BioChem
Labor für biologische und chemische Analytik GmbH

List of services

Valid from July 1, 2026

BioChem Labor für biologische und chemische Analytik GmbH
Daimlerstraße 5b • 76185 Karlsruhe, Germany • +49 721 9737-0
biochem@biochem.de • www.biochem.de • A member of the BioChem Group

OUR EXPERIENCE - YOUR PROFIT

For over 50 years now, the independent family-owned contract laboratory **BioChem Labor für biologische und chemische Analytik GmbH**, has been offering laboratory services in the GMP environment.

Our expertise includes **microbiological, physico-chemical and molecular biological contract analysis** for global customers in the pharmaceutical and chemical industries as well as for manufacturers of medical devices and diagnostics.

Our strengths:

- internationally oriented, modern full-service provider
- broad range of services
- Analysis of all dosage forms, intermediate or finished products and raw materials
- Authorization to handle BtMs, raw materials, etc.
- Working with GMOs (§3 GenTG) as well as pathogens and animal disease agents (§44 IfSG) up to safety level 2

In addition to **GMP and GLP certification**, BioChem is **FDA registered** and has a **manufacturing authorization in accordance with the German Medicines Act (AMG).**

We regularly and successfully demonstrate our company's compliance with **the EU GMP guidelines**, the **OECD** and in particular the quality requirements of **21 CFR part 820** during inspections by the authorities and customer audits.

Below you will find an overview of our services including indicative prices. The prices quoted are net prices plus German VAT (where applicable).

With the publication of this list of services as on January 1, 2026 previous versions become invalid. Prices, errors and technical changes are reserved.

We would be pleased to create a product- and project-specific offer, which of course takes quantity-specific synergy effects within the scope of combination or graduated prices into account.

New in 2026!

Purity and heterogeneity testing of monoclonal antibodies (mAB):

- Bio-inert (U)-HPLC (size exclusion (SEC)/ion exchange (IEC) chromatography)
- Molecular weight determination using CE-SDS (reducing/non-reducing)
- Charge heterogeneity by capillary isoelectric focusing (cIEF)
- N-glycan profiling to determine post-translational modifications
- Purity and integrity determination of mRNA and other IVT RNAs
- Detection of host cell contamination (host cell DNA/HCP)
- MAT test (monocyte activation test)

We look forward to your inquiry!

Your BioChem team

TABLE OF CONTENTS

1. MICROBIOLOGY

1.1 MICROBIOLOGICAL TESTING OF NONSTERILE PRODUCTS

1.1.1 MICROBIAL ENUMERATION TESTS

According to current versions of Ph. Eur., Chapter 2.6.12 plus USP, Chapter <61>

Basic prices

Pour plate, spread plate or spiral plate method:
TAMC (total aerobic microbial count) with max. 2 product dilutions .....
TYMC (total yeasts/moulds count) with max. 2 product dilutions .....
Combination of TAMC and TYMC .....
Any further product dilution within the same testing .....
Required sample volume: at least 10 g or ml

Membrane filtration method without additional rinsing of membrane filter:
TAMC (total aerobic microbial count) with max. 1 product dilution .....
TYMC (total yeasts/moulds count) with max. 1 product dilution .....
Combination of TAMC and TYMC .....
Any further product dilution within the same testing .....
Required sample volume: at least 10 g or ml

Membrane filtration method for CMR substances without additional rinsing of membrane filter:
TAMC (total aerobic microbial count) with max. 1 product dilution .....
TYMC (total yeasts/moulds count) with max. 1 product dilution .....
Combination of TAMC and TYMC .....
Any further product dilution within the same testing .....
Required sample volume: at least 10 g or ml

Additional charges

Membrane filtration method including rinsing of membrane filter
with 100 ml rinsing volume per membrane .....
Membrane filtration method including rinsing of membrane filter
with 3 x 100 ml rinsing volume per membrane .....
Quantitative detection of obligatory anaerobic microorganisms .....
Testing for the detection of obligatory anaerobic microorganisms is performed before and after heat treatment (80 °C, 10 min.) of a test solution or product dilution.

1.1.2 TEST FOR SPECIFIED MICROORGANISMS

According to current versions of Ph. Eur., Chapter 2.6.13 and USP, Chapter <62>

Basic prices

Detection of *P. aeruginosa, Staphylococcus aureus, Salmonella species* and
E. coli as well as other gram-negative bile tolerant Enterobacteriaceae
in 1 g/ml or 10 g/ml
together .....

Combined Prices

Microbial enumeration test (TAMC and TYMC) as well as qualitative detection of specified microorganisms (according to section 2.1.1 and 2.1.2) ..... [1]
..... [2]

Required sample volume: at least 30 g or ml

Combined prices include all testing parameters for the respective dosage forms and areas of application in accordance with the acceptance criteria of Ph. Eur., Chapter 5.1.4.

1.1.3 TESTING IN ACCORDANCE WITH ACCEPTANCE CRITERIA OF PH. EUR., CHAPTER 5.1.4

Basic prices

Preparations for rectal use (required sample volume: at least 10 g or ml)
Microbial enumeration test (TAMC and TYMC)
..... [1]
..... [2]

Preparations for oromucosal, gingival, cutaneous, nasal and auricular use
(required sample volume: at least 10 g or ml)
Microbial enumeration test (TAMC and TYMC)
and detection of *P. aeruginosa* and *S. aureus* in 1 g/ml
..... [1]
..... [2]

Aqueous and non-aqueous preparations for oral use (required sample volume: at least 10 g or ml)
Microbial enumeration test (TAMC and TYMC) and detection of *E. coli* in 1 g/ml
..... [1]
..... [2]

Oralia with raw materials of natural origin (required sample volume: at least 30 g or ml)
Microbial enumeration test (TAMC and TYMC) and qualitative determination of salmonellae in 10 g/ml plus *E. coli*, *S. aureus* und quantitative determination of gram-negative bile tolerant bacteria in 1 g/ml
..... [1]
..... [2]

Preparations for vaginal use (required sample volume: at least 10 g or ml)
Microbial enumeration test (TAMC and TYMC)
and determination of *P. aeruginosa*, *S. aureus* and *C. albicans* in 1 g/ml
..... [1]
..... [2]

Inhalables (required sample volume: at least 20 g or ml)
Microbial enumeration test (TAMC and TYMC) and determination of
P. aeruginosa, *S. aureus* and gram-negative bile tolerant bacteria in 1 g/ml
..... [1]
..... [2]

Transdermal patches (required sample volume: at least 10 patches)
Microbial enumeration test (TAMC and TYMC) by membrane filtration
and qualitative determination of *P. aeruginosa* and *S. aureus* in 1 g/ml .....
Sample preparation for transdermal patches (per 10 pieces) .....

