

Structural Analysis of Glycans

in Accordance with ICH Guidelines

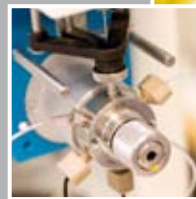
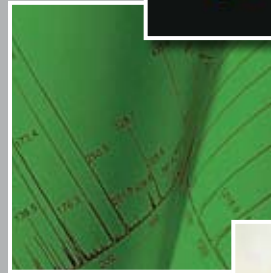
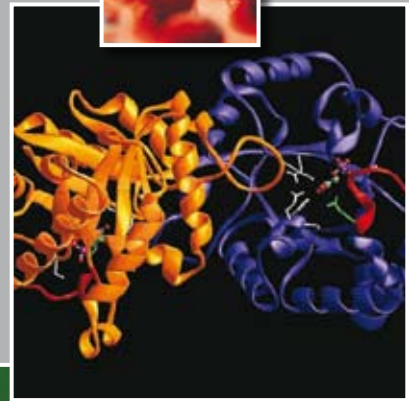
ICH Q6B states "For glycoproteins, the carbohydrate content (neutral sugars, amino sugars and sialic acids) is determined. In addition, the structure of the carbohydrate chains, the oligosaccharide pattern (antennary profile) and the glycosylation site(s) of the polypeptide chain is analysed, to the extent possible."

- Glycosylation is a dynamic, biologically active post-translational modification.
- Factors affecting glycosylation include the cell-line and bioreactor conditions, which may produce the same protein backbone with differences in overall structure, linkage and composition of glycans, potentially affecting bioactivity, safety and efficacy of the final product.
- Characterisation of the glycan structure is important from early stage cell line selection right through development of the manufacturing process to consistency of final product.

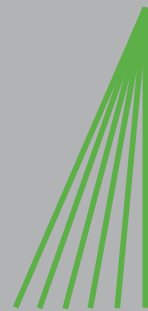
M-Scan provides a full analysis package for glycosylation analysis to GLP/cGMP.

ICH Q6B requires	M-Scan provides
Monosaccharide Composition Analysis	✓
Glycan Population Analysis	✓
Glycan Antennary Profiling Analysis	✓
Glycosylation Site Analysis	✓

Expert Analytical Services



M-Scan



Please see the web-site for your local marketing office

www.m-scan.com

Structural Analysis of Glycans

For over 30 years M-Scan has provided a full analytical package for carbohydrate analysis, including novel structure elucidation.

Monosaccharide Composition Analysis

- Confirms the presence of carbohydrate in a product.
- Neutral and amino sugars are identified and quantified by GC-MS, sialic acid species N-Acetylneuraminic acid and N-Glycolylneuraminic acid by HPAEC-PAD.

Glycan Population Analysis

- Provides a detailed picture of the N- and O-glycan structures present on a glycoprotein.
- Isolated glycans are analysed by MALDI-MS and/or ES-MS. Chromatographic N- and O-glycan profiles are obtained using HPAEC-PAD.

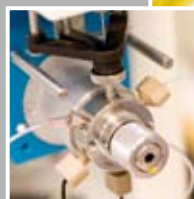
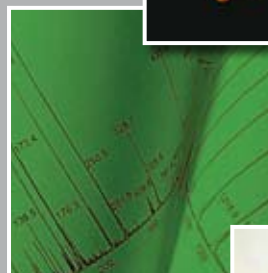
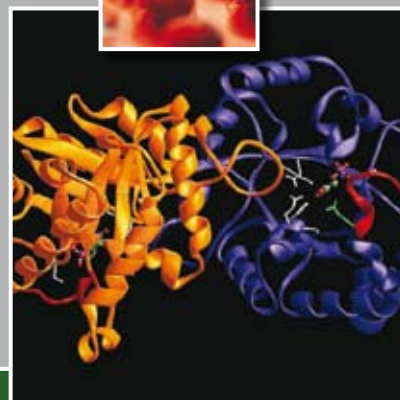
Glycan Antennary Profiling Analysis

- Information is obtained on antennal structures using ES-MS of derivatised samples.
- Specific enzymatic digestions are performed to assess the presence of particular structures such as galactosyl residues.
- Linkage (methylation) analysis by GC-MS is performed to determine specific monosaccharide linkages e.g.
 - Linkage of sialic acid species (α 2-3 vs α 2-6)
 - Assessment of the presence of multiantennary or bisected N-glycans

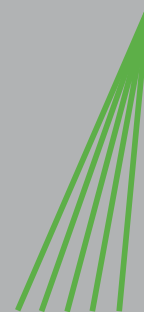
Glycosylation Site Analysis

- Sites of glycosylation are identified using M-Scan's strategies based on a combination of protein analytical techniques and Peptide Mass Mapping.
- Glycans at each individual glycosylation site are studied in detail using M-Scan's glycosylation analysis strategies.

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