

Protein and Glycoprotein Analysis

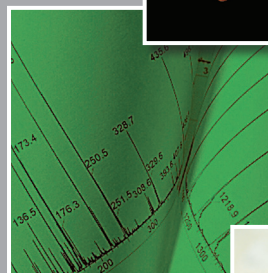
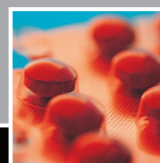
in Accordance with ICH Guidelines
(ICH Q6B)

Biotechnological and biological products should be characterised according to ICH Guidelines. ICH Topic Q6B outlines procedures for analysis of **peptide, protein, glycoprotein and antibody products**.

M-Scan provides a full analysis package for physicochemical characterisation to GLP/cGMP.

ICH Q6B requires	M-Scan provides
Amino Acid Sequencing	✓
Amino Acid Composition	✓
N- and C-Terminal Sequencing	✓
Peptide Mapping	✓
S-S Bridge Analysis	✓
Glycosylation Analysis	✓
Post Translational Modifications	✓
Molecular Weight	✓
Isoform and Electrophoretic Patterns	✓
Extinction Coefficient	✓
Liquid Chromatographic Patterns	✓
Spectroscopic Profiles	✓
Process and Product Related Impurities	✓
Aggregation Analysis	✓

Expert Analytical Services



M-Scan

Please see the web-site for your local marketing office

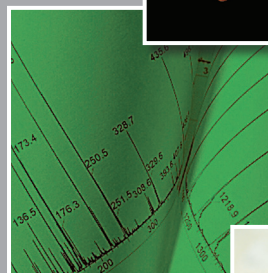
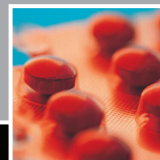
www.m-scan.com

Protein and Glycoprotein Analysis

M-Scan provides a full analytical package or individual analyses depending on your needs:

- Amino acid sequence analysis using automated Edman sequencing and/or MS/MS
- Amino acid composition to provide protein concentration, extinction coefficient and/or molar amino acid ratios
- N- and C-Terminal analysis using automated Edman and/or MS sequencing
- Peptide Mapping by MS
- Disulphide bridge analysis using MS and MS/MS
- Glycan characterisation including:
 - Monosaccharide composition
 - Sialic acid analysis
 - Oligosaccharide population
 - Linkage analysis
 - Glycosylation site determination
- Identification of post-translational modifications e.g. acetylation, phosphorylation etc
- Determination of intact molecular weight by MS
- Electrophoretic and isoform patterns - isoelectric focusing, cIEF and SDS-PAGE
- Liquid chromatographic patterns - RP-HPLC, SEC and IEX
- Spectroscopic profiles - CD and NMR
- Aggregation by AUC and SEC/MALLS
- Analysis of process and product related impurities and degradation products e.g. isomerisation, deamidation, oxidation, mismatched S-S bridge forms
- Extractables and leachables from packaging/containers and closure systems by MS
- Validation of Cleaning Protocols to CFR Title 21 Part 211.67 using TOC
- Analysis of residual solvents by TD GC-MS

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