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 degradantrelated 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 products, across all major dosage forms and delivery systems, including unit dose vials (UDVs) and metered dose inhalers (MDIs).

We can help determine the most suitable strategies for monitoring impurities and accelerating your drug development programs.

Our 30-year history of cGMP regulatory compliance ensures that you get the highest quality data.

Testing Available

Process Impurities

- Customized method development/validation
- Finished product and API specific methodology
- Qualitative/Quantitative analysis
- Tracking/cumulative reporting of stability study data

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

Degradation Products

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

Trace Metals

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

Elemental Analysis

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

Peak Identification

- Identification of organic compounds using modern mass spectrometry

Nitrosamine Impurities

- Eurofins offers nitrosamine impurity analysis, as well as support testing for risk assessments.

Instrumentation

Chromatography Equipment

- Agilent GCs with either headspace or direct injection sample introduction
- Agilent/Waters/Thermo Scientific HPLC/UHPLC
- Dionex/Thermo Fisher Scientific ICS-5000/+ and ICS-6000/+
- Thermo Scientific Integrion HPIC

Mass Spectrometers

- Agilent GC/MS and GC/MS/MS
- Agilent LC/MS-TOF and QTOF
- Applied Biosystems Voyager DE PRO MALDI-TOF
- Perkin Elmer Inductively Coupled Plasma ICP/MS
- Thermo ICP/MS
- Thermo Scientific Accela LC/LTQ Orbitrap XL
- Thermo Scientific Vanquish LC/Orbitrap Exploris 120
- Waters Xevo G2 LC-MS/TOF and LC/MS/MS
- SCIEX Triple Quad 4500

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, DAD)
- Conductivity

Spectrophotometers

- PE Analyst 800 Flame Atomic Absorption
- PE Analyst 400 Flame Atomic Absorption
- PE CHN Analyzer
- PE Graphite Furnace Atomic Absorption
- Thermo iCE3500 Flame/Furnace Atomic Absorption
- Perkin Elmer PinAAcle 500 Flame Atomic Absortion
- Perkin Elmer AAnalyst 600 Furnace Atomic Absortion
- Perkin Elmer PinAAcle 900Z Furnace Atomic Absortion
- Perkin Elmer ICP/Optical Emission Optima 8300

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

Contact Us

North America: BioPharmaProductTesting@BPT.EurofinsUS.com
Europe: Information@BPT.EurofinsEU.com
APAC: easl.cserv@BPJP.EurofinsAsia.com
www.Eurofins.com/BPT

eurofins | BioPharma Product Testing