

## Analytical Services

### Protein Analytics

Bioactivity and Cellular Assays  
Host Cell Contaminants  
Immunomonitoring



## Protein Analytics

For demonstration and documentation of the batch-to-batch consistency of any given biopharmaceutical material, its identity, purity, quantity, bioactivity and profile of impurities must be confirmed. These tasks are addressed by our portfolio of analytical routine methods for quality control of biopharmaceuticals and complemented by qualified external partners. Thus we are able to provide full quality control of biological API's and clinical samples.

### Stability Studies

Stability data can be generated under controlled conditions as part of product relevant data according to the ICH guidelines.

### Our Core Competencies

#### Identity Tests

- Western blotting
- SDS-PAGE
- Isoelectric focusing
- Mass spectrometry
- Monosaccharide analysis

#### Purity Tests

- HPLC (SEC, IEC, RP)
- Endotoxin content (LAL-test)
- Host cell protein assay (Threshold® and ELISA)
- Host cell DNA assay (Threshold®)
- Host Cell Contaminants, e.g. Protein A, HSA, Insulin (ELISA)

- Bioburden
- Virus testing
- Residual solvents (GC)
- Sterility
- Determination of water content

#### Quantification Tests

- Protein determination (Bradford, BCA)
- UV/Vis spectroscopy
- ELISA,
- HPLC (SEC) and FPLC (Affinity)

#### Potency Tests

- Bioactivity assays
- Specific binding assays. For more information please see our page "bioactivity and cellular assays"

#### General Tests

- Appearance
- pH
- Osmolality
- Ion chromatography

For more information please contact us

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