



QC Report

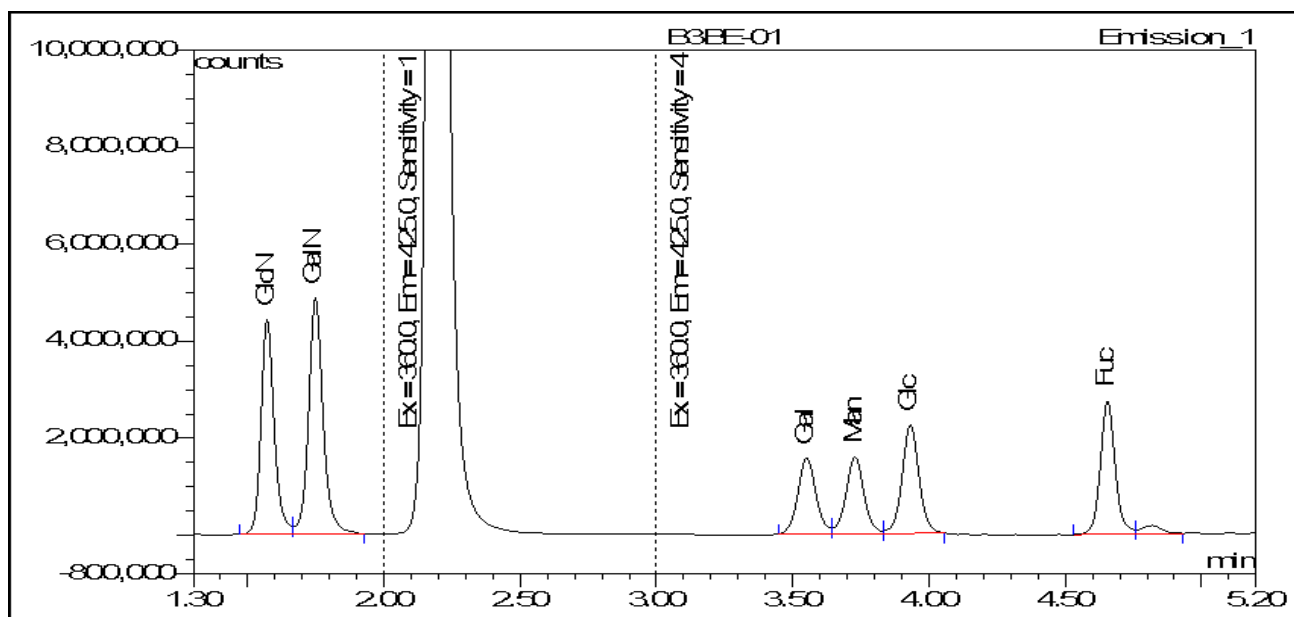
Monosaccharide Standard Mixture

Cat. #: CM-MONO-MIX-10

Batch: B3BE-01

Size: 10 nmol

CM-MONO-MIX-10 contains a mixture of monosaccharide standards containing 10 nmol per vial each of glucosamine, galactosamine, galactose, mannose, glucose (dextrose) and fucose.



2AA-Monosaccharide Standard Analysis of CM-MONO-MIX-10 against USP Standards.

Introduction

In order to check the validity of the mono mix standards quantities we compare them against a standard curve produced from USP traceable quantitative standards using the LT-MONO-96 kit and LudgerSepR2 chromatography.

Pass Criterion 1: We wish to see that the monomix give the quantities of each monosaccharide within 5% RSD for all replicates.

Pass Criterion 2: The actual quantity of each glycan can be given within 95% confidence levels with a standard error of less than 5%. The monosaccharides average amount should be out by no more than 10% from expected value.

Experimental

Run replicates of a 6 point standard curve of each monosaccharide (in a mix) made up from USP traceable standards. For 12 replicates of our monomix samples, make up to a known dilution that fits roughly in the middle of the standard curve. Analyse by HPLC with a LudgerSep UR2 column.

Results

QC run performed on 09th January 2014.

Monosaccharide	Nmols monosaccharide per vial
GlcN	10.99 ± 0.35
GalN	10.86 ± 0.30
Gal	10.35 ± 0.30
Man	10.38 ± 0.28
Glc	10.42 ± 0.26
Fuc	10.09 ± 0.28

Table 1: Monosaccharide amounts for CM-MONO-MIX-10 (batch B3BE-01) taken from 12 independent replicates. The amount range quoted is calculated with a 95% degree of confidence.

Monosaccharide	Nmols monosaccharide per vial
GlcN	10.09 ± 0.22
GalN	10.03 ± 0.12
Gal	10.34 ± 0.21
Man	10.01 ± 0.28
Glc	10.46 ± 0.20
Fuc	10.06 ± 0.15

Table 2: Monosaccharide amounts for CM-MONO-MIX-10 (batch B31L-01) taken from 12 independent replicates. This is the previous batch of CM-MONO-MIX-10 and was analysed simultaneously with batch B31L-01. The amount range quoted is calculated with a 95% degree of confidence.

Monosaccharide amount values (with CI95) are within 5% RSD and 5% standard error. – QC PASS

Amount values are within 10% of expected amount values – QC PASS

The average nmol amount of each monosaccharide is 10.52 nmols with a %RSD for all monos of 3.25% - QC PASS