

BioChem – analytical laboratory full service provider



microbiology



analytics



molecular biology/
bioanalytics



quality
management





analytical laboratory full service provider

BioChem Labor für biologische und chemische Analytik GmbH, founded in 1973, is one of the leading analytical contract laboratories in German-speaking countries. At our site in Karlsruhe, in southwestern **Germany**, we employ about 100 well-trained specialists. Our laboratory is independent, family-owned and is a member of the BioChem Group.

Our core competencies are:

- ▶ **microbiology** (see p. 3)
- ▶ **analytics** (see p. 4)
- ▶ **molecular biology/bioanalytics** (see p. 5)

Our worldwide customers value us as a flexible and quality-tested full service provider. We understand the challenges our clients are facing and solve important issues together with them. Our broad range of services is tailored precisely to the needs of customers from the **life science industry**, i.e. from the **pharmaceutical, chemical, medical device, cosmetics and diagnostics sectors**. We embrace the challenges our customers face and focus our attention on interdisciplinary work.

This includes, for example

- ▶ tests of raw, intermediate and finished products any dosage form within the scope of quality control
- ▶ method development, transfer and validation
- ▶ release tests within EU re-analyses
- ▶ stability studies according to ICH guidelines
- ▶ consulting on analytical issues i.e. for start-ups and biotech companies
- ▶ support in the development of pharmaceuticals

All of our high-quality laboratory services are focused on analytical issues in **GMP- and GLP-regulated and FDA-compliant areas**. In regular audits by authorities and customers we always prove compliance with current GMP-/GLP-regulations.

Our scientific experts are dedicated contacts for our customers and we work together on a reliable, trustful and long-term basis. If required, we are supported by external expertise so that our customers receive all analytical services from a single source.

With this brochure we would like to show which solutions we can offer you in your daily business. More information about BioChem can be found on our homepage **www.biochem.de** (see QR code).

We cordially invite you to get to know us!





BioChem's quality management

If you trust in BioChem, you are in the best of hands, because you work together with a quality-tested full service provider. Our high-quality standards are also regularly confirmed by the authorities during inspections.

BioChem's certifications:

- ▶ **GMP-certified** (last inspection: July 2019)
- ▶ **GLP-certified** (last inspection: December 2017)
- ▶ **FDA-registered** and repeatedly successfully inspected (last inspection: November 2017)

During 30-40 audits per year our customers review the implementation of all regulations and catch up on the details of our quality management system. Regular self-inspections by external experts also help us to identify possible weaknesses at an early stage and to implement improvements.

BioChem has the authorisation for:

- ▶ handling of **narcotics** according to § 3 BtmG
- ▶ handling of **narcotic precursors** according to GÜG and (EG) 273/2004 article 3 paragraph 2 of category 1 substances
- ▶ operation of a **genetic engineering facility** according to GenTG and GenTAufzV as well as GenTSV of security level 1 and 2 according to GenTSV (S2 project-bound, according to agreement)

In addition, BioChem has reported to the authorities:

- ▶ handling of **pathogenic organisms** according to §§ 44 IfsG
- ▶ handling of **epizootic disease organisms** according to TierSeuchErV

Furthermore, we meet the requirements for working with highly effective and toxic substances such as cytostatic drugs, hormones, narcotics, CMR substances (carcinogenic, mutagenic or reprotoxic), etc.

For further information please get in touch with our contact persons in the quality assurance unit.



BioChem's MICROBIOLOGY

Excerpt from the range of services offered by our microbiological department:

