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Application News

No. G287A

Gas Chromatography

System Suitability Testing for Hydroxypropyl Cellulose

On December 1, 2014, the quantitative testing section on hydroxypropyl cellulose was modified in Stage 6 Harmonization of the United States Pharmacopeia (USP).

This article introduces examination results of system suitability for quantitative testing of hydroxypropyl cellulose in conformance with the USP.

Y. Nagao, T. Murata

System Suitability

An internal standard solution (methylcyclohexane in o-xylene) and a standard solution of isopropyl iodide were prepared according to the USP monograph.

Using the system and conditions given in Table 1, 2.0 µL of the prepared standard solution was injected. Fig. 1 shows the obtained chromatogram.

System performance: When operating under the conditions in Table 1, it is stated that isopropyl iodide elutes before the internal standard with a relative retention time of 0.8 with reference to the internal standard, and the resolution is no less than 2.0. The relative retention time of isopropyl iodide and the internal standard (methylcyclohexane) in the chromatogram shown in Fig. 1 was 0.77, and the resolution was 15.70.

System reproducibility: It is stated that the relative standard deviation is to be no more than 2.0 % using the response factor calculation (F) for six injections with a standard solution of 2.0 µL. Fig. 2 shows the six chromatograms which were used to verify reproducibility. The relative standard deviation using the response factor (F) was 0.32 %.

For reference, Table 2 and 3 are the peak tables produced from analyses of isopropyl iodide and internal standard.

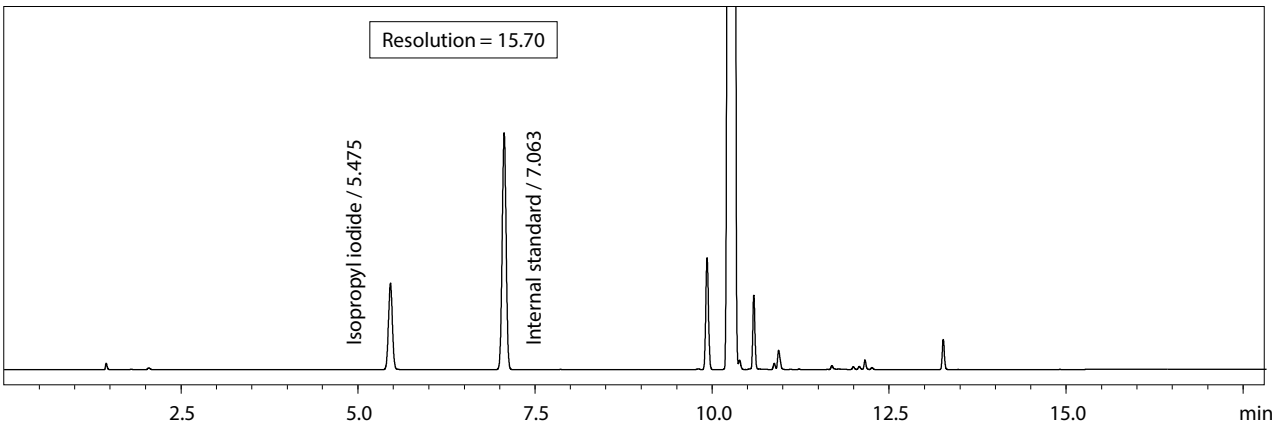

Fig. 1 Chromatogram of Standard Solution

Table 1 Analysis Conditions

Model	:	GC-2010Plus AF (230 V) /AOC-20i
Column	:	SH-1 (30 m, 0.53 mm I.D., df=3.0 µm) *1
Column Temp.	:	40 °C (3 min) - 10 °C/min – 100 °C - 50 °C/min - 250 °C (3 min)
Detector	:	FID
Carrier Gas	:	He, 52 cm/sec
Inj. Temp.	:	180 °C
Det. Temp.	:	280 °C
Split Ratio	:	1:50
Inj. Volume	:	2.0 µL

*1 P/N: 221-75733-30

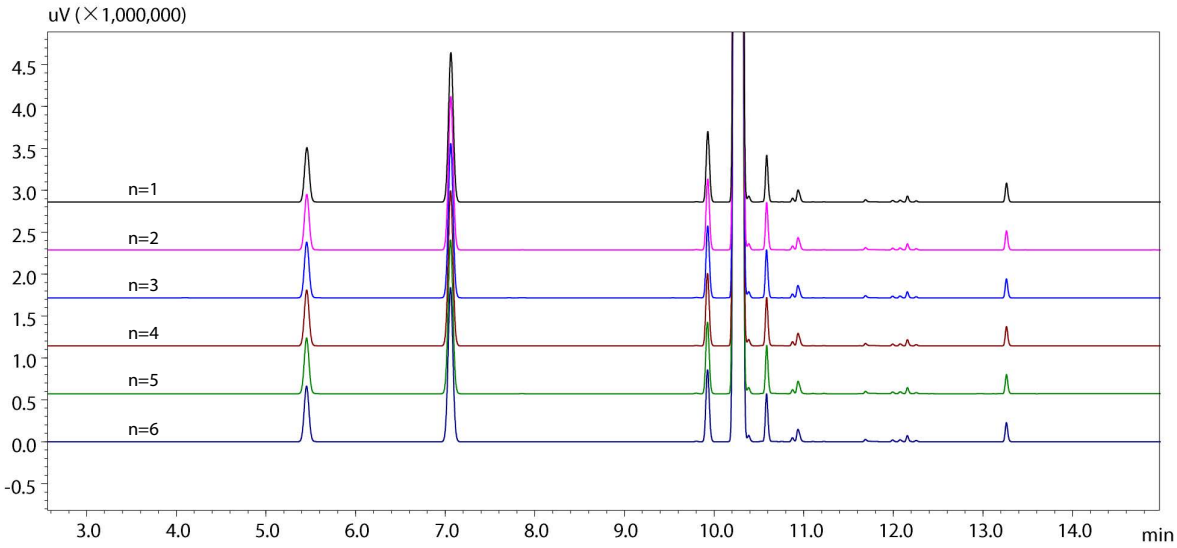

Fig. 2 Verification of Chromatogram Reproducibility (n=6)

Table 2 Analysis Results of Isopropyl Iodide

	Retention Time (min)	Peak Area (μV·sec)	Peak Height (μV)
n=1	5.457	2500496	648329
n=2	5.456	2543782	660353
n=3	5.455	2554064	663212
n=4	5.456	2562147	662210
n=5	5.455	2555863	662440
n=6	5.454	2555863	661868
%RSD	0.024	0.886	0.859

Table 3 Analysis Results of the Internal Standard (Methylcyclohexane)

	Retention Time (min)	Peak Area (μV·sec)	Peak Height (μV)
n=1	7.063	6907258	1778606
n=2	7.063	7072027	1824079
n=3	7.062	7118386	1832215
n=4	7.061	7145447	1838619
n=5	7.061	7110825	1827032
n=6	7.059	7078672	1835287
%RSD	0.020	1.232	1.219

Note: The above are reference values, not guaranteed values.

Reference
USP Stage 6 Harmonization (December 1, 2014)

Shimadzu Corporation
www.shimadzu.com/an/

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