

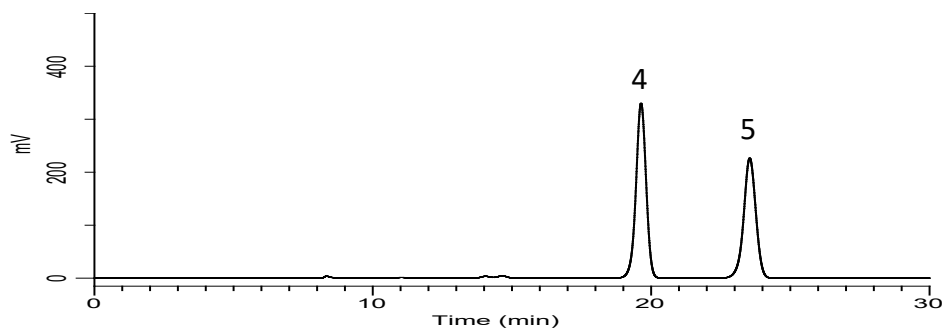
United States Pharmacopoeia (USP), European Pharmacopoeia (EP), and Japanese Pharmacopoeia (JP) have harmonized the analytical method for Mannitol. As a result of the harmonization, a HPLC method was added.

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.

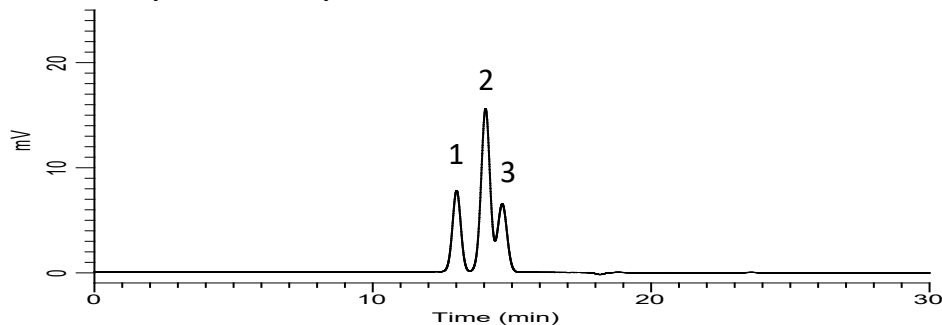
(Y. Yui, R. Hirano)

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 μ m, 300 x 7.8 mm I.D.)
Eluent : H₂O
Col. Temp. : 85 °C
Detection : RI (40 °C)
Injection Vol. : 20 μ L
Flow rate : 0.5 mL/min

System suitability (Assay and Related Substances)