1 Microbial enumeration test (TAMC and TYMC) by means of surface spread, pour plate or spiral plate method
2 Microbial enumeration test by means of membrane filtration method incl. rinsing of membrane filter with at least 1 x 100 ml rinsing volume

Qualitative determination of obligatory anaerobic microorganisms in 1 g/ml

Testing for the detection of obligatory anaerobic microorganisms is performed before and after heat treatment (80 °C, 10 min.) of a test solution or product dilution by means of enrichment process

Additional testing or other combinations of specified microorganisms

With simultaneous testing of the above-mentioned combinations, per specified germ

For individual testing without bacterial count, per specified germ

1.1.4 TESTING OF HERBAL PHARMACEUTICALS FOR ORAL USE IN ACCORDANCE WITH PH. EUR., CHAPTER 2.6.12 AND 2.6.31 AND ACCEPTANCE CRITERIA OF CHAPTER 5.1.8

Category A-Products (required sample volume: at least 35 g or ml)
Microbial enumeration test (TAMC and TYMC) and quantitative detection of
E. coli in 1 g/ml and qualitative detection of salmonellae in 25 g/ml

[1]

[2]

Category B- and C-Products (required sample volume: at least 45 g or ml)
Microbial enumeration test (TAMC and TYMC) and qualitative detection of
E. coli in 1 g/ml, Salmonella in 25 g/ml and quantitative detection of
gram-negative, bile tolerant bacteria in 1 g/ml

[1]

[2]

The above prices do not include the identification of grown colonies. All microorganisms detected during enrichment procedures are identified according to state-of-the-art methods (see section 1.2 Identification of microorganisms) to provide clients a comprehensive, GMP-compliant view of the microbial status. At client's request, we also carry out identifications of microorganisms from enumeration tests. The above prices refer to tests according to methods defined in the pharmacopoeias.
Product-specific suitability tests (validation) are not included in the prices and will be invoiced separately according to offer. The suitability tests are a prerequisite for the proof of a valid test procedure and are required in the pharmacopoeia.

1.1.5 ADDITIONAL CHARGES FOR MICROBIOLOGICAL TESTS

Special sample preparations
e.g. emulsification in Tween® 80, sonication, Ultra-Thurrax®, Stomacher®, tablet mill, etc.
per each weighed sample

pH value adjustment of stock solutions
for each product dilution or stock solution

Buffer and culture medium volumes other than specified by pharmacopoeia (e.g. 500 ml up to a maximum of 1,000 ml) after method modification following validation
per container

Additional weighing, per weighing

1 Microbial enumeration test (TAMC and TYMC) by means of surface spread, pour plate or spiral plate method
2 Microbial enumeration test by means of membrane filtration method incl. rinsing of membrane filter with at least 1 x 100 ml rinsing volume

Working with highly effective and/or toxic substances e.g. narcotics, cytostatic drugs, hormones, antibiotics and CMR substances (carcinogenic, mutagenic, reproductive toxicity)
per test .....

1.1.6 PRODUCT-SPECIFIC VALIDATION OF TEST METHODS

depending on test methods, acceptance criteria and product .....
We would be pleased to give personal advice and prepare an individual offer for your specific questions.

1.2 IDENTIFICATION OF MICROORGANISMS

Colony morphological identification up to family or genus level
within microbial purity testing in accordance with Ph. Eur., Chapter 2.6.13
.....
additionally: Gram-colouring .....
additionally: catalase test, oxidase test, aminopeptidase .....

Identification of microorganism isolates on sent-in agar media up to the species
(also within microbial purity testing in accordance with Ph. Eur., Chapter 2.6.13)
by means of MALDI TOF by means of
- extended direct transfer method .....
- formic acid extraction method (following extended direct transfer method, if necessary) in addition .....
- formic acid extraction method (depending on microorganism spectrum) .....
- Gram-colouring, catalase/oxidase test after MALDI-TOF identification without result.....
.....
- additional cultivation in liquid growth media and special sample preparation for the identification of moulds, in addition .....

The above prices for microorganism identification include the inoculation of a maximum of two subcultures to produce pure cultures and purity controls at the common incubation temperatures of 20-25 °C, 30 °C or 30-35 °C.

Further subcultures, if necessary, in the case of non-growth, to verify the purity control or to verify colony-morphologically not clearly identical microorganism isolates prior to identification
per subculture .....

Sub-cultivation of mould cultures in the context of plausibility checks on three different growth media (e.g. DG18, malt extract and Sabouraud agar), macroscopic and microscopic evaluation as well as literature research
per microorganism .....

Identification of moulds via colony-morphological and microscopic characteristics
on different growth media .....

Storage of vegetative microorganisms after identification by BioChem:
Isolation of microorganism isolates with different colony morphologies, preservation of pure cultures as master cultures (1 container with 25 cryo perls or 10 containers with 1 to 2 ml microorganism suspension) and storage for one year at -75 °C to -80 °C as well as client-specific documentation of the measures carried out.
per microorganism .....

per additional year (per cryo box with max. 144 microorg.).....

Verification of purity and identity as part of further storage.....

Molecular biological methods for the identification of microorganisms possible, please refer to:
MOLECULAR BIOLOGY/BIOANALYTICS, PAGE 25, CHAPTER 3.8

Storage of aerobic spore-forming microorganisms after identification by BioChem:
In the case of aerobic spore-forming microorganisms, preparation of a spore suspension after prior identification, preparation of spores on sporulation agar, cultivation, washing off of the spores after sporulation, washing of the spores and heat treatment to kill vegetative cell forms, storage/preservation of the spores in absolute ethanol, preservation of the pure cultures as master cultures (10 containers with 1 to 2 ml suspension) and storage at -75 °C to -80 °C, determination of the microorganism count of the spore suspension as well as client-specific documentation of the measures carried out.
per microorganism .....

1.3 STERILITY TESTING

Testing in accordance with Ph. Eur., Chapter 2.6.1 and USP, Chapter <71> in the current version. Tests are carried out in sterility test isolators.

1.3.1 MEMBRANE FILTRATION METHOD

By means of cellulose mixed ester membrane
Testing of 1 to max. 20 individual containers, without rinsing the membrane filters
2 growth media, incubation time 14 days, per test .....
additionally, from 21 to max. 40 individual containers, per test .....

