



Ludger

Quantitative glycopeptide standard

Quantitative sialic acid or monosaccharide analysis is an important step for developers and manufacturers of biologic drugs. Regulators are putting increasing pressure on companies to perform accurate glycoprofiling on their biopharmaceuticals. These analyses fall within **ICH guidelines Q6B and Q5E** for comparability studies during product development and after major manufacturing changes. Furthermore, the recent EMA monograph on monoclonal antibodies and forthcoming **USP chapters <1084> and <1094>** on glycosylation analysis reinforce the need to perform glycoprofiling throughout the drug life cycle.

Ludger Ltd. (www.ludger.com) has produced a purified glycopeptide standard which can be used as an internal standard and positive control when performing sialic acid or monosaccharide analyses in house. This Ludger BioQuant™ Standard (**Cat# BQ-GPEP-A2G2S2-10U**) is a disialylated complex biantennary N-linked glycan containing 2 galactose residues.

Purity of >90% has been assessed by HPLC, correct mass identity assessed by MALDI mass spectrometry. The exact amount of material/concentration is determined by quantitative NMR (qNMR) and quantitative monosaccharide analysis (MA). Quantity values by qNMR and MA agree within 90-110%. MA is traceable to internationally accepted references from USP and dispensed using NIST traceable labware. qNMR is traceable to a NIST SRM traceable CRM analysed to the ISO 17025 standard. A detailed certificate of analysis is given for each standard. This contains comprehensive documentation, lot-specific values, expiration date and storage information.

Features and benefits of the BioQuant GPEP-A2G2S2 standard:

Confidence in your glycan release, labeling and recovery techniques

Use the BioQuant GPEP-A2G2S2 standard during the sialic acid or monosaccharide release and labeling process. This will enable you check the efficiency of glycan release, labeling and recovery.

Confidence in your sialic acid or monosaccharide measurements

The BioQuant GPEP-A2G2S2 standard gives you confidence in the accuracy of your results.

Other products:

Sialic Acid Analysis:

LudgerTag™ DMB kit	LT-KDMB-A1
HPLC analysis	LS-R1-4.6x150
UHPLC analysis	LS-UR2-2.1x100

Monosaccharide Analysis:

LudgerTag™ monosaccharide kit	LT-MONO-96
HPLC analysis	LS-R2-4.6x150
UHPLC analysis	LS-UR2-2.1x50

If you would like a quotation please contact us via e-mail: info@ludger.com