eurofins | BioPharma Product Testing



Impurities Testing for Pharmaceutical Products and APIs

Eurofins BioPharma Product Testing offers comprehensive support for impurities testing and contaminant investigations--from residual solvents and process-related impurities to extractables/leachables and degradant-related issues. And with complementary expertise in method development, method validation and stability testing, our biopharmaceutical testing team is the perfect partner to provide corrective action follow-up support.

Why Choose Eurofins BioPharma Product Testing?

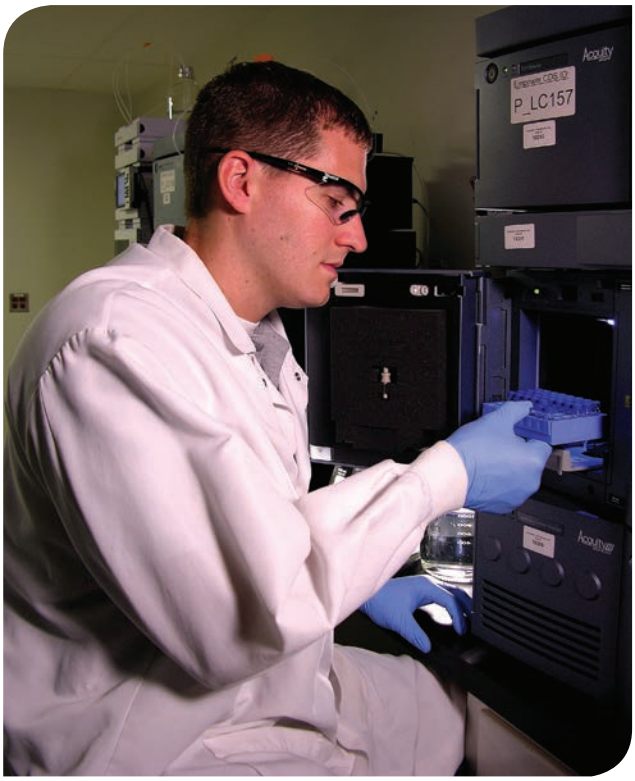
- Our scientists are experts at identifying and quantifying very low levels of impurities in the most difficult of sample matrices.
- We have decades of experience working with active pharmaceutical ingredients and drug product, across all major dosage forms and delivery systems, including unit dose vials (UDVs) and metered dose inhalers (MDIs).
- If you have a short-term or infrequent need for testing, our self-validating method approach for residual solvents testing is a faster and more cost-effective option.
- We can help determine the most suitable strategies for monitoring impurities and accelerating your drug development programs.
- Our self-validating method approach for residual solvents testing offers a faster and more cost-effective option for those with a short-term or infrequent testing needs.
- Our 30-year history of cGMP regulatory compliance ensures that you get the highest quality data.

Testing Available

Residual Solvents/Impurities

- USP <467> and Ph. EUR Method 2.4.24 (all classes of residual solvents in current chapter)
- Customized method development/validation
- Extractables/Leachables
  - Controlled extraction studies
  - Simulation studies
  - Leachable method development, validation & monitoring
- Validation of disposables for use in Biomanufacturing
- Customized method development/validation

  Specific example of methods include:
  - Establishment of methods for residual solvents using either GC or HPLC
  - Leachable methods is process intermediates or final formulations
  - Trace metals by Inductively Coupled Plasma in drug products



Process Impurities

- Customized method development/validation
- HPLC product and API specific methodology
- Qualitative/Quantitative analysis
- Tracking/trending of resulting stability studies

Degradation Products

- Customized method development/validation
- Forced degradation studies and assessment of peak purity
- Finished product and API specific methodology
- Qualitative/Quantitative analysis
- Tracking/trending of resulting stability studies

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Trace Metals

- Qualitative/Quantitative limits testing (using ICP and ICP/MS approaches)

Elemental Analysis

- Qualitative/Quantitative limits testing (using AA and CHN approaches)

Instrumentation

Mass Spectrometers

- Agilent GC/MS
- Agilent LC/MS-Iontrap
- Agilent LC/MS-TOF
- Applied Biosystems Voyager DE PRO MALDI-TOF
- Perkin Elmer Inductively Coupled Plasma ICP/MS
- Thermo Scientific Accela LC/LTQ Orbitrap XL
- Thermo Scientific TSQ Vantage LC/MS/MS systems with either Agilent 1290 or Thermo Scientific Accela LC's
- Waters Xevo G2 LC-MS/TOF
- Bruker ultrafleXtreme MALDI-TOF/TOF

Chromatography Equipment

- Agilent GCs with either headspace or direct injection sample introduction
- Agilent/Waters/Thermo Scientific HPLCs
- Dionex ICS-3000 Ion Chromatograph (IC)

Detectors

- Corona Charged Aerosol (CAD$^+$)
- Electrochemical (ECD)
- Evaporative Light Scattering (ELSD)
- Fluorescence (FL)
- Laser-Induced Fluorescence (LIF)
- Refractive Index (RI)
- Ultraviolet (UV)
- Photodiode Array (PDA)
- Diode Array (DAD)

Spectrophotometers

- PE Analyst 800 Flame Atomic Absorption Spectrometer
- PE Analyst 400 Flame Atomic Absorption Spectrometer
- PE CHN Analyzer
- PE Graphite Furnace Atomic Absorption Spectrometer

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

Flexible Service Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
Professional Scientific Services® (PSS)

Global Facilities

Australia	Denmark	India	Japan	Spain	UK
Belgium	France	Ireland	Netherlands	Sweden	US
Canada	Germany	Italy	New Zealand	Switzerland	

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