By means of PVDF (polyvinylidene difluoride) membrane
Testing of 1 to max. 20 individual containers, without rinsing the membrane filters
2 growth media, incubation time 14 days, per test .....
additionally, from 21 to max. 40 individual containers, per test .....

1.3.2 DIRECT INOCULATION METHOD

Growth media volume 200 ml, sample to growth media ratio 1:10 for liquid formulations,
1:100 for solid, insoluble preparations
2 growth media, incubation time 14 days .....
Multiple tests to be compliant with minimum sample volumes per culture medium
each additional culture with 2 culture media within the same test .....

1.3.3 ADDITIONAL CHARGES FOR STERILITY TESTING

Rinsing of the membrane filter (flushing of both membrane filters) to remove inhibiting substances
with 3 x 50 ml each (3 x 100 ml per test), per test .....
with 3 x 100 ml each (3 x 200 ml per test), per test .....
with 5 x 100 ml each (5 x 200 ml per test), per test .....

Dissolving of lyophilizates, powders, etc. (up to 20 containers)
depending on volume, per test .....
for each additional container .....

Penicillinase treatment .....

Preparation of mixed samples for creams and eye ointments

from a maximum of 10 tubes .....

Larger volumes of culture media (> 200 ml up to a maximum of 2,000 ml) for 2 growth media
.....

Detection of microbial growth with substantial turbidity at the end of the sterility test
by transferring aliquots from the nutrient bouillons into fresh bouillons
per test .....

Subcultures from growth media at the end of sterility testing
by means of inoculation loops if bacterial growth is suspected on 5 to 6 different growth media with aerobic and anaerobic incubation
per test.....

Identification of microorganism isolates in case of a positive sterility test
..... prices according to section 1.2

Working with highly effective and/or toxic substances e.g. narcotics, cytostatic drugs, hormones, antibiotics and CMR substances (carcinogenic, mutagenic, reproductive toxicity)
per test .....

Tests in accordance with validated methods with increased effort .....

Testing for air tightness of primary container during
hydrogen peroxide sterilization in the isolator .....

Notes on sterility testing

Prices include batch-specific testing and documentation of sterility and growth properties of culture media and solutions used; in addition, microbiological environmental monitoring using settle plates, contact agar plates and active air sampling is conducted for every test.
The above prices refer to tests performed in accordance with the methods defined in the pharmacopoeias. Product specific suitability tests (validation) of sterility testing are not included in the prices and will be invoiced separately according to offer. The suitability tests are a prerequisite for the proof of a valid test procedure and are required in the pharmacopoeia.

1.3.4 PRODUCT-SPECIFIC VALIDATION OF TEST METHODS

Depending on test method and product .....
We would be pleased to give personal advice and prepare an individual offer for your specific questions.

1.4 BIOLOGICAL INDICATOR TESTING

Sterility testing (e.g. for checking the efficacy of sterilization processes)
one biological indicator + positive control .....

Each additional biological indicator at the time of result presentation
in one combined report .....

Quantitative determination of population of spores on spore strips, discs and in spore suspensions.
Individual testing of 4 units

following USP

Preparation and testing of **one** dilution series in decimal order
each unit .....

in accordance with USP

Preparation and testing of **two** dilution series in decimal order
each unit .....

1.5 BACTERIAL ENDOTOXIN TESTING BY LAL-TESTING

Performance in accordance with Ph. Eur., Chapter 2.6.14 and USP, Chapter <85> in the current version

1.5.1 GEL CLOT AND KINETIC-TURBIDIMETRIC METHODS

One sample or prepared test dilution of the preparations to be tested
up to the maximum valid dilution (MVD)
as single sample or as mixed sample beginning/middle/end .....

Any further dilution within the same test series on the same plate
or against the same standard series .....

1.5.2 KINETIC-CHROMOGENIC METHOD

One sample or prepared test solution of the preparations to be tested
up to the maximum valid dilution (MVD)
as single sample or as mixed sample beginning/middle/end .....

Any further dilution within the same test series on the same plate .....

Any further sample within the same test series on the same plate .....

All tests in accordance with the requirements of the current pharmacopoeias including standard series, negative controls with water-LAL/buffer in duplicate, positive controls with water-LAL/buffer in duplicate, positive controls for each measured test solution in duplicate.

1.5.3 ADDITIONAL CHARGES FOR LAL-TESTING

Each additional test solution or dilution with a new standard series or after new plate loading
Gelclot and kinetic-turbidimetric .....

Kinetic-chromogenic .....

pH value adjustment of the test solution .....

Use of endotoxin-free Tris buffer for adjustment of pH value
or as dilution medium for the test solution
each test dilution .....

Test of pH value of non-product-specific validated samples .....

Sample processing (e.g. for medical devices) .....

Working with highly effective and/or toxic substances e.g. narcotics, cytostatic drugs, hormones, antibiotics and CMR substances (carcinogenic, mutagenic, reproductive toxicity)
per test .....

1.5.4 PRODUCT-SPECIFIC VALIDATION OF TEST PROCEDURES

Depending on test procedure and product .....

We would be pleased to give personal advice and prepare an individual offer for your specific questions.

1.6 MICROBIOLOGICAL ASSAYS OF ANTIBIOTICS

According to Ph. Eur., Chapter 2.7.2 in the current version, agar diffusion method

Determination of potency of active substances and drug products with official pharmacopoeia or client's working standards including variance analysis
single test .....

Combined drug products against mixing standards, per antibiotic .....

Working with highly effective and/or toxic substances e.g. narcotics, cytostatic drugs, hormones, antibiotics and CMR substances (carcinogenic, mutagenic, reproductive toxicity)
per test .....

Determination of potency in combined drug products .....

Additional charges

Extraction of antibiotics from ointments and
further elaborately sample preparation .....

Calculation of weighted mean values for multiple determinations .....

Non aliquotable reference standard substances (declared in IU/container or µg/container)
per standard substance and container .....

Product-specific validation of test procedures following ICH guidelines

According to client requirements and depending on product .....

1.7 EFFICACY OF ANTIMICROBIAL PRESERVATION (ANTIMICROBIAL EFFECTIVENESS TEST)

1.7.1 ACCORDING TO USP, CHAPTER <51> IN THE CURRENT VERSION

5 test organisms
for category 1 products .....
for category 2 to 4 products .....

