



## Analysis of D-Mannitol in Japanese Pharmacopoeia Sixteenth Edition Supplement II

The test items for D-mannitol in the Japanese Pharmacopoeia Sixteenth Edition Supplement II, which was put into force in February 2014, have been revised, and the analysis by HPLC has been added. For D-mannitol, the analysis for Purity (4) Related Substances and Quantitative Method is performed at 85°C with a 300 mm column, and thus a large column capacity as well as the temperature control to ensure stable analysis even at a high temperature will be required. Chromaster 6310 Column Oven can store a maximum of three 300 mm columns. It provides a wide temperature setting range of 4-90°C and excellent temperature stability and is capable for the low volume preheating to reduce the peak diffusion. As a result, the system can be used for various applications. This time, the analysis of D-mannitol was performed under the conditions for Quantitative Method described in the Japanese Pharmacopoeia Sixteenth Edition Supplement II and the analysis is introduced here.



High Performance Liquid Chromatograph Chromaster®

### Quantitative Method of D-Mannitol – Confirmation of System Suitability

- ✓ Standard solution: 0.5 g of D-mannitol is dissolved in purified water, and the volume is made up to 10 mL (5%).
- ✓ System suitability test solution (1): 0.25 g of D-mannitol and 0.25 g of D-sorbitol are dissolved in purified water, and the volume is made up to 10 mL (2.5% each).
- ✓ System suitability test solution (2): 0.5 g of maltitol and 0.5 g of isomalt are dissolved in purified water, and the volume is made up to 100 mL (0.5% each). Purified water is added to 2 mL of this solution to make the volume to 10 mL (0.1% each).
- ✓ Table 2 shows the result of the system suitability test for the Quantitative Method of D-mannitol. Results satisfying the specifications were obtained for all the items.

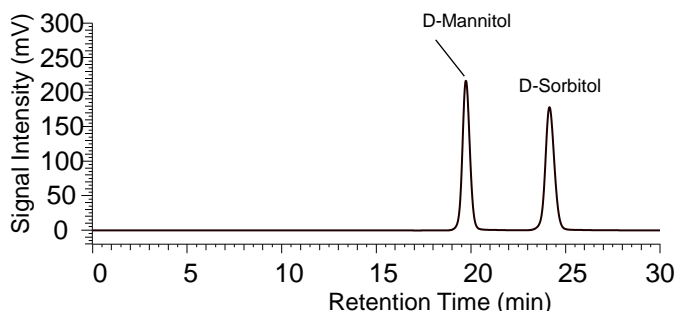


Figure 1 Chromatogram of System Suitability Test Solution (1)

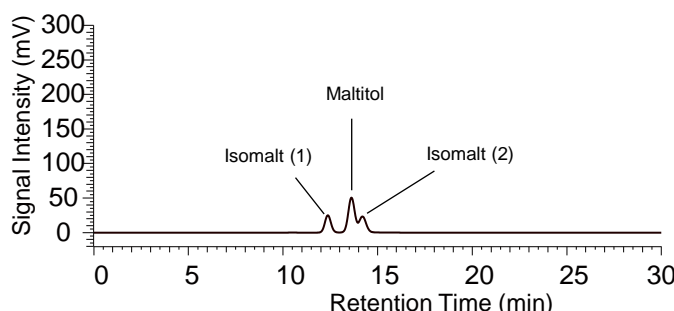


Figure 2 Chromatogram of System Suitability Test Solution (2)

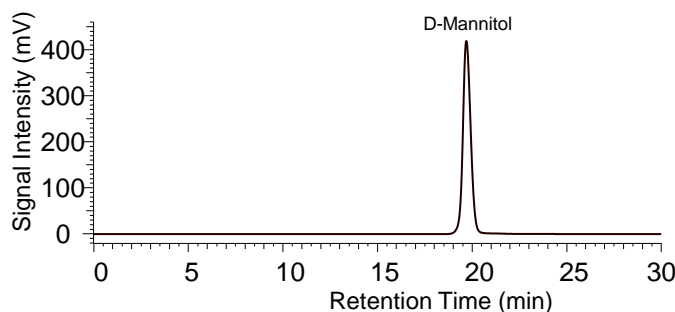


Figure 3 Chromatogram of Standard Solution

Table 1 Analytical Conditions

Column (Transgenomic)	CARBOsep COREGEL-87C 7.8 mm I.D. X 300 mm
Mobile phase	H <sub>2</sub> O
Flow rate	0.5 mL/min
Column temperature	85°C
Detector	RI (Cell temperature: 40°C)
Injection vol.	20 µL

Table 2 Quantitative Method of D-Mannitol – System Suitability Test Result

Item		Specification value	Result
System performance (relative retention time) (Figure 1, Figure 2)	D-Mannitol – Isomalt (1)	Approx. 0.6	0.63
	D-Mannitol – Maltitol	Approx. 0.69	0.69
	D-Mannitol – Isomalt (2)	Approx. 0.73	0.73
	D-Mannitol – D-Sorbitol	Approx. 1.2	1.23
System performance (resolution) (Figure 1)	D-Mannitol – D-Sorbitol	NLT 2.0	5.74
System reproducibility (Figure 3)	D-Mannitol Relative standard deviation (n=6) of peak area (%)	NMT 1.0	0.21

<Main System Configuration> Chromaster 5110 Pump, 5280 Autosampler, 6310 Column Oven, 5450 RI Detector

NOTE: These data are an example of measurement; the individual values cannot be guaranteed.