

Safety and Activity Testing Services



QUALITY CONTROL TESTING OF BIOPHARMACEUTICALS (BIOLOGICS)

BSL BIOSERVICE and LPU (Labor für Pharma und Umweltanalytik; located in the vicinity of BSL) offer a broad range of physico-chemical and biological test systems for the quality control testing of Biopharmaceuticals in compliance with GMP regulations.

1. Active product and product related impurities

General Quality	<ul style="list-style-type: none">• Container closure integrity• Clarity and Opalescence (Turbidity)• Colour• Extractable volume• pH• Karl Fischer (coulombmetric and direct titration)• Osmolality (EP, USP)• Particulate Matter (visible and non-visible particles)
Quantity	<ul style="list-style-type: none">• UV absorbance
Identity, purity, integrity	<ul style="list-style-type: none">• Capillary Electrophoresis (Capillary Zone Electrophoresis (CZE); Micellar Electrokinetic Chromatography, Capillary (MEKC); Isoelectric Focusing (cIEF); SDS-PAGE)• SEC-HPLC• RP-HPLC (UV, DAD, Fluorescence, ELSD, RI)• IC (Ion Chromatography)• GC (Headspace, FID)• IEX (Ion Exchange)-HPLC• AAS, ICP-OES• Ligand binding assay
Bioactivity	<ul style="list-style-type: none">• Bioassay (cell-based + in vivo)
Identity, integrity	<ul style="list-style-type: none">• Peptide mapping• Mass spectrometry (LC-ESI_MS; LC-MS-IT-TOF)• Immunoassay & ELISA
Identity, quantity	<ul style="list-style-type: none">• Amino acid analysis
Microbiological quality	<ul style="list-style-type: none">• Test for sterility• Test for endotoxins• Microbial limit test

2. Process related impurities/substances

Leachables and extractables	<ul style="list-style-type: none">• GC, ICP, HPLC
Protein A	<ul style="list-style-type: none">• ELISA
TMBP	<ul style="list-style-type: none">• GC-FID

Analytical Support for:

- **Product Characterization**
- **Stability Testing**
- **Release Testing**

Your Benefits

- **Expertise**
25+ years experience in design, validation and performance of Bioassays and physico-chemical tests
- **Experience**
Regular participation at international conferences and workshops, cooperation with "big" pharma and with Biotech industry, close collaboration with academic institutes
- **Quality**
Successfully US-FDA inspected in 2005, 2006 and 2009 (without any findings)
- **Stability studies**
Various storage capacities available (walk in chambers and stand alone devices)
- **Customer service**
Timely reporting and close communication with Sponsors, individual advice regarding scientific and regulatory issues
- **Location**
Laboratories located in the center of Europe
- **QP certification and release / manufacturing license**