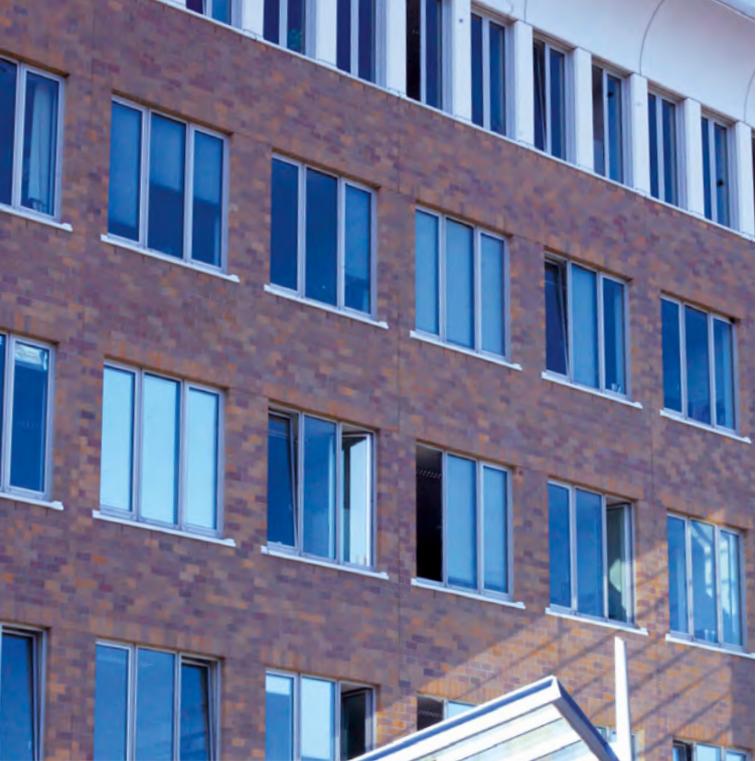


Analytical laboratory full service provider





Your contact person:

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Managing Director

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Since the early 1970s BioChem has been one of the leading analytical contract laboratories in the German-speaking (D-A-CH) region. Our laboratory stands for quality, reliability and the highest level of expertise in the field of microbiological, molecular biological and chemical-physical testing of pharmaceutical API, excipients and finished products. At our headquarters in **Karlsruhe** and the microbiological laboratory in **Gerichshain**, we employ around 130 well-trained, dedicated staff on over 5,000 square meters laboratory space. We are independent, family-run and part of the BioChem group. Our core competences are:

- ▶ **MICROBIOLOGY**
- ▶ **PHYSICAL-CHEMICAL ANALYTICS**
- ▶ **BIOANALYTICS/ MOLECULAR BIOLOGY**

Daily, we convince our global clients from the pharmaceutical, chemical, medical devices, cosmetics, and diagnostics industries of our quality-tested full-service solutions. They value us as a reliable, competent, and trustworthy business partner.

Our wide range of services includes for example:

- ▶ Testing of API, excipients and finished products of any dosage form as part of quality control
- ▶ Method development, transfer, and validation
- ▶ Dissolution testing within the scope of EU re-analytics
- ▶ Stability studies according to ICH-guidelines

Our high-quality testing laboratory services are focused on analytical issues in a **GMP-regulated and FDA-compliant environment**. In regular authority inspections and customer audits, we constantly prove our compliance with GMP requirements. If required we can outsource services to qualified partners, so all your analysis requirements are available from us as a single source. Further information and our current list of services can be found at www.biochem.de.

Welcome to the BioChem Group!

Dr Jochen Kolb
Managing Director



MICROBIOLOGY

Coming soon: Rapid Sterility Testing

Extract from the list of services:

- ▶ **Sterility testing in sterility test isolators**
 - Membrane filtration- and direct inoculation method
- ▶ **Bacterial endotoxin testing by LAL-methods**
 - Gel Clot-, kinetic-turbidimetric or kinetic-chromogenic method
- ▶ **Microbiological testing of nonsterile products**
 - Microbial enumeration tests
 - Test for specified microorganisms
 - Drinking water testing in accordance with German Drinking Water Regulation (TrinkwV)
- ▶ **Identification of microorganisms**
 - Colony morphological identification up to family or genus level
 - Mass spectrometric identification up to species level
- ▶ **Biological indicator testing**
 - Quantitative determination of population of spores and sterility testing
- ▶ **Microbiological assay of antibiotics**
- ▶ **Efficacy of antimicrobial preservation (Antimicrobial effectiveness test)**
- ▶ **On site environmental monitoring**
 - Air sampling and surface monitoring, including supply of the media
 - Incubation and evaluation of the media
- ▶ **Further microbiological services**



