# Protein analytics and assay development

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 a recombinant protein. Glycotope GmbH provides comprehensive expertise in the development and validation of analytical assays.

**Stability studies & formulation development**
Stability data can be generated under ISO 9001 according to the ICH guidelines. Accelerated stability data can be used for formulation development.

## Our core competencies

**Purity tests**
- HPLC (SEC, IEC, RP)
- Endotoxin content (LAL-test, Haemotox rFC, EndoLISA®)
- Host-cell protein (generic kits, GEX®-specific ELISA, or development of customized test)
- Process related impurities, e.g. Protein A, HSA, Insulin (ELISA)

**Identity tests**
- SDS-PAGE, Western blot
- Isoelectric focusing, WCX
- Mass spectrometry
- Peptide mapping
- Mono- and Oligosaccharide analysis

**Quantification tests**
- Bradford, BCA
- UV/Vis spectroscopy
- ELISA
- HPLC (SEC) and FPLC (Affinity, e.g., analytical Protein A measurement)

**Potency tests**
- Bioactivity assays
- Antigen ELISA
- Binding kinetics using DRX (Dynamic biosensors; substitution of Biacore SPR technology)
- Other specific binding assays: For more information please see our page "bioactivity and cellular assays"

**General tests**
- Appearance
- pH
- Osmolality

**For more information please contact us**

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