- **Microbiological examination of non-sterile products**
 - ▶ microbial enumeration tests (total microbial count/bioburden)
 - ▶ detection of specified microorganisms (by means of enrichment methods)
 - ▶ testing in accordance with acceptance criteria of Ph. Eur., Chapter 5.1.4
 - ▶ testing of herbal medicinal products for oral use
- **Identification of bacteria, yeasts and moulds**
 - ▶ colony morphological identification up to family or genus level
 - ▶ mass spectrometric identification up to species (MALDI TOF)
 - ▶ identification of microorganism isolates on sent-in agar media up to species
- **Sterility testing in sterility test isolators**
 - ▶ membrane filtration method
 - ▶ direct inoculation method
- **Biological indicator testing**
 - ▶ sterility testing
 - ▶ quantitative determination of spores
- **Bacterial endotoxin testing by LAL methods**
 - ▶ by means of gel clot, kinetic-turbidimetric or kinetic-chromogenic methods
- **Microbiological assays of antibiotics**
 - ▶ by means of agar diffusion method in active substances or finished products
- **Efficacy of antimicrobial preservation (antimicrobial effectiveness test)**
 - ▶ all dosage forms, with 4 or 5 test organisms
- **On-site environmental monitoring**
 - ▶ sampling, determination of the number of airborne microbes, laying out settle plates, surface monitoring and swab tests including supply of the media
- **Drinking water testing** in accordance with German drinking water regulation (TrinkwV)
- Non-routine tests and specific tests for almost all microbiological questions

For further information please get in touch with our contact persons in the microbiological department or ask for our service specifications.



BioChem's ANALYTICS

Excerpt from the range of services offered by our analytical department:

- **Analysis of water for pharmaceutical purposes**
 - ▶ determination of total organic carbon (TOC), conductivity, etc.
- **Particle measurement**
 - ▶ testing for visible and non-visible particles
- **Chromatography**
 - ▶ thin layer chromatography (TLC)
 - ▶ high performance liquid chromatography (HPLC)
 - ▶ ion chromatography (IC)
 - ▶ capillary gas chromatography (GC)
- **Spectroscopy/spectrometry**
 - ▶ UV/VIS spectroscopy/photometry
 - ▶ infrared spectroscopy (FT-IR)
 - ▶ atomic absorption spectroscopy (AAS)
 - ▶ inductive coupled plasma mass spectrometry (ICP-MS)
- **Electrochemical and physical analysis**
 - ▶ e.g. pH value (potentiometric), ions with selective electrode, conductometry (conductivity), titration (visual endpoint determination), titration (potentiometric), water content according to Karl Fischer (volumetric), polarimetry, specific rotation, etc.
 - ▶ visual tests, testing for visible and non-visible particles
- **Elemental analysis**
- **Release analysis** and determination of mass/content
- **Stability studies (storage and testing)**
 - ▶ stress and photostability testing
 - ▶ short-term and long-term stability studies
 - ▶ climatic conditions according to ICH guidelines or customer specifications

For further information please get in touch with our contact persons in the analytical department or ask for our service specifications.



BioChem's BIOANALYTICS/ MOLECULAR BIOLOGY

Excerpt from the range of services offered by our bioanalytical/molecular biological department:

- **Detection of mycoplasma**
- **Detection of biological contaminations**
 - ▶ detection of DNase, human DNA, bacterial DNA, RNase, RNA, PCR inhibitors and ATP in consumables (e.g. pipette tips, reaction tubes, etc.), reagents, etc.
 - ▶ further PCR- and real-time PCR based detections according to customer requirements
- **Determination of content and identity of nucleic acids**
 - ▶ fluorometric DNA determination
 - ▶ UV/VIS DNA determination
 - ▶ size determination of nucleic acids
 - ▶ determination of nucleic acid identity
- **Determination of biological activity**
 - ▶ determination of streptokinase activity
 - ▶ determination of Heparin Anti-Factor Xa or Anti-Factor IIa activity
- **Protein analysis**
 - ▶ determination of amino acid compositions in amino acid analyser
 - ▶ determination of identity and purity by means of SDS-PAGE
 - ▶ determination of content according to Bradford, Lowry, BCA, Biuret, OD280, ELISA
 - ▶ capillary electrophoresis
- **Detection of host cell proteins, residual DNA or small molecules**
 - ▶ determination by real-time PCR/ELISA or capillary electrophoresis/ELISA
- **Identification and determination of plants, animal species, bacteria, yeasts and moulds**
 - ▶ identification up to the species by PCR/sequencing
 - ▶ matching with „ID by tree database“
 - ▶ DNA fingerprinting - genetic typing of microorganisms (molecular phylogenetics)

For further information please get in touch with our contact persons in the bioanalytical/molecular biological department or ask for our service specifications.



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