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)
Release Testing Capabilities

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Test</th>
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<tbody>
<tr>
<td>Physical Properties</td>
<td>Appearance, pH, Water (LOD or KF), Hardness, Melting Point, Density, Viscosity, Coating Integrity, Particle Size</td>
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<tr>
<td>Identity</td>
<td>ID by IR, ID by UV, ID by packaging inspection, Molecular weight by SEC, Enantiomers</td>
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<tr>
<td>Potency</td>
<td>Assay by HPLC/UPLC/IC, Assay by UV, Assay By Titration, Preservatives, Dimers</td>
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<tr>
<td>Elution/Dissolution</td>
<td>Dissolution (App 1,2,3,5), Solution Solubility</td>
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<tr>
<td>Purity/Contaminants</td>
<td>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</td>
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<tr>
<td>Microbiology</td>
<td>Sterility, Endotoxin, Microbial Limits, Organism Identification</td>
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<tr>
<td>Packaging Assessment</td>
<td>Constant Uniformity, Packaging ID, Packaging Stability (Container Integrity)</td>
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