1.7.2 ACCORDING TO PH. EUR, CHAPTER 5.1.3. IN THE CURRENT VERSION

At the relevant times of reisolation (see below) depending on product type
parenteral and ophthalmic preparations (4 test organisms) .....
oral preparations (5 test organisms) .....
topical preparations (4 test organisms) .....

Indicated prices refer to the following times of reisolation:

Parenteral and ophthalmic preparations:

bacteria: t_0, 6 hours, 24 hours, 7 and 28 days
yeasts: t_0, 7, 14 and 28 days (according to requirements of criteria A and B)

Oral preparations:

bacteria and yeasts: t_0, 14 and 28 days

Topical preparations:

bacteria: t_0, 48 hours, 7, 14 and 28 days

yeasts: t_0, 7, 14 and 28 days (according to requirements of criteria A and B)

1.7.3 ACCORDING TO DIN ISO EN 11930

on request according to offer

1.7.4 ADDITIONAL CHARGES FOR ANTIMICROBIAL EFFECTIVENESS TEST

Per additional test organism .....

Each additional point of time of reisolation in addition to the required times of reisolation, per test strain .....

Complex sample preparations e.g. emulsification of ointments with Tween® 80 each reference organism and point of time .....

Complex sample preparation of semi-solid dosage forms, e.g ointments each reference organism at t0 .....

Modified tests varying from pharmacopoeial requirements .....

Working with highly effective and/or toxic substances e.g. narcotics, cytostatic drugs, hormones, antibiotics and CMR substances (carcinogenic, mutagenic, reproductive toxicity) per test .....

1.7.5 PRODUCT-SPECIFIC VALIDATION OF TEST METHODS

Product-specific validation of test methods depending on the test procedure, product and product category .....

We would be pleased to give personal advice and prepare an individual offer for your specific questions.

Please note:

The basic prices for microbiological tests shown under section 1.1 to 1.7 apply based on the test methods specified in the pharmacopoeias, for which the testing costs can be estimated. Depending on the respective test sample, there may be an increase in additional work involved in sample preparation and test performance.

If this additional expenditure should be known in advance or becomes obvious based on validation studies, the client will be informed in advance of any additional charges incurred. This also applies to tests of additional specification parameters that are not shown in our service specifications.

Please contact us, we would be pleased to advise you and send you an individual offer for any questions.

1.8 ON SITE ENVIRONMENTAL MONITORING

Active air sampling is performed using RCS®Plus microbial air sampler or semiquantitative by settle plates. Surface monitoring is performed using Rodac® plates as well as swab tests including supply of the media by BioChem.

Round trip

at an hourly rate of .....

per km travelled .....

Sampling on site

at an hourly rate of .....

Incubation and evaluation of air sampling strips, settle plates, Rodac® plates

per air sampling strip or plate .....

per swab test .....

Additional charges

Identification of microorganism isolates .....

Rental of an air sampler including days of dispatch and return

per day .....

Supply of culture media for environmental monitoring .....

1.9 FURTHER MICROBIOLOGICAL SERVICES

Incubation and evaluation of tests within the scope of hygiene inspections of ventilation and air conditioning systems according to VDI 6022 .....

Drinking water testing in accordance with German Drinking Water Regulation (TrinkwV)
Determination of the total bacterial count at 22 °C ± 2 °C and at 36 °C ± 2 °C.
Testing for absence of *E. coli*, coliform germs, faecal enterococci in 100 ml, per sample .....

Testing for absence of *P. aeruginosa*, *C. perfringens* and *Legionella spp.* .....

Determination of minimum inhibitory concentration .....

Bactericidal and fungicidal testing .....

Microbiological qualification of sterilisation processes,
e.g. by use of bio indicators and endotoxin reduction .....

Disinfectant tests under simulated practical conditions .....

Simulated microbiological in use stability tests .....

Microbiological container closure integrity tests .....

Growth controls of culture media with test organisms according to pharmacopoeia
depending on test organisms, number of test organisms and simultaneously ordered tests
per test organism .....

Media Fills: storage, incubation, evaluation, checking of growth characteristics, depending on
the number of sample containers to be stored and evaluated .....

Testing of medical products

Bioburden, sterility, bacterial endotoxins and further tests with microbiological background can be offered. Testing depending on the product geometry, test methods and number of items

Further services

Shipment of culture media or sample container

Shipment of microorganism cultures on culture media

The microbiological tests listed in this service specification represent the majority of tests required for pharmaceutical quality control in accordance with the current pharmacopoeias and other guidelines. Further microbiological tests that we offer in our laboratory with a wide variety of microbiological questions are not listed in this service specification. All prices quoted relate to validated test methods. Additional charges need to be invoiced for non-validated test methods.

We would be pleased to give personal advice and prepare an individual offer for your specific microbiological questions. Please do not hesitate to contact us.

2. ANALYTICS

2.1 CHEMICAL AND PHYSICAL ANALYSES

2.1.1 SAMPLE PREPARATION

The following sample preparation techniques are established as standard at BioChem:

- Preparation of sample, standard or reference solutions
- Mechanical sample preparation, e.g. crushing, washing, homogenization, recrystallization
- Concentration of solutions by means of rotary evaporators
- Distillation
- Extraction
- Solid-phase extraction
- Filtration
- Ashing
- Drying
- Digestion, e.g. closed digestion, open digestion, microwave digestion
- Column chromatographic processing
- Sample preparation for chromatography
- Derivatization
- Preparation of mixed samples etc.

Prices will be calculated on a time and material basis. We would be pleased to give personal advice and prepare an individual offer for your specific questions.

2.1.2 CHROMATOGRAPHY

2.1.2.1 Thin layer chromatography (TLC)

Including photographic documentation

TLC identity testing .....

TLC purity testing (semi-quantitative), limit testing .....

Application of special spray reagents .....

2.1.2.2 High performance liquid chromatography (HPLC)

Detection: UV-VIS, diode array detector (DAD), refractive index (RI),
fluorescence detector und light scattering detector (ELSD), mass spectrometry (MS)[1]

(U)HPLC identity testing .....

(U)HPLC identity/content testing .....

(U)HPLC purity testing /related substances .....

2.1.2.3 Ion chromatography (IC)

Conductivity detection; anions/cations with/without suppressor technology, amperometric detection

IC identity testing .....

IC identity/content testing .....

IC purity testing .....

