eurofins | BioPharma Product Testing



Biopharmaceutical Release Testing

To support your commercial product and clinical trial material release testing needs, Eurofins BioPharma Product Testing offers the capacity and breadth of capabilities to test your formulated bulk, final product or in-process materials in a timely manner.

We test materials against specifications for identity, purity, potency, impurities, physical properties and safety under strict cGMP compliance, and we customize individual programs to streamline lab documentation and reporting for the most efficient and quality-focused data deliverable possible.

Our multi-shift laboratory operations are designed to provide extensive capacity for larger volume release programs, as well as flexibility for smaller programs in a manner that allows for aggressive cycle times.

Our release testing services are backed by an outstanding scientific approach to problem solving and extensive expertise in Method Development and Validation.

Why Choose Eurofins BioPharma Product Testing?

- We have in-depth experience working with every type of modality and have the flexibility and extensive instrument capacity within our team to meet the ever-changing demands of production schedules and timelines.
- We are a center of excellence for development, optimization, and transfer of *in vitro* bioassays for potency.
- Our breadth of capabilities allows us to perform all testing of even the most complex conjugated molecules at one laboratory.
- Our global capabilities allow us to support your EU batch release requirements.

Our Experience Includes

- Therapeutic Proteins (MAbs, Biosimilars, Fusion & Recombinant)
- Synthetic Peptides
- Therapeutic Enzymes
- Conjugates
- Cell/Gene Therapy
- Vaccines

Potency/Bioassay Services

- Development and validation of cell-based bioassays using multiple formats, including absorbance, fluorescence, time-resolved fluorescence and luminescence as well as binding and competitive ELISAs.
- Assay optimization to eliminate sources of variability and ensure consistent performance for QC release.
- Multiple software packages available for data analysis, including Softmax Pro and StatLIA.

Instrumentation

- HPLC/UPLC
- UV
- qPCR
- CE/iCE
- Plate Readers
- MFI
- Mass Spectrometry
- IC
- KF

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Release Testing Capabilities*

Purpose	Test	Test
General (Compendial)	Appearance	
	pH	
	Osmolarity	
	Moisture	KFT
Identity	Insoelectric Point	CE, Gel, Strip
	Peptide Map	HPLC
	Western Blot	ELISA
Purity	Chromatographic Purity	HPLC
	Gel Purity	SDS Reduced & Non-Reduced
Potency	Protein Concentration	A280
	Binding Assay	ELISA
	Biological Activity	Cell Based Bioassay
Safety	Sterility	MF/DT
	Endotoxin	Kinetic
	Bioburden	
	Particulate Matter	Light Obscuration, MFI
Impurities	Specific to the Manufacturing Process	

*Example for an IgG1 mAb.

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

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