LT147

GL Sciences Inc.

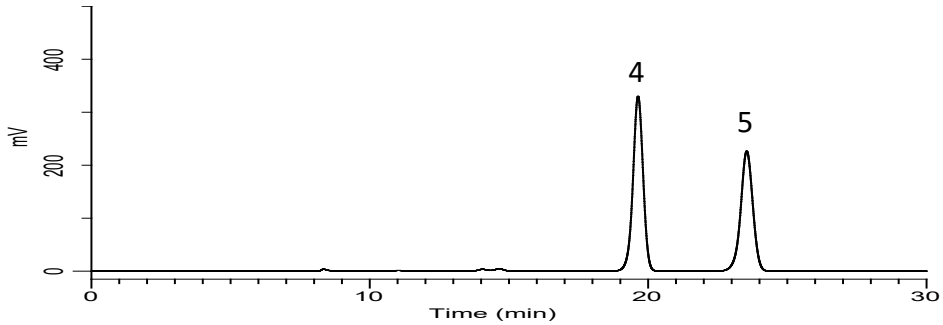
D-Mannitol Analysis Under USP Method

United States Pharamacopoeia (USP), European Pharmacopoeia (EP), and Japanese Pharmacopoeia (JP) have harmonized the analytical method for Mannitol. As a result of the harmonization, a HPLC method was added.
In this note, chromatograms obtained with an InertSphere Sugar-2 column, which was developed for sugar analysis, according to the harmonized method are shown. Whereas the original Japanese version of this note was written according to the JP, in this English version, the results are shown with reference to the USP monograph.

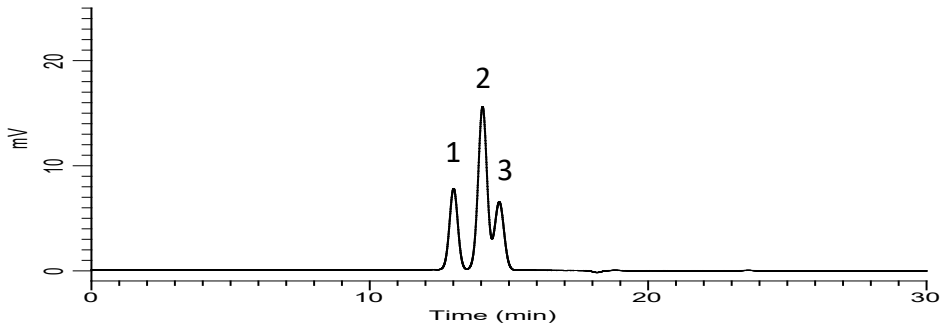
(Y. Yui, R. Hirano)

Analyte: 1,3. Isomalt
2. Maltitol
4. D-Mannitol
5. D-Sorbitol

System suitability solution A



System suitability solution B



HPLC conditions

Column	: InertSphere Sugar-2 (9 µm, 300 x 7.8 mm I.D.)
Eluent	: H_2O
Col. Temp.	: 85 ℃
Detection	: RI (40 ℃)
Injection Vol.	: 20 µL
Flow rate	: 0.5 mL/min

System suitability (Assay and Related Substances)

Resolution (4, 5)	: 5.46 (> 2.0)

Relative retention time (Related Substances)

Isomalt (1st peak)	: 0.66 (0.60)*
Maltitol	: 0.71 (0.69)*
Isomalt (2nd peak)	: 0.74 (0.73)*
Sorbitol	: 1.19 (1.2)*