2.1.2.4 Capillary gas chromatography (GC)

Detection: flame ionization detection (FID), electron capture detection (ECD), phosphorus nitrogen detection (PND), thermal conductivity detection (WLD or TCD), mass spectrometry (MS)[1]

Carrier gases: helium, hydrogen. Make-up gases: helium, nitrogen

Sample feeding systems: liquid: autosampler or manual; gaseous: headspace

GC content testing
GC limit testing
GC testing for related substances
GC testing for residual solvents
GC fatty acid composition
GC ethylene oxide (EO)/dioxane determination
GC residual oxygen determination
GC ethylene oxide (EO)/ethylene chlorohydrin (ECH)/ethylene glycol (EG) determination

2.1.2.5 Special chromatographic methods

Chromatographic enantiomer separation

2.1.3 SPECTROSCOPY/SPECTROMETRY

2.1.3.1 UV/VIS spectroscopy/photometry

UV/VIS identity testing
UV/VIS content testing

2.1.3.2 Infrared spectroscopy (FT-IR)

Measurement: liquid or solid/ KBr pellet or via ATR
FT-IR identity testing: KBr pellet
Film
Measurement by attenuated total reflection ATR
FT-IR quantitative

2.1.3.3 Atomic absorption spectroscopy (AAS)

AAS flame, graphite furnace or cold steam/hydride technology
Additional special techniques and reprocessing steps
in case of interferences caused by sample matrix

2.1.3.4 Inductive coupled plasma mass spectrometry (ICP-MS)

qualitative and quantitative determination/
identity, content, purity and residue testing
Additional reprocessing steps
in case of interferences caused by sample matrix

2.1.4 ELECTROCHEMICAL ANALYSES AND TITRATION

pH value (potentiometric)
Ions with selective electrode
Conductometry (conductivity)
Titration (visual endpoint determination)
Titration (potentiometric)
Water content according to Karl Fischer (volumetric)

2.1.5 PHYSICAL ANALYSES

Polarimetry, specific rotation at 589 nm
Refractometry, refractive index at 20 °C

1 Tests are carried out at a qualified partner laboratory

Gravimetry to constant weight (e.g. loss on drying)
Density by densimeter (oscillation measurement)
Density by pycnometer - liquids
Melting point/solidification range
Boiling point
Viscosity according to Ubbelohde
Viscosity by rotational viscometer (spindle)
Surface tension
Osmolality (by freezing point reduction)
Osmolality (by vapour pressure osmometer)
Consistency (micro-penetrometer)

2.1.6 TOTAL ORGANIC CARBON (TOC)

Total organic carbon (TOC)
Additional processing steps
Cleaning validation

2.1.7 TOTAL NITROGEN (TN)

Total nitrogen (TN)
Combined with TOC

2.1.8 VISUAL TESTS

Clarity and opalescence of solutions
Colouring of solutions

2.1.9 PARTICLE TESTING

Testing for visible particles
Testing for non-visible particles:
Measurement by light blockage (method 1)
Microscopic determination (method 2)
Determination of the particle size distribution by sieve analysis (Ph.Eur. 2.9.38/USP<786>)

2.1.10 ADDITIONAL ANALYSES ON REQUEST, E.G.

Elemental analyses, per element [1]
Nuclear magnetic resonance spectroscopy (NMR) [1]
Mass spectrometry (MS) [1]

2.2 SPECIAL PHARMACEUTICAL ANALYSES

2.2.1 IN-PROCESS CONTROL, RELEASE AND STABILITY TESTING FOR PHARMACEUTICAL QUALITY CONTROL AND DEVELOPMENT

We accompany you with our analyses through all phases of the life cycle management of your raw materials and pharmaceutical products: from the first pharmaceutical developments within clinical studies phase I, II, III and IV, or comparative studies of generic drug development to registration and routine quality control up to launch and market release. The prices for Individual testing of characteristics, identity, purity and content correspond to the indicative basic prices of the chemical, physical and instrumental analyses listed above. We would be pleased to prepare a project-based individual offer that consider the desired procedure, matrix and deadline. Please do not hesitate to contact us.

1 Tests are carried out at a qualified partner laboratory

2.2.1.1 Testing according to a monograph

full analyses according to specification of the respective current pharmacopoeia or client's test instruction

2.2.1.2 Method development, validation and transfer

Method development/optimization

Validation/verification of procedures/product-specific validation according to ICH guidelines including test plan and report in agreement with the client (test scope)

Method transfer including test plan and report

2.2.1.3 Technological characteristics of solid dosage forms

Dimensions (n = 10)

Abrasion/friability

Resistance to crushing of tablets (n = 10)

Disintegration of tablets or capsules (n = 6)

2.2.1.4 Uniformity of mass/content

Uniformity of mass (n = 20)

Tablets, film-coated tablets

Divided tablets

Hard gelatine capsules

Uniformity of content, depending on analytical method

Photometry, HPLC, titration, etc. (n = 10)

2.2.1.5 Release of active substances

Paddle or rotating basket (n = 6), depending on analytical method

Photometry, HPLC, etc.

comparative dissolution profiles (f_2 test)

2.2.1.6 Water for pharmaceutical purposes

Physico-chemical tests according to current Ph. Eur.

Aluminium

Ammonium

Calcium, Magnesium

Chloride

Conductivity

Non-visible particles

Nitrate

oxidable substances

Acidic or alkaline reacting substances

Sulphate

Heavy metals

TOC

Evaporation residues

2.2.2 STABILITY STUDIES (STORAGE AND ANALYSES)

BioChem is your experienced partner for all issues regarding stability studies of pharmaceutical products (stress and photostability testing, short-term and long-term stability studies, on-going studies according to ICH guidelines).

Computer-monitored and alarm-secured climate rooms and climate chambers are available for the storage of samples. Beside storage conditions according to ICH guidelines (- 20 °C, 5 °C, 25 °C/60 % r.h., 30 °C/65 % r.h., 40 °C/75 % r.h.), further climatic settings can be offered on request. In addition, the storage of narcotics is possible. Costs for storage, logistics and analysis result from the specifications of the test material, the quantities to be stored and the stored study protocols. Please specify the number of batches, the volume of test samples, storage conditions needed and, if already determined, the test parameters and testing schedule, so we can prepare an offer for you. We would be happy to advise you.

Basic prices for storage and testing:

Initial storage (receipt etc.) of samples and preparation of stability test plans .....
Storage per batch, storage condition and month .....
Preparation of stability reports per test time .....
Return of test samples .....
Stability tests depending on scope .....

2.2.3 PHOTOSTABILITY TESTING/STRESS TESTS

Irradiation according to ICH Q 1B .....
Stress tests according to ICH Q 1A .....

