eurofins | BioPharma Product Testing



Pharmaceutical Stability & Release Testing

To support your commercial product and clinical trial material stability and release testing needs, Eurofins BioPharma Product Testing Hamburg 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 laboratory operations are designed to provide capacity for release programs, as well as flexibility for smaller programs in a manner that allows for aggressive cycle times.

Why 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 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 stability chambers provide the most representative conditions for stability storage.
- Our network of global facilities allows us to support your EU batch release requirements.

Our Instrumentation

- HPLC / UPLC
- GC / GC-Headspace
- IC
- GPC
- TOC
- KF
- SEC
- UV-VIS and IR
- Dissolution Baths
- Stability chambers and refrigerators

Our Experience

- Active pharmaceutical ingredients (APIs)
- OTC products
- Herbal Drugs
- Cosmetics
- Injectables
- Liquids
- Capsules (IR/SR)
- Patches
- Suppositories
- Suspensions
- Tablets (IR/SR)
- Food supplements

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Release Testing Capabilities

Purpose	Test
Physical Properties	Appearance
	pH
	Water (LOD or KF)
	Hardness
	Melting Point
	Density
	Viscosity
Identity	ID by IR
	ID by UV
	ID by Packaging Inspection
	Molecular Weight by SEC
	Enantiomers
Potency	Assay by HPLC/UPLC/IC
	Assay by UV
	Assay by Titration
	Preservatives
	Dimers
Elution	Dissolution (App 1,2,5)
	Solution Solubility
Purity/Contaminants	Impurities by HPLC, GC and Headspace
	Degradation Products by HPLC
	Residual Solvents by GC
	Trace Metals by ICP/ICP-MS
	ID of Unknowns by LC/MS and GC/MS
Microbiology	Sterility
	Endotoxin
	Microbial Limits
	Organism Identification
Packaging Assessment	Constant Uniformity
	Packaging ID
Stability Storage	25°C 60% Relative Humidity
	30°C 70% Relative Humidity
	40°C 75% Relative Humidity
	5°C Ambient Relative Humidity

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

www.eurofins.com/biopharma