

# Raw Materials and Excipient Testing

No bio/pharmaceutical product can be manufactured without first **establishing the identity, purity and quality** of its starting materials to ensure the product is suitable for its intended use. When this critical step in the bio/pharmaceutical manufacturing process is performed successfully, costly production problems and delays can be avoided.

Eurofins BioPharma Product Testing has a wide range of chemistry expertise and state-of-the art instruments required to perform all types of raw materials testing, **including qualification of compendial methods, as well as development, qualification and validation of new methods.**

Whether you are looking for assistance in the release of your raw materials for production purposes or in the qualification of your vendors, we can help keep your project on track. **All of our testing is performed in accordance with Ph. Eur, USP/NF, BP, JP, ACS and FCC** methodologies and monographs, in addition to any client-supplied or vendor-defined methods.

## Why Choose Eurofins BioPharma Product Testing?

Our laboratories are organized by function to allow analysts to apply their specialized techniques to your project.

We provide the most comprehensive raw materials testing package, 24/7 online access to data and flexible service models such as Fee-For-Service, Full-Time-Equivalent and Professional Scientific Services®.

Our extensive testing experience, coupled with expertise in scientific problem solving and compendial consultation, allows us to successfully meet your testing challenges and help you prevent costly production problems and delays.



## Testing Available

- Complete Compendial Analysis (USP, Ph. Eur, JP, BP, ACS, FCC)
- Residual Solvents
- Pharmaceutical Water (USP, Ph. Eur, JP)
- Elemental Analysis
- Thermodynamic Properties
- Trace Metals (USP <232> and <233>)
- Harmonized Microbial Limits Testing

## Testing Available

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| • AAS  | • NMR  |
| • Amino Acid Analyzer                                  | • Osmometry  |
| • AA, GFAA   | • Polarimetry  |
| • Autotitration  | • ROI  |
| • CHN Analysis   | • SEC  |
| • Conductivity   | • SFC  |
| • Differential Scanning Calorimetry/TGA/ Melting Point | • TLC  |
| • Fourier Transform Infrared Spectroscopy              | • TOC  |
| • GC   | • Turbidity  |
| • GPC  | • UV Spectroscopy  |
| • HPLC-IC/PAD/ELS/RI/ UV/DAD                           | • Viscosity  |
| • ICP/MS, ICP  | • Water Determination by Karl Fischer (Volumetric & Coulometric) |
| • LC-QTOF  | • X-Ray Diffraction (XRD)  |
| • Loss On Drying/ Gravimetric Analyses                 | • Microscopy   |
| • NIR  | • Nitrogen content by Kjeldahl                                   |

### 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)  
PSS Insourcing Solutions®

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