



EXTRACTABLES / LEACHABLES (E/L)

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 simulate-use conditions.

Controlled Extraction Studies

- Custom protocols
- Screening studies
- Identification of extractable compounds
- Medical device components
- Packaging components
- Drug-delivery systems
- Elastomeric closures
- Single-use systems for biomanufacturing
- Material changes / process changes

Leachable Studies

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



Our labs are cGMP-compliant, FDA registered, DEA registered and ISO/IEC 17025:2005 accredited.



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