eurofins | BioPharma Product Testing



Impurities Testing for Pharmaceutical Products and APIs

From residual solvents and process-related impurities to extractables/leachables and degradant-related impurities, Eurofins BioPharma Product Testing offers a broad range of services in support of impurities testing. We are able to identify and quantify very low levels of impurities in the most difficult of sample matrices.

Why Choose Eurofins BioPharma Product Testing?

- 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.
- For unknown impurity identification, we offer the most extensive range of mass spectrometric approaches, including accurate mass.
- Our 30-year history of cGMP regulatory compliance ensures that you get the highest quality data.
- With extensive expertise in developing, validating and providing testing support for impurities, we can provide you with the best strategy for monitoring impurities and accelerating your drug development programs.

Testing Available

Residual Solvents/Impurities

- USP <467> (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

Trace Metals

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

Elemental Analysis

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

eurofins | BioPharma Product Testing



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)

Spectrophotometers

- PE Analyst 800 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	France	Italy	Sweden
Belgium	Germany	Netherlands	Switzerland
Canada	India	New Zealand	UK
Denmark	Ireland	Spain	US

9111_EU 0817

www.eurofins.com/biopharma