Structural Analysis of Glycans in Accordance with ICH Guidelines

ICH Q6B requires SGS provides a full package for Glycosylation analysis to GLP/cGMP.

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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

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