* Reference value written in USP monograph

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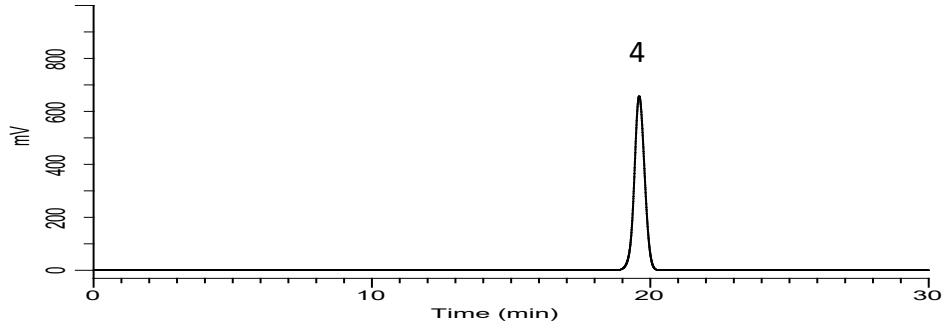
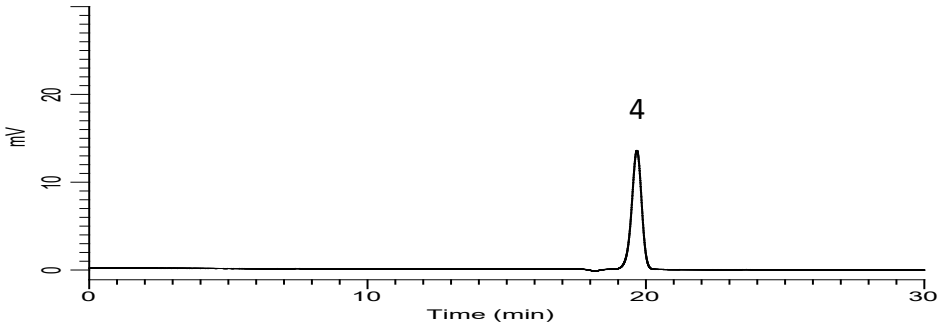
Analyte: 4. Mannitol

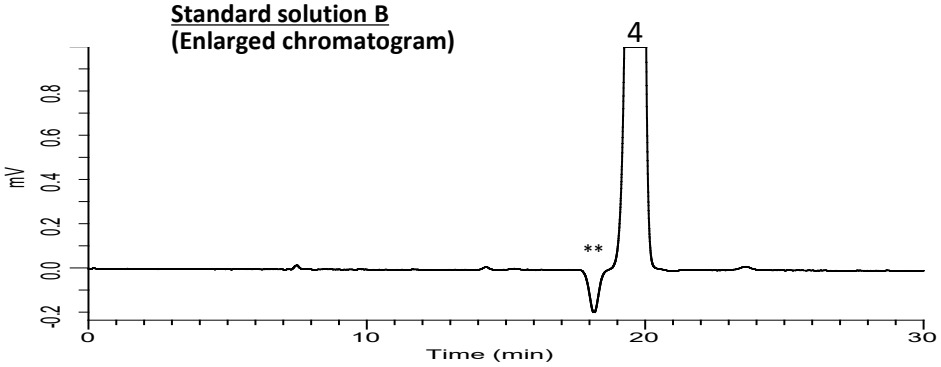
Standard solution A



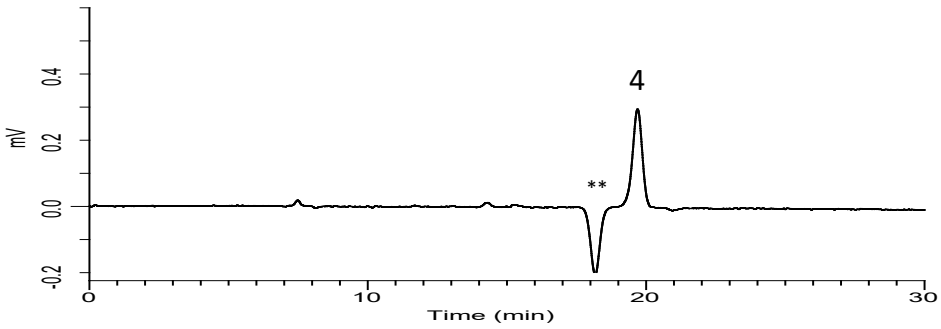
Standard solution B



Standard solution B
(Enlarged chromatogram)



Standard solution C



** Negative peak detected at about 18 min is increased or decreased depending on dissolved air in eluent and sample solution.

Analytical Column for Mannitol analysis

USP Code: L19
Description: Strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the calcium form, about 9 µm in diameter.

InertSphere Sugar-2

Description	: InertSphere Sugar-2 (9 µm, 300 x 7.8 mm I.D.)
Cat.No.	: 5020-11000
Base Material	: Styrene-divinylbenzene copolymer
Functional Group	: Sulfonic acid
Counter Ion	: Ca^{2+}

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