2.2.4 PHARMACEUTICAL DEVELOPMENT

Within pharmaceutical development, BioChem supports you in any analytical issues: starting from the selection of suitable raw material batches, through the analyses of the first product formulations and testing for their suitability, to the first short-term stability studies and testing of pilot batches based on your preliminary release and runtime specifications, right up to testing first approval batches including preparation of the analytical documentation for registration.

This includes a screening of raw materials for impurities, the set-up of comparative release profiles and evaluation by means of f_2 tests or packaging material tests to optimize the duration as well as further tests according to client specifications.

For complex and long-term pharmaceutical developments, a BioChem project member is appointed to provide capable and consulting support in all project phases to ensure the success of your project: the approval.

2.2.5 PHARMACEUTICAL APPROVAL

We would be pleased to support you in planning and implementation of analytical questions in the context of your approval projects. Please ask for an offer related to your current project.

3. MOLECULAR BIOLOGY/BIOANALYTICS

MISCELLANEOUS

We would be pleased to offer you further molecular biological analyses on request. We also offer method validations and transfers on request. We will be happy to advise you in this regard and prepare an offer individually tailored to your requirements.

Prices listed refer to first samples, scale prices for samples in parallel analysis (follow-up samples) are possible.

Surcharges for working with highly effective and/or toxic samples and reagents such as narcotics, cytostatic drugs, hormones, antibiotics and CMR substances (carcinogenic, mutagenic, reproductive toxic) may be incurred.

For material costs and surcharges, see also the section ‘General additional charges’.

The tests are generally carried out in accordance with the current versions of Ph. Eur. and USP.

3.1 DETECTION OF MYCOPLASMA (NAT)

By Real-time PCR

cell-free material, aqueous solutions, etc., per sample .....

Cell-containing material, complex matrices, per sample .....

3.2 DETECTION OF BIOLOGICAL CONTAMINANTS

IN CONSUMABLES (E.G. PIPETTE TIPS, REACTION TUBES, ETC.), REAGENTS ETC.

DNase .....

Human DNA .....

Bacterial DNA .....

Human and bacterial DNA .....

RNase .....

Human RNA .....

Bacterial RNA .....

Protease .....

PCR inhibitors .....

ATP .....

On request, we offer further PCR and real-time PCR based detections. We would be pleased to prepare you a project-based individual offer. Please do not hesitate to contact us.

3.3 QUANTIFICATION OF NUCLEIC ACIDS AND PROTEINS

Fluorometric or UV/VIS DNA determination .....

Protein quantification (OD280, Bradford, Lowry, BCA, Biuret) .....

3.4 DETERMINATION OF BIOLOGICAL ACTIVITY

Determination of enzymatic activity (e.g. trypsin according to USP, streptokinase, etc.) .....

Determination of Heparin Anti-Factor Xa- or Anti-Factor IIa-activity
testing according to Ph. Eur. in the current version ..... *

3.5 PROTEIN ANALYSES (BIOSIMILARS, LARGE MOLECULES, ANTIBODIES ETC.)

Determination of identity and purity

SDS-PAGE (reducing/non-reducing)

Determination of proteins

ELISA

Capillary electrophoresis

Testing for related substances, identity and purity determination, chiral purity, etc.

Determination of anion and cation content

New in 2026!

Purity and heterogeneity testing of monoclonal antibodies (mAB)
Molecular weight determination using CE-SDS (reducing/non-reducing)
Charge heterogeneity using capillary isoelectric focusing (cIEF)
N-glycan profiling to determine post-translational modifications
Purity and integrity determination of mRNA and other IVT RNAs
Detection of host cell contamination (host cell DNA/HCP)

Amino acid analyses

Testing for ninhydrin positive substances

Testing for ammonium

Testing for ninhydrin positive substances and ammonium

Determination of the amino acid profile of peptides/proteins

Further analyses are available on request. Please ask for an offer related to your current question.

New in 2026!

Bio-inert (U)-HPLC

Size exclusion chromatography (SEC)
Ion exchange chromatography (IEC)

* plus material costs and surcharges if applicable (please also see section "miscellaneous", page 22)

3.6 DETECTION OF HOST CELL PROTEINS OR RESIDUAL DNA CONTENT

Determination by quantitative real-time PCR
Determination by capillary electrophoresis
Determination by ELISA

3.7 IDENTIFICATION OF MICROORGANISMS (PCR/SEQUENCING)

Identification of bacterial and fungal isolates (up to species level) by PCR amplification of the 16S rRNA gene (1,500 bp) or the ITS regions with sequencing and phylogenetic classification by means of our database *ID by tree*.
Identification of microorganisms (up to species level)
per isolate

Microbiological methods for the identification of microorganisms possible, please refer to:
MICROBIOLOGY, PAGE 8, CHAPTER 1.2

3.8 DNA-FINGERPRINTS

DNA-fingerprints for intra-species-relationship analyses
(molecular phylogenetics)

3.9 TESTING OF BACTERIAL ENDOTOXINS AND PYROGENS

Testing using the RFC test (recombinant Factor C assay)
Product-specific suitability test of the test method

New in 2026!

Testing using the MAT test (monocyte activation test)

3.10 CELL-BASED ASSAYS

Potency assay testing (e.g. calcitonin salmon bio-identity)
Bioassays (e.g. in-vitro cytotoxicity, potency assays, MoA studies

4. GENERAL ADDITIONAL CHARGES

Project meeting

first project meeting .....

each additional project meeting (incl. travel expenses, excl. hotel expenses)

- daily rate for expert .....
- daily rate for senior expert .....

Audits/Inspections

initial audit (one day) .....

each further audit

- remote audit ½ day .....
- remote audit 1 day .....
- on site audit 1 day .....
- on site audit ½ day .....

unannounced inspection from notified bodies .....

Materials

special materials like chromatography columns, reference substances,
special reagents etc., unless provided by the client

.....

Working with highly effective and/or toxic samples or reagents e.g.
narcotics, cytostatic drugs, hormones, antibiotics and CMR substances (carcinogenic, mutagenic, reproduction-toxic) or substances with high or unknown hazard potential
incl. inactivation and disposal; per sample and test .....

Documentation

shipping of certificate of analysis (CoA) by post, per shipment .....

copies of raw data (including control and authorization)

.....

preparation of a validation plan or report (if not included)
in German or English language .....

interim certificates and new issues of certificates of analysis
one page/multiple pages .....

translation of documents in German or English language .....

