have been there for our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. Despite our growing global footprint, we conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do. That's the Recipharm way.