

STRUCTURAL ANALYSIS OF GLYCANS

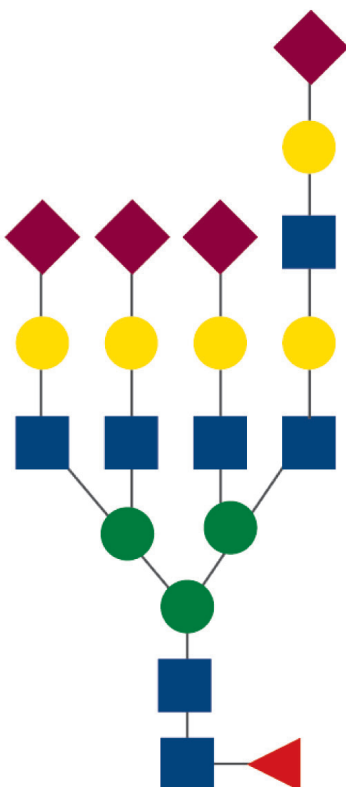
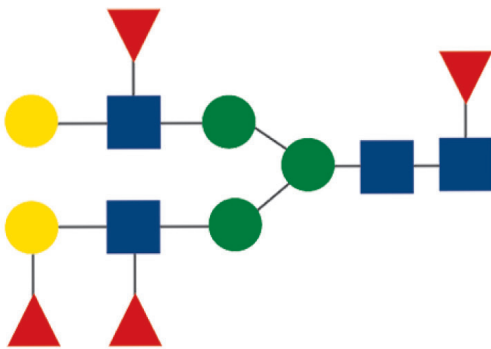
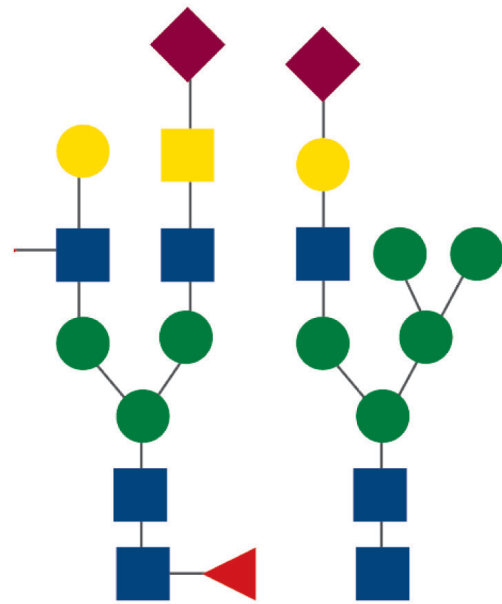
IN ACCORDANCE WITH ICH GUIDELINES

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 analyzed, 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
- Characterization of glycan structures is important from early stage cell line selection right through development of the manufacturing process to consistency of final product
- A detailed analysis of glycosylation is key for the development of a Biosimilar product

SGS provides a full package for Glycosylation analysis to GLP/cGMP.

ICH Q6B REQUIRES	SGS PROVIDES
Monosaccharide Composition Analysis	✓
Glycan Population Analysis	✓
Glycan Antennary Profiling Analysis	✓
Linkage Analysis	✓
Glycosylation Site Analysis	✓



All available procedures can be employed from early phase drug development (e.g. selection of cell lines), to product characterization, GMP batch release and stability studies.

For over 35 years SGS has provided a full analytical package for carbohydrate analysis, including novel structure elucidation.

Monosaccharide Composition Analysis

to confirm 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 or HILIC-FLD, respectively

Glycan Population Analysis to provide detailed picture of the N- and O-glycan structures present on a glycoprotein.

- Isolated glycans are analyzed by MALDI-MS and/or ES-MS
Chromatographic N- and O-glycan profiles are obtained using either HPAEC-PAD or HILIC-FLD, or on-line HILIC-FLD-MS

Glycan Antennary Profiling Analysis to obtain information on antenna structures. Information is obtained by using ES-MS/MS or MALDI-TOF/TOF of derivatised sample.

- Specific enzymatic digestions are performed to assess the presence of particular structures such as gal α gal

Linkage Analysis to determine specific monosaccharide linkage.

- Assessment of the presence of N-glycans
- Linkage of sialic acid species (α 2-3 vs α 2-6)

Glycosylation Site Analysis to identify site of glycosylation and to obtain information on the occupancy rate of the glycans.

- Sites of glycosylation are identified using SGS'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 SGS's glycosylation analysis strategies

CONTACT INFORMATION

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WHEN YOU NEED TO BE SURE

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