

EXTRACTABLES / LEACHABLES

LIFE

Pace Analytical Life Sciences (PLS) has developed a comprehensive approach towards extractable and leachable testing. PLS designs studies to identify extractables, compounds that can be extracted from a component under exaggerated conditions, and leachables, compounds that could migrate into a drug product or patient during direct contact under normal or simulated-use.

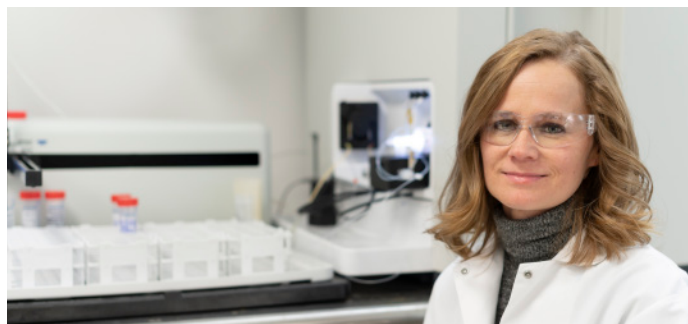
Extractable/Leachable and material characterization studies are critical to the pharmaceutical, biopharmaceutical, and medical device industry in evaluating the safety of packaged products and the biocompatibility of materials.

CONTROLLED EXTRACTION STUDIES

- Custom protocols
- Screening studies
- Identification of extractable compounds
- Material changes / process changes

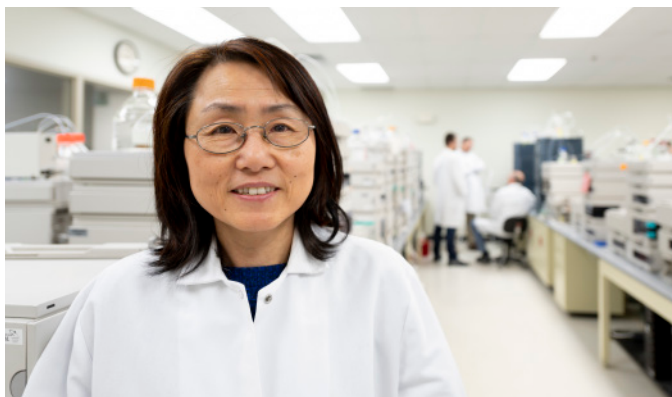
COMPONENT / MATERIAL EVALUATIONS

- Packaging components / Elastomeric closures
- Single-use systems for biomanufacturing
- Drug-delivery systems
- Medical device components



LEACHABLE STUDIES

- Method optimization / development / validation
- Identification and quantification of leachable compounds:
 - Monomers / Oligomers
 - Plasticizers
 - Catalysts
 - Lubricants
 - Adhesives
 - Antioxidants/Stabilizers
 - Impurities
- Real time, simulated, in-use studies
- Compliant with Good Manufacturing Procedures (GMPs)
- Submission-ready reports



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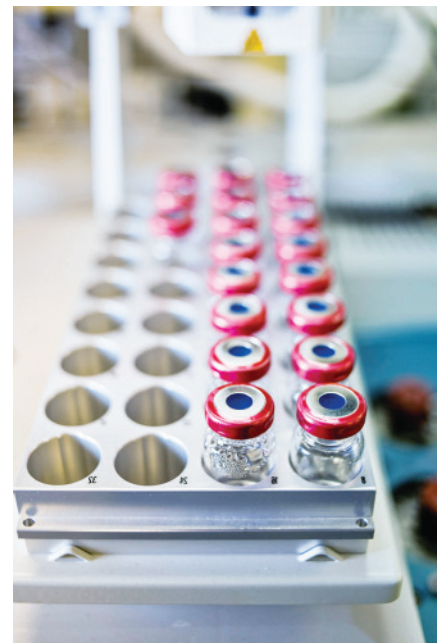


PLS COMPLIES WITH INDUSTRY GUIDANCE AND REGULATIONS:

- International Conference on Harmonization (ICH)
- U.S. Food & Drug Administration (FDA) Guidance for Industry
- European Medicines Agency (EMA)
- United States Pharmacopoeia series <381> / <661> / <1661> / <1663> / <1664> / <1665>
- European Pharmacopoeia (Ph.Eur.)
- Product Quality Research Institute (PQRI) recommendations
- Biophorum Operations Group (BPOG)
- Committee for Medicinal Products for Human Use (CHMP)
- Association for the Advancement of Medical Instrumentation (AAMI)
- Material Characterization, ISO 10993-18

PLS UTILIZES A WIDE RANGE OF POWERFUL ANALYTICAL INSTRUMENTATION:

- Headspace GC/MS for volatile organics
- Direct inject GC/MS for semi-volatile organics
- UPLC/MS and high-resolution MS (QTOF) for semi- and non-volatile organics
- Ion Chromatography (IC) for inorganic ions
- ICP/MS and ICP/OES for elemental impurities
- Gel-Permeation Chromatography (GPC) and Size-Exclusion Chromatography (SEC) for molecular weight distributions
- Fourier-Transform Infrared (FTIR) spectroscopy
- Differential Scanning Calorimetry (DSC) and Thermal-Gravimetric Analysis (TGA) for thermal analysis



PLS REFERENCES SPECTRAL LIBRARIES, ACCESSING THOUSANDS OF COMPOUNDS FOR ANALYTE SCREENING AND IDENTIFICATION:

- Proprietary high-resolution MS database targeting:
 - container-closure systems
 - medical device materials
- National Institute of Science & Technology (NIST)
 - Volatile and semi-volatile compounds by GC-MS
 - Semi-volatile and non-volatile compounds by LC-MS
- ChemSpider database for cross-referencing molecular formula determinations
- Customer-specific proprietary compounds and libraries



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