EXTRACTABLE / LEACHABLES SERVICES

The Challenge

The challenge to identify, quantify, and minimize impurities related to drug products can demand a significant investment in time, resources and costs.
To ensure drug safety and purity and successful Regulatory Authority review, comprehensive extractable and leachable studies of components within the product packaging or container closures systems (CCS) are required to meet the safety requirements for marketed medicines.
Controlled extractables and leachables (E/L) studies are applied to a wide variety of compounds and materials, including both organic and inorganic elements.

Our Experience

Intertek undertake extractables and leachables studies for a wide range of drug products in a variety of packaging types, conducted in accordance with GLP and GMP requirements. Products can include CCS such as pre-filled syringes and vials, inhalation devices for OINDP, single use and disposable medical equipment as well as related labelling and printing.
These studies provide qualitative and quantitative data to build a comprehensive profile of extractable components and determine the extent to which such components actually leach and potentially contaminate a drug substance or drug product.

We also conduct glass delamination and extractables studies for glass packaging. Scientific support is available at every stage of the testing program, including identification of unknowns or toxicological risk assessment of identified extractables leachables.

Controlled Extractables Studies (CES)

- Developing and validating methods for controlled extractables from pharmaceutical containers, closures and devices
- Identification of extractables using GC/MS and LC/MS/MS
- Complex polymer formulation component identification
- Screening or quantitative studies for additives and stabilizer ingredients
- Rapid, decisive identification of extractables including transformation or degradation products
- Modifying specific controlled extractables methods or routine E/L testing
- Extractables studies for medical devices and medical packaging
- Glass delamination studies

Leachables Studies

- Detection and quantification of leachables even in complex drug matrices
- Validation of leachables methods for use in storage and stability analysis
- Conduct leachability or migration studies on polymeric material, medical devices or packaging
- Identification of leachables identification of leachables
- Risk assessments and toxicological evaluations