OOS procedures

processing of OOS procedures in case of a non-obvious laboratory error

- for sterility testing, estimated time approx. 2.5 hours, flat .....
- other analysis, estimated time approx. 1.5 h, flat .....
- increased time expenditure.....

Failure investigation

performing of failure investigation and preparing a report
for OOE/OOT results .....

Changes

Processing of customer-initiated changes

- estimated time approx. 2.5 hours, flat .....
- increased time expenditure .....

Client specific documentation

preparation of customer-specific test specifications/working procedures ... on request according to offer

updating and storage of customer-specific work instructions/SOPs (standard operating procedures)

Miscellaneous

Approval for testing on behalf of pharmacies by experts for the

Testing of counter samples of medicinal products in accordance with section 65, paragraph 4 AMG

each test report

Confirmation of quality control by a Qualified Person

each test report

authentication of documents

without apostille

with apostille

service fee for the handling of data loggers

disposal of materials with increased volume/effort

return of raw data after expiry of the archiving period

disposal of raw data after expiry of the archiving period

compilation of data for Product Quality Review (PQR)

processing of Self-disclosure forms, confirmations, customer-specific documents

processing of administrative request

for the handling of narcotics

storage of retention samples

Working on weekends (Saturday/Sunday) or holidays

Evaluation of results by an employee on a Saturday
with an average workload of up to max. 3 hours

Evaluation of results by an employee on a Sunday or on a holiday
with an average workload of up to max. 3 hours

Performance of tests by two employees on a Saturday
with an average workload of up to max. 3 hours, together

Performance of tests by two employees on a Sunday or on a holiday
with an average workload of up to max. 3 hours, together

5. GENERAL TERMS AND CONDITIONS

1. Scope of validity

The following terms and conditions apply to all business transactions between BioChem Labor für biologische und chemische Analytik GmbH, Daimlerstraße 5b, 76185 Karlsruhe - hereinafter referred to as BioChem - and entrepreneurs, legal entities under public law and special funds under public law which commission BioChem with the services to be provided, in particular investigations or tests - hereinafter referred to as Customer - even if they are not specified in later agreements. By placing the order, the Customer acknowledges these conditions as legally binding. Any general terms and conditions of the Customer are hereby rejected in their entirety, these shall not become part of the contract even if BioChem carries out a service for the Customer without reservation while aware of any conflicting, additional or deviating conditions, unless the applicability of the general terms and conditions of the Customer is agreed separately in writing.
Rights to which BioChem is entitled under statutory regulations or under other agreements beyond these General Terms and Conditions of Order shall remain unaffected.

2. Establishment, scope and execution of the order, withdrawal from the contract

All BioChem offers are non-binding. Details regarding the services and other service descriptions in information material and documents pertaining to the quote do not constitute a binding agreement or guarantee, unless they are expressly designated as binding. BioChem reserves all property, copyright, protection and other rights to all documents forming the offer. Such documents may not be made available to third parties.
Generally, the Customer places an order in writing or by e-mail. For other orders, the Customer bears the risk of transmission. The contract shall enter into force when an order confirmation is issued in writing or text form or, if an order confirmation is not issued, when the commissioned investigation or test by BioChem begins. Verbal declarations, confirmations or commitments on the part of BioChem employees must be confirmed in writing or text form in order to be effective. BioChem has the right to determine the method and the type of investigation or test at its own discretion, unless otherwise agreed in writing or text form. Amendments or supplements to any order placed must be requested in writing or text form and are only considered agreed if they have been confirmed by BioChem in writing or text form.
BioChem is entitled to withdraw from the contract in whole or in part,

a) if BioChem is unable to fulfil the order through no fault of BioChem. In this case, the Customer shall be informed immediately;
b) if the Customer fails to make any payments on account requested by BioChem in accordance with section 5 of these GTC within the period set for such payment and continues to fail to do during any reasonable extension of such period;
c) if the Customer applies for insolvency or similar proceedings to be opened in respect to Customer's own assets, or if, following a substantiated application by a third party to open insolvency or similar proceedings in respect to the Customer's assets, the proceedings are opened or the opening of proceedings is refused due to a lack of assets.

3. Obligations of the Customer

The Customer fully supports BioChem in its activities to the best of Customer's ability. In particular, the Customer shall immediately provide BioChem with all necessary documents and information that are required and expedient for providing the service. The nature and scope of the Customer's other duties of cooperation are specified in the quotation or order.
If BioChem and the Customer agreed deadlines, these will only commence once the Customer has provided BioChem with all the necessary documentation and established all the necessary prerequisites (e.g. permits, test samples, reference substances). Where reasonable, the Customer shall grant BioChem a reasonable grace period for completing the order, even if BioChem does not comply with agreed deadlines for reasons BioChem is responsible for.

4. Prices

The most recent price stated by BioChem for completing the order shall apply. If BioChem is to provide Additional Services not yet taken into account at the time the contract is concluded ("**Additional Services**"), these shall be agreed separately with the Customer and will be charged in addition. BioChem may also – after communication of a cost estimate – charge the Customer for any "**Additional Costs**" necessary to provide the service that were not considered when the contract was concluded. If the Customer objects to the Additional Services being provided or refuses to pay the estimated Additional Costs and if BioChem cannot execute the order without the Additional Services or the cost-triggering measures, BioChem may withdraw from the contract in accordance with section 2.
For charging for Additional Services or costs, BioChem can use the current service specifications as the basis for pricing standard services, in particular examinations or tests. The prices listed therein are base prices for such services. BioChem may calculate surcharges and discounts depending on the individual case. For all services not covered by the service specifications, the price is agreed on a project-specific basis. At the request of the Customer, BioChem shall prepare project-specific offers.
Price information by telephone is always non-binding and is only considered agreed if it has been confirmed by BioChem in writing or text form.
All prices are in euro plus statutory value added tax.

5. Delivery and payment terms

The Customer ships samples from within the EU, including from within Germany, subject to INCOTERMS 2020 DPU Karlsruhe, receipt of the samples on BioChem's business premises. The Customer ships samples from outside the EU subject to INCOTERMS 2020 DDP Karlsruhe, receipt of the samples on BioChem's business premises; the Customer is therefore also obliged to cover the unloading of samples from the means of transport, in deviation from INCOTERMS 2020 DDP. When shipping highly potent and/or toxic substances, as well as infectious and/or genetically modified organisms (GMOs), the requirements specified in the section "Further provisions and information" in BioChem's offer apply in addition to and, in case of contradictions to these GTC, with priority over these GTC.
Unless otherwise agreed, all invoices shall be due 8 days after the invoice date, without deductions, and amounts shall be transferred to the account specified on the invoice. Depending on the order volume, BioChem reserves the right to invoice a partial amount as an advance payment after the order has been placed or after the test plan has been returned or after certain test phases have been reached.

