eurofins | BioPharma Product Testing



Active Ingredients and Excipients

No biologic/pharmaceutical product can be produced without the identity, purity and quality of the underlying raw materials first being tested. Only if this critical step in the production process of biologic and pharmaceutical products has been successfully completed can costly production problems and delays be avoided.

We offer you a full range of services related to the analysis of active substances and additives. Regardless of whether you need support in the approval of your raw materials for production or in the qualification of your suppliers – we can help.

The review of entire monographs, whether of properties, identities, or of purity and content, is routine for us. In addition to chemical, microbiological and physical examinations in accordance with methods from widespread pharmacopoeias or based on your own methods, we offer advice in analytical matters.

Why Choose Eurofins BioPharma Product Testing?

The Eurofins BioPharma Product Testing Group is the largest network of harmonized BioPharma Product Testing labs in the world and has at its disposal the largest range of analytical experience and state-of-the-art equipment for performing all types of testing on raw materials. We are ready to assist you as a full service provider.

We offer an extensive raw material analysis package, including 5-day express testing and flexible service models, including “Fee for service”, “full-time equivalent” and Professional Scientific Services® (PSS). Ask us for further details!

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.

In addition to raw materials, we of course also offer testing services for finished pharmaceuticals, intermediates and starting materials, both for small and large molecules.

Our Service

Validation / Method Development

Method transfer, method verification and method validation services in accordance with ICH Q2 guidelines and method development are also offered. We have experts around the world in all fields available for this. They communicate closely with one another to address complex problems and work to find the perfect solution to your issue as quickly as possible.

Residual Solvents

We routinely perform analyses of residual solvents in accordance with ICH Q3C, EP and USP, for which we have at our disposal a variety of GCs with headspace and liquid injectors as well as FID and multiple GC-MS systems.

Heavy Metals

We offer you the choice between limit tests and analyses using GAAS, FAAS or mercury analyzers. Of course, we also offer you ICP-MS examinations in accordance with ICH Q3D, USP or Ph. Eur. guidelines and will be glad to advise you in this regard.

Microbiology

Do you also need testing for microorganism content and pathogenic microbes? No problem – our microbiological facility specializes in testing raw materials and additives in accordance with EP or USP.

eurofins | BioPharma Product Testing



Stability Chamber Conditions:
Whether for imminent approval or as an "ongoing study", we offer you stability storage under the following conditions in Hamburg:

Long-term:	25°C / 60%
Intermediate:	30°C / 65%
Accelerated:	40°C / 75%
Cool/ambient:	5°C

In addition, it is also possible to examine the quality parameters directly on-site after outsourcing.

If your product requires other storage conditions, we have a variety of climatic conditions in a storage space of around 2,300 m^3 in France and in Sweden. Feel free to ask us for an up-to-date list.

Characterization of Organic Substances:
Do you require characterization of your pure organic substance? If so, we offer not only all common characterization methods such as IR, UV/VIS and mass spectrometry but also NMR (1H, 13C, 31P), XRD and elemental analysis (C, H, O, S, N) under GMP.

Specialized Equipment

If there are other test methods that you cannot perform in your own laboratory, we also have specialized testing equipment at your disposal in our group:

- AAS
- Amino acid analyzer
- CHN analyzer
- Differential scanning calorimetry
- FT-IR
- (Capillary) electrophoresis
- GC
- GPC
- HPLC-PAD/ELS/RI/MS/UV/DAD
- IC
- ICP-OES/MS
- NIR
- NMR
- Osmometer
- SEC
- SFC
- TOC
- Turbidity
- Karl-Fischer titration (volumetric, coulometric)
- X-Ray

Pharmacopoeias

We always analyze in accordance with the most recent version of Ph. Eur., USP and FCC. If you are missing a test because the monograph has changed, we also have a well-maintained archive to refer to. Our library contains not only conventional pharmacopoeias (including DAB, DAC, BP, JP) but also the less common ones such as the Chinese Pharmacopoeia, the Ayurvedic Pharmacopoeia, the Homeopathic Pharmacopoeia and the Pharmacopoeia Helvetica. And of course, we also analyze based on any method provided by customers or manufacturers.

Quality

We are GMP-certified and have been for over 20 years. First, a sample is taken upon arrival to determine that it is undamaged, and storage conditions are reviewed and registered in our LIMS system. From this time, each sample container is uniquely marked with a barcode. Of course, each step is performed in accordance with a second person review. Additionally, each test report is reviewed in regulatory terms by QA. We would be pleased to send you our template for a Quality Agreement and/or Master Service Agreement on request.

pharma-hamburg@eurofins.de
Phone: +49 40 49294 5900

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