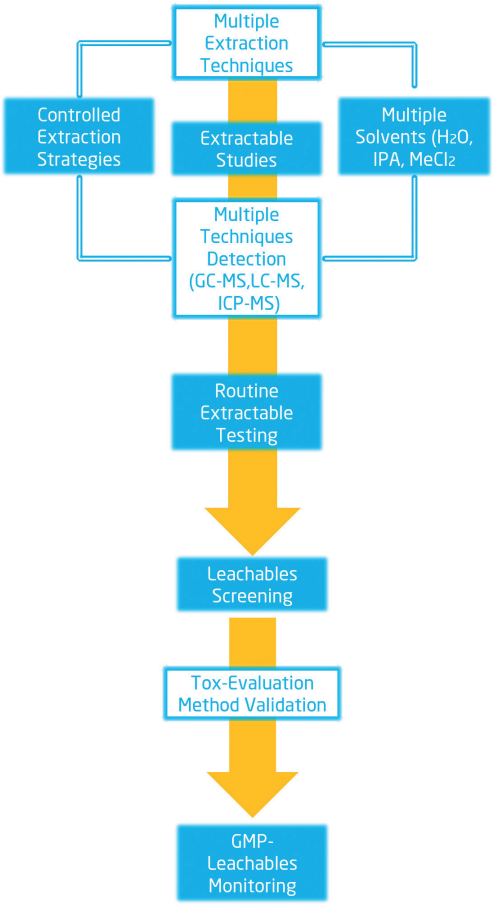

FIGURE
Full package supported for full compliance with the E+L guidelines

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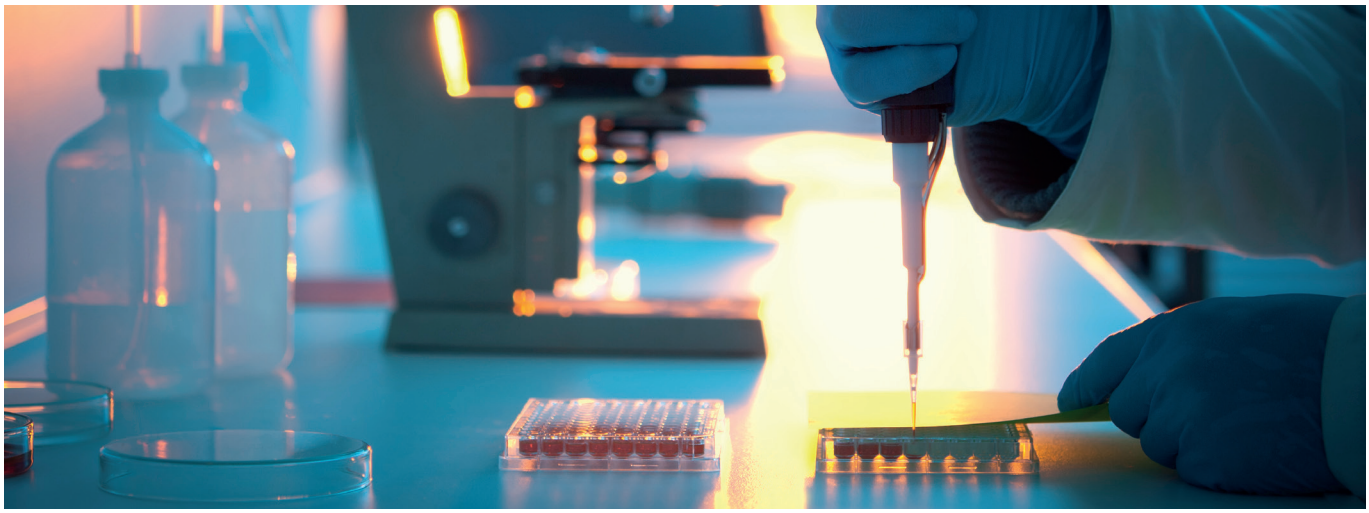
intertek
Total Quality. Assured.



What we deliver to our E/L customers:

- Tailor-made extractables and leachables studies for all types of container closure systems and packaging materials, process equipment or medical devices including printings and adhesives according to EMA and FDA requirements
- Consultancy for E/L studies in all phases of drug or device development of, e.g. evaluation and assessment of already available E /L data, gap analyses
- Toxicological assessment of the results of extractables and leachables studies
- Validation of analytical methods for leachables studies (according to GMP)
- Interaction studies for APIs with the packaging materials (according to GMP)
- Additive analysis in all types of polymer
- Assessment & analyses of process materials
- Structural elucidation of unknowns
- Seminars and training on extractables & leachables
- NMR + LC-MS-capabilities for structure evaluation absolute quantification and determination of the response factor.

Extractables / Leachables Toolbox

Intertek uses advanced analytical equipment to characterize both organic and inorganic elements and compounds:

- GC/MS: thermodesorption, headspace, liquid injection
- HPLC: LC-DAD, LC/MS, LC/MS/MS (ESI and APCI)
- MS: EI, CI, high resolution, commercial and in-house mass spectral libraries

- Elemental using and quantiative determination sing X-ray fluorescence, ICP-AES or ICP-MS
- TOC determination in aqueous extracts
- Modern tools for structural elucidation and absolute quantification (1H-, 13C-NMR, FTIR, UV, HRMS with LC-HRMS, HRMS, GC-HRMS, prep-LCMS)
- Reference standards (commercial + in-house synthesized)

Our Experts

Our centre of excellence for cGMP-compliant extractable and leachable services is located in Reinach close to Basel (Switzerland).
Our experts have specialized in analytical support for the pharmaceutical and medical device extractables / leachables and have over 25 years experience in this field coupled with an extensive knowledge of the polymer and packaging industries.

FOR MORE INFORMATION

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Dr. Tino Otte
Senior Scientific Consultant

Tino Otte, Senior Scientific Consultant at Intertek, is an expert for extractables-leachables-studies. He holds a degree in polymerchemistry from the University of Halle/Saale and a Ph.D. from the Darmstadt Technical University, where he graduated in 2010. He joined Intertek Switzerland in 2016. Prior to joining Intertek, he worked with different research, development and manufacturing companies where he served in several functions in product management and development of analytical services.
He has more than 7 years of experience in GMP regulated environment within multiple areas of product analysis including method development, validation and QC.