

**SYMBIOSIS – part of BIOPHARM GmbH offers services and solutions for biopharmaceuticals and classical pharmaceuticals. SYMBIOSIS integrates the extensive experience and expertise of BIOPHARM GmbH in analytical services for more than 30 years combined with a customer-focused approach driven by excellence in process, communication and quality. GMP and GLP certified as well as FDA inspected we operate according to the highest quality assurance standards.**



### PROCESS

Applying the right approach and accelerating your product time-to-market

## SOLUTIONS

SYMBIOSIS solutions are customer-driven sets of analytical methods designed to meet regulatory requirements. An extensive range of methods combined with our expert knowledge provides accurate analysis and consistent results in accordance with GMP and GLP requirements. SYMBIOSIS solutions are designed to accelerate drug product development and to provide analytical support throughout drug product life cycles.

- Analysis of drug substances and drug products of biopharmaceuticals and classical pharmaceuticals
- Stability testing according to ICH/FDA guidelines, incl. Storage
- Release testing
- Development and validation of analytical methods in accordance with ICH/FDA guidelines
- Comparability testing (incl. Biosimilars/Biobetters)
- Safety testing

### COMMUNICATION

Project visibility and flexibility for changing market needs and regulatory requirements



## SERVICES

We offer analytical methods for a wide range of substances from small molecules to antibodies.

### Identity

- Protein sequencing (N- and C-terminal)
- Mass spectrometry (MALDI-TOF-MS)
- Peptide mapping
- Amino acid analysis
- Western blot
- Isoelectric focussing (IEF)
- Spectrometry (UV-VIS, IR, Fluorescence)

### Content

- RP-HPLC
- Protein determination (CBB, BCA, UV)
- ELISA
- Titrimetry
- Sialic acid determination

### Purity

- Size exclusion chromatography (SEC)
- Ion exchange chromatography (IEX)
- SDS-PAGE
- Thin layer chromatography

### Impurity

- ELISA for host cell proteins (HCP)
- Determination of process related impurities
- Silicone oil determination by IR spectrometry

We support you through all stages of the development life cycle of your product from discovery to market.

### Functionality/Potency

- Bioassay
- Dissolution testing

### Safety

- Bioassay
- Immunogenicity

### Physicochemical

- Colour
- Clarity/Opalescence
- Visible particles
- Osmolality
- Optical rotation
- pH
- Residual moisture (Karl Fischer)
- Loss on drying
- Melting point
- Resistance to crushing

### SYMBIOSIS

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