ANTIBODY PRODUCT ANALYSIS

IN ACCORDANCE WITH REGULATORY GUIDELINES

Antibody products should be characterized according to ICH, EMA and FDA guidelines. SGS provides a full GLP/cGMP analysis package for product characterization and identification of post translational modifications, which include:

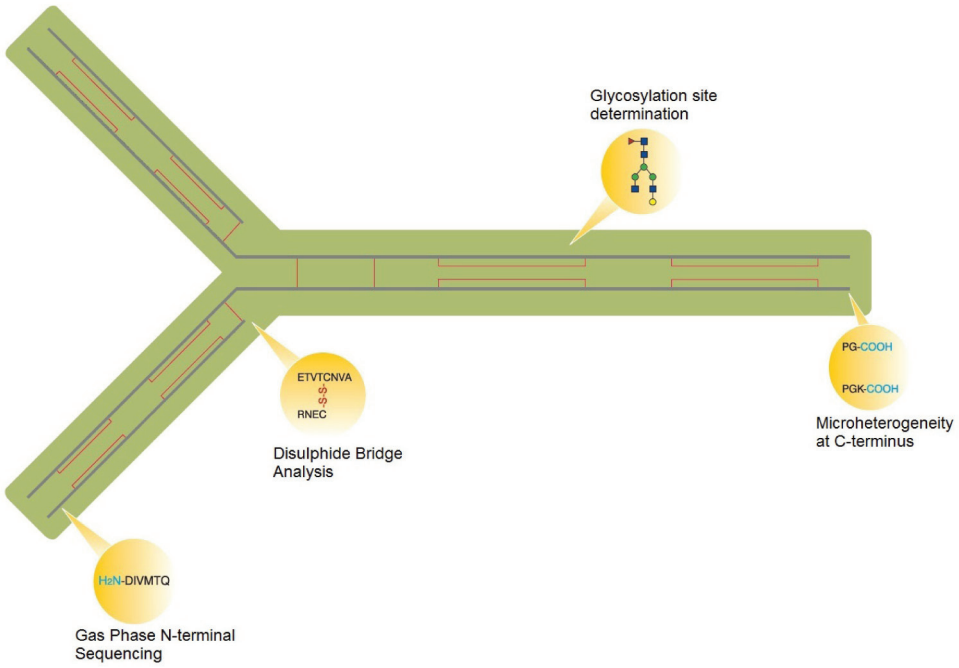
Structural characterization and confirmation:

- Amino acid sequence
- Amino acid composition
- N- and C- terminal sequence
  - N-terminal sequencing (automated Edman)
  - MS/MS peptide sequencing
- Peptide map
- Sulphydryl groups and disulphide bridges
- Carbohydrate structure
  - Monosaccharide composition analysis
  - Sialic acid analysis
  - Oligosaccharide profiling by HPAEC-PAD, HILIC-FLD and MS
  - Linkage analysis
  - Glycosylation site analysis
- Deamidation
- Oxidation

Physicochemical properties:

- Molecular weight or size
  - Gel electrophoresis
  - MALDI-TOF or ES-Q-TOF-MS
- Isoform pattern
- Extinction coefficient
- Electrophoretic pattern
  - Imaging cIEF
- Liquid Chromatographic patterns
  - Reverse Phase
  - Size Exclusion
  - Ion-Exchange
- Spectroscopic profiles
  - UV/Vis
  - Circular Dichroism
  - NMR
  - FTIR
  - Intrinsic Fluorescence
  - Extrinsic Fluorescence
  - 2nd derivative UV-VIS
- Aggregation
  - Analytical Ultracentrifugation (AUC)
  - SEC-MALS
  - DLS
- Thermal stability characterization
  - DSC
  - Thermal Unfolding curves with spectroscopic probes

SGS



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WHEN YOU NEED TO BE SURE