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PHYSICAL- CHEMICAL ANALYTICS

Extract from the list of services:

► **Chromatography**

- High Performance Liquid Chromatography (HPLC)
- Ion Chromatography (IC)
- Gas Chromatography (GC)
- Thin Layer Chromatography (TLC)

► **Spectroscopy/Spectrometry**

- Absorption Spectrophotometry, ultraviolet and visible
- Absorption Spectrophotometry, infrared (FT-IR)

► **Electrochemical and physical investigations**

- E.g. pH-value, ionic concentration by using electro ion-selective electrodes, conductometry, water content according to Karl Fisher, optical rotation, refractive index, density, viscosity, osmolarity
- Visual determination of appearance, determination of visible and sub-visible particles

► **Element analytics**

- Atomic absorption spectrometry (AAS)
- Inductively coupled plasma mass-spectrometry (ICP-MS)

► **Characteristic tests for tablets**

- Dissolution
- Disintegration testing, resistance on crushing of tablets, friability

► **Analysis of water for pharmaceutical purposes**

- Total organic carbon, total nitrogen, conductivity

► **Stability testing**

- Stress- and photostability testing
- Short- and long-term stability studies
- Climatic conditions according to ICH-guideline and customer's specifications



Your contact person:

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BIOANALYTICS/ MOLECULAR BIOLOGY

Extract from the list of services:

► **Bioanalytics**

- Capillary electrophoresis (2.2.47): CZE, MEKC, CGE, cIEF Chiral purity/ related substances, determination of anion / cation content
- Amino acid analysis (2.2.56): Ninhydrin-positive substances and ammonium, amino acid profiles of proteins and peptides

► **Detection of host cell proteins and residual DNA**

- Host cell proteins (HCP) using ELISA
- Residual DNA (e.g. CHO, HEK293, E.coli) using NAT method

► **Cell-based assays**

- Efficacy test (e.g. calcitonin salmon bioidentity)
- Bioassays e.g. in vitro cytotoxicity, potency assays, MoA studies (2.7.26)

► **Detection of biological contaminants**

- Human and bacterial DNA/RNA, DNase, RNase, PCR inhibitors, ATP in consumables, reagents, etc.
- Mycoplasma (2.6.7)
- Endotoxins using the rFC test (2.6.32)

► **Protein analysis**

- Biological activity determination (e.g. heparin, trypsin, etc.)
- ELISA techniques

► **Identification and detection of bacteria, fungi and yeasts**

- Identification to species by PCR/sequencing
- Phylogenetic classification using a GMP-compliant database
- DNA fingerprinting - genetic classification of microorganisms



Your contact person:

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QUALITY MANAGEMENT

With BioChem as your quality-tested full-service provider you are in the best of hands. Our high-quality standards are regularly confirmed by authorities during inspections.

BioChem is:

- ▶ **GMP-certified**
- ▶ **FDA-registered and successfully inspected repeatedly**

Since 2022 BioChem has held a manufacturer's authorisation for:

- ▶ **Human medical products** and **clinical investigational medical products** according to § 13 AMG and (EU) 536/2014
- ▶ **Veterinary medical products** according to § 28 TAMG and (EU) 2019/6

In 40-50 audits per year, our customers assess the implementation of the regulations directly in our laboratory and familiarize themselves with our quality management system. Additionally, regular self-inspections help us to identify potential weaknesses at an early stage and to implement improvements.

BioChem has the authorisation for:

- ▶ the handling of **narcotics** according to §3 BtmG
- ▶ the handling of **basic substances according to GÜG** and (EG) 273/2004 Art. 3 Para. 2 with substances according to Cat 1.
- ▶ the operation of a genetic engineering facility according to GenTG and GenTAufzV as well as GenTSV safety levels 1 and 2 according to GenTSV (S2 only project-related by arrangement)

In addition, BioChem has officially reported:

- ▶ Activities with pathogens according to § 44 IfSG
- ▶ Activities with epizootic pathogens according to Tier-SeuchErV

We also fulfil the requirements for working with highly effective and toxic substances e.g. cytostatics, hormones, anaesthetics, CMR substances, etc.



Your contact person:

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Qualified Person

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