eurofins | BioPharma Product Testing



# Eurofins BioPharma Product Testing Hamburg

## Active Ingredients and Exipients

We provide the entire service concerning the analysis of active ingredients and excipients. No matter whether you require assistance in the release of your raw materials for production or assistance in the qualification of your suppliers we will be able to help.

The complete analysis according to monographs belongs to our daily business, no matter if it comes to characteristics, identities, impurities or assays. We have a huge variety of equipment for these tests including TOC, CAMAG TLC system, IR, UV, polarimeter, refractometer, and density meter, Kjeldahl, HPLC, GC, Karl-Fischer, Brookfield-viscosimeter, AAS and ICP-MS.

We do not only offer chemical, microbiological and physical analysis according to the methods of the current pharmacopoeias; additionally we also offer the implementation of customer methods as well as consulting concerning analytical problems.

## Validation / Method Transfer

Of course we also offer the possibility of method transfer as well as method verification or validation according to ICH Q2 guidelines. Our experts for all areas are gathered all over the world. Due to our close and constant contact, we are able to help with any complex problem you might have and find a suitable short-term solution.

## Residual Solvents

We perform the analysis of residual solvents according to EP or USP on a routine basis. Our equipment for this analysis consists of a multitude of GCs with headspace- and liquid-injectors, FID and several GC-MS systems.

## Heavy Metals

We offer a wide variety for the analysis of heavy metals. You may choose between limit test or the analyses with GAAS, FAAS or mercury-analyzer. Of course we can also offer the analysis according to the regulations of the EP, USP or ICH Q3D by ICP-MS.

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## Microbiology

Do you additionally need the analysis of bioburden or the presence of pathogens in your product? No problem, our microbiology department is specialized on the analysis of raw materials and additives according to EP, USP or ISO-methods.

## Stability Studies

Whether needed for registration or for ongoing studies, in Hamburg we can offer the following conditions:

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

After removal of the materials from the climate chambers, the quality control parameters can be analyzed directly on-sight. In case your product requires additional conditions, we also have access to a wide range of climate conditions in Sweden and France, adding up to 2,300 $m^3$.

Please feel free to ask us for the current list.

## Analysis of Persistent Organic Pollutants

You need the GMP analysis of Persistent Organic Pollutants (POPs)? Since 2011 we are the worldwide only laboratory, which analyses dioxins, PCBs, BFRs and PAHs according pharma-GMP standard. We are FDA audited and have experiences in the analysis of dioxins since 1985.

## Process Water Testing (EP/USP/JP/BP)

- On-Site Sample Collection
- Total Aerobic Microbial Count (membrane filtration or pour plate)
- Endotoxin Testing
- Total Organic Carbon Testing
- Conductivity Testing
- Nitrate Testing
- Heavy Metals Testing
- Total Coliform/Fecal Coliform Testing (source water)

## Quality

Eurofins BioPharma Product Testing Hamburg has been certified in accordance with Good Manufacturing Practice (GMP) and has been accredited with DIN EN ISO 17025.

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### 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**