6. Claims for defect and limitation period

The Customer shall be obliged to accept the work result within twelve days of it being announced or to object to it in writing or in text form in the event of evident defects. In the event of hidden defects, the Customer is obliged to notify BioChem immediately after they have been discovered.
In the event of defects being reported in good time within the meaning of the preceding sentences 1 and 2 of this clause 6 concerning the examinations, tests or other services provided (advice, information), the Customer shall be entitled to subsequent performance through rectification or re-performance of the service, at BioChem's choice. The Customer is obliged to provide BioChem with a new sample at the latter's expense, if this is necessary for subsequent performance and is reasonable for the Customer. If any subsequent performance is unsuccessful twice, the Customer has the right to reduce the remuneration or to withdraw from the agreement. The Customer has no right of withdrawal if the Customer is unable to return the received service, unless a return is not possible due to the nature of the received service or if BioChem is responsible for it being impossible to return the service.
The right to subsequent performance is excluded if the Customer has not reported the defect in good time within the meaning of sentences 1 and 2 of this clause 6 or if the defect is not significant and the costs of subsequent performance are disproportionate to the significance of the defect.
Rights arising from defect in accordance with this clause 6 become time-barred after one year, starting (i.) on the date the Customer accepts the work result or (ii.) on the thirteenth day after BioChem released the work result if no complaints are raised *(whichever is earlier)*. This does not apply in case of intentional action, gross negligence or malice. BioChem may correct obvious inaccuracies in the work result, such as typographical errors or formal defects, at any time.

7. Liability

BioChem shall be liable without limitation for any damage resulting from violation of a guarantee or from injury to life, limb or health. The same applies to intentional misconduct and gross negligence.
Regarding damage resulting from minor negligence, BioChem shall only be liable if and to the extent that essential contractual obligations (cardinal obligations) are violated. In the event of such obligation being violated or in case of delay and impossibility, BioChem's liability shall be limited to only that foreseeable damage the occurrence of which is typically to be expected within the framework of the agreement. Furthermore, the liability of BioChem in these cases is limited to a maximum amount of EUR 5,000,000.
Any further liability of BioChem is excluded. Insofar as BioChem's liability is excluded or limited, this also applies to the personal liability of BioChem's staff, employees, personnel, representatives and vicarious agents.

8. Applicability of the work result/intellectual property

The results of the services carried out in accordance with the contract shall only apply to the test sample(s) submitted and used in accordance with the contract. No further conclusions can be derived from the results.
BioChem reserves any and all rights to the data, method developments and validation processes used or provided to complete the services, as well as to trademarks and know-how, without any restrictions. BioChem reserves all rights to the results of the services provided, in particular the test results, expert opinions, advice and information produced within the scope of the order ("**Performance Results**") until payment of the agreed remuneration. This also applies if the Performance Results are communicated to the Customer before the agreed remuneration is paid. To the extent that BioChem owns the Performance Results, ownership shall pass to the Customer upon full payment of the agreed remuneration and delivery of the Performance Results. To the extent that the Performance Results are subject to copyright, BioChem grants the Customer an irrevocable right of use, unrestricted in regard to time, location and content, for the transmitted Performance Results for all known types of use once the agreed remuneration is paid in full. Without prejudice to above, BioChem may continue to use the Performance Results in an anonymised form, in particular for research and benchmarking purposes.

9. Confidentiality

The parties are mutually obligated to treat any information that becomes available to them and is designated as confidential or is in other ways recognisable as a business secret as confidential for a period of five years beginning with the disclosure of the confidential information and, unless this is required for the business relationship, to neither record nor pass on nor use it.
The obligation to treat information as confidential does not apply if

a) the receiving party demonstrably already had access to the information before the business relationship was established or if the information was generally known or generally accessible before the business relationship was established; or
b) the information becomes generally known or accessible through no fault of the receiving party; or
c) the receiving party is required, by law, by an administrative or other legal act or judicial decision, to disclose the confidential information; in that case, the party asked to disclose the information shall immediately notify the party whose confidential information is concerned of the request in writing; any disclosure shall be limited to the relevant judicial or administrative proceedings.

The burden of proof lies with the receiving party.
In addition, without prior written consent, (a.) BioChem shall not publish or disclose to third parties any results obtained in connection with the order and (b) the Customer shall not publish or disclose BioChem's method developments and validation processes at any time. Section 8 shall remain unaffected.
The parties will ensure through appropriate contractual arrangements with their employees and agents that these also maintain confidentiality at least to the extent set out above.

10. Storing samples and documents

Unless agreed otherwise, residual material of the samples submitted for testing shall be kept for a period of up to two weeks after testing, insofar as permissible by the nature of the sample, and documents and measurement data shall be kept for a period of up to ten years in accordance with the applicable testing regulations (e.g. GMP). After the end of retention or storage periods, BioChem or third parties commissioned by BioChem dispose of the residual material in a professional manner at the expense of the Customer and all documents and measurement data are destroyed or deleted. If a return of residual material or documents is desired, this must be communicated in writing or text form when the order is placed and must be noted on the test order or receipt when the sample is sent. In this case, the Customer shall bear the costs and the risk of returning the items.
If it is planned to store samples (e.g. in the case of a stability test) or to take reference samples, the stored sample or the reference sample is disposed of or destroyed at the expense of the Customer, according to the professional discretion of BioChem, at the end of the storage period. Sentences 3 and 4 of this clause 10 shall apply accordingly.

11. Offsetting and right of retention

The Customer is only entitled to offset against BioChem's payment claims if the Customer's counterclaims have been legally established or are undisputed.
The Customer can only assert a right of retention if the Customer's counterclaim is based on the same contractual relationship.
The Customer's rights regarding defects remain unaffected.

12. Applicable Law, place of fulfilment and jurisdiction

The legal relationship between BioChem and the Customer is governed exclusively by German law, excluding German international private law. The place of fulfilment for all services of the Customer and BioChem is Karlsruhe. The exclusive place of jurisdiction for all disputes arising from the business relationship between BioChem and the Customer, for both parties, shall be Karlsruhe.