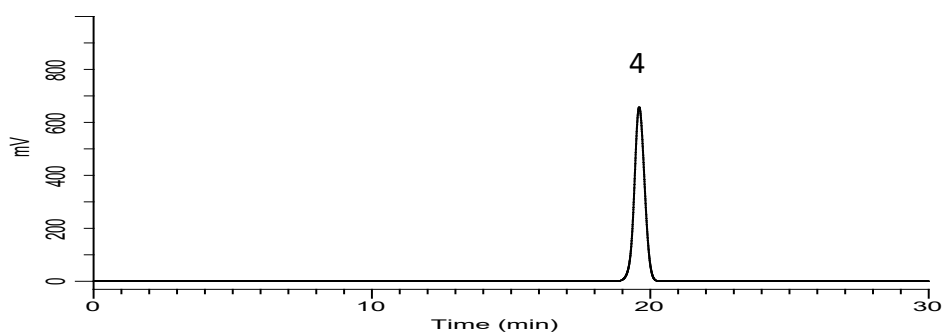
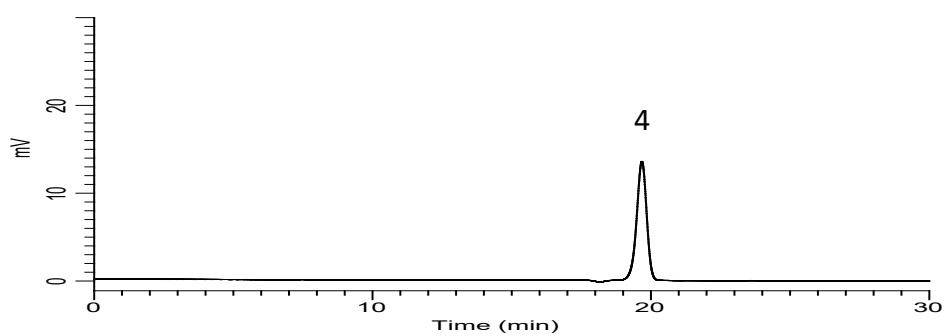
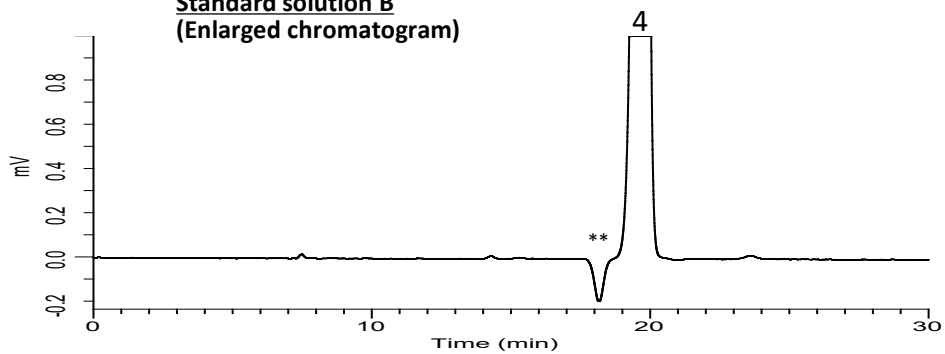
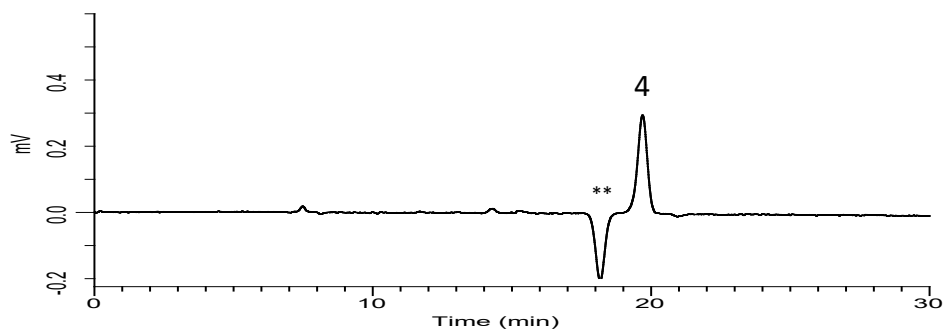
Resolution (4, 5) : 5.46 (> 2.0)

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

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 : Ca²⁺



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GL Sciences, Inc. Japan

22-1 Nishishinjuku 6-Chome
 Shinjuku-ku, Tokyo,
 163-1130, Japan
 Phone: +81-3-5323-6620
 Fax: +81-3-5323-6621
 Email: world@glsc.co.jp
 Web: www.glsciences.com

GL Sciences B.V.

De Sleutel 9
 5652 AS Eindhoven
 The Netherlands
 Phone: +31 (0)40 254 95 31
 Email: info@glsciences.eu
 Web: www.glsciences.eu

GL Sciences (ShangHai) Ltd.

Tower B, Room 2003,
 Far East International Plaza,
 NO,317 Xianxia Road,
 Changning District.
 Shanghai, China P.C. 200032
 Phone: +86 (0)21-6278-2272
 Email: contact@glsciences.com.cn
 Web: www.glsciences.com.cn

GL Sciences, Inc. USA

4733 Torrance Blvd. Suite 255
 Torrance, CA 90503
 Phone: 310-265-4424
 Fax: 310-265-4425
 Email: info@glsciencesinc.com
 Web: www.glsciencesinc.com

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