eurofins | BioPharma Product Testing

Pharmaceutical 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 drug substance, drug product or in-process materials in a timely manner.

We test materials against specification for identity, 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.

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.

Our breadth of capabilities allows us to perform all testing of even the most complex molecules at one laboratory location, helping to minimize the time between production and release. This includes chemical and microbiological testing, as well as more specialized testing such as pyrogen, antibiotic potency, bioassay and toxicity testing.

Our network of global facilities allows us to support your EU batch release requirements.

Instrumentation

- LC/MS, LC/MS/MS
- HPLC/UPLC
- GC/GC-Headspace
- IC
- ICP-MS/OES
- GPC
- GC/MS, GC/MS/MS
- KF
- SEC
- TOC
- Dissolution Baths: Apparatus 1,2,3 & 5-Distek/Agilent-(formerly Varian)/Hanson/SOTAX
- Particle Size Testers (Malvern)

Our Experience Includes

- Capsules (IR/SR)
- Contact Lenses
- Implantables (including stents, coronary sleeves and pacemakers)
- Injectables
- Inhalers

- Ocular Implants
- Oral Grades
- Liquids
- Patches
- Suppositories
- Suspensions
- Synthetic Blood
- Tablets (IR/SR)

Our Experience Includes

Purpose	Test
Physical Properties	Appearance
	pH
	Water (LOD or KF)
	Hardness
	Melting Point
	Density
	Viscosity
	Coating Integrity
	Particle Size
Identity	ID by IR
	ID by UV
	ID by packaging inspection
	Molecular weight by SEC
	Enantiomers

Purpose	Test
Potency	Assay by HPLC/ UPLC/IC
	Assay by UV
	Assay by Titration
	Preservatives
	Dimers
Elution/Dissolution	Dissolution (App 1,2,3,5)
	Solution Solubility
Purity/Contaminants	Impurities by HPLC/ UPLC, LC/MS/MS, GC/MS/MS
	Degradation Products by HPLC/UPLC
	Particles (Visible, Malvern, Sieve)
	Residual Solvents by GC
	Trace Metals by ICP/ ICP-MS
	ID of Unknowns by LC/MS and GC/MS
	Chiral Purity
Microbiology	Sterility
	Endotoxin
	Microbial Limits
	Organism Identification
Packaging Assessment	Constant Uniformity
	Packaging ID
	Packaging Stability (Container Integrity

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

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