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Application News

No. G318

Gas Chromatography

System Suitability Test of Low-Substituted Hydroxypropyl Cellulose for USP42-NF37

On May 1st, 2019, the United States Pharmacopeia (USP) monograph for the low-substituted hydroxypropyl cellulose was shifted its GC method with a packed column to one with a capillary column in USP42-NF37.

This article shows that Shimadzu Nexis™ GC-2030 AF satisfies system suitability requirements set in USP42-NF37.

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Test Method

As a standard solution, isopropyl iodide was diluted in a mixed solution of o-xylene and hydroiodic acid with n-octane also added as an internal standard in accordance with the USP monograph.

Table 1 below shows the instrument composition and analysis conditions.

The column flow rate was set in such a way that the internal standard elutes in approximately 10 mins as suggested in the USP.

Verification of System Suitability

Fig. 1 shows the chromatogram obtained by injecting 1 µL of the standard solution.

<Resolution>

One of the system suitability requirements by the USP is resolution between isopropyl iodide and n-octane (IS) be greater than 5. In this experiment, resolution was measured 28.3.

<Relative standard deviation>

For repeatability, with the injection volume being 1-2 µL, relative standard deviation (n=6) of peak areas of isopropyl iodide corrected by those of the internal standard be less than 2.0%. The chromatograms from the 6 SST injections were shown in Fig. 2. In this experiment, RSD% of the peak areas of isopropyl iodide corrected by those of n-octane (IS) was 0.083%.

The actual peak areas of isopropyl iodide and n-octane obtained in this experiment are listed in Table 2.

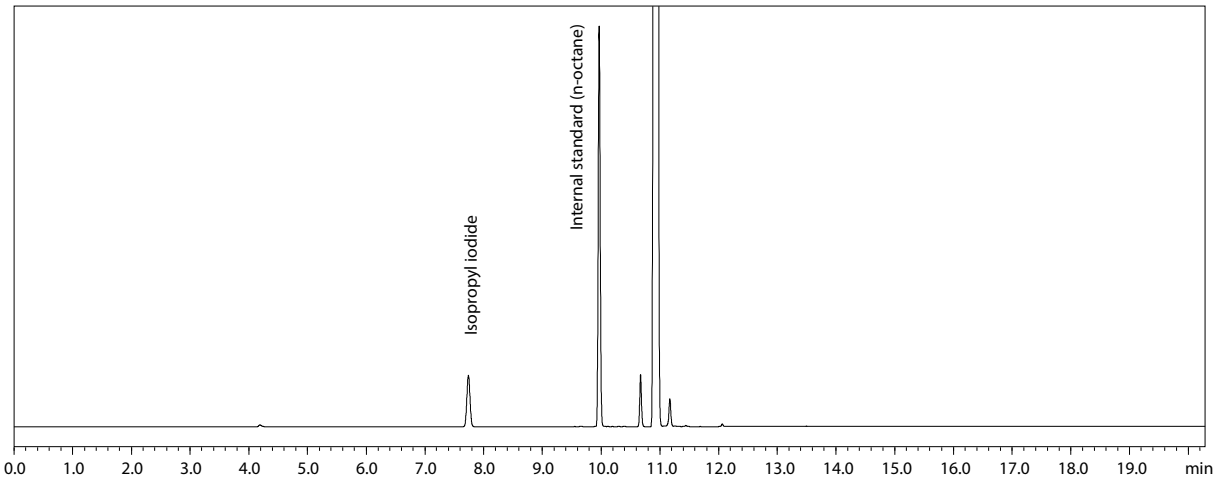

Fig. 1 Chromatogram of Standard Solution

Table 1 Instrument Composition and Analysis Conditions

Model	:	Nexis GC-2030AF (230 V) /AOC™-20i
Column	:	InertCap-1 (30 m, 0.53 mm I.D., df=3.0 µm)
Column Temp.	:	50 °C (3 min) - 10 °C/min - 100 °C - 35 °C/min - 250 °C (8 min)
Detector	:	FID
Carrier Gas	:	He, 2.8 mL/min
Inj. Temp.	:	250 °C
Det. Temp.	:	280 °C
Split Ratio	:	40
Inj. Volume	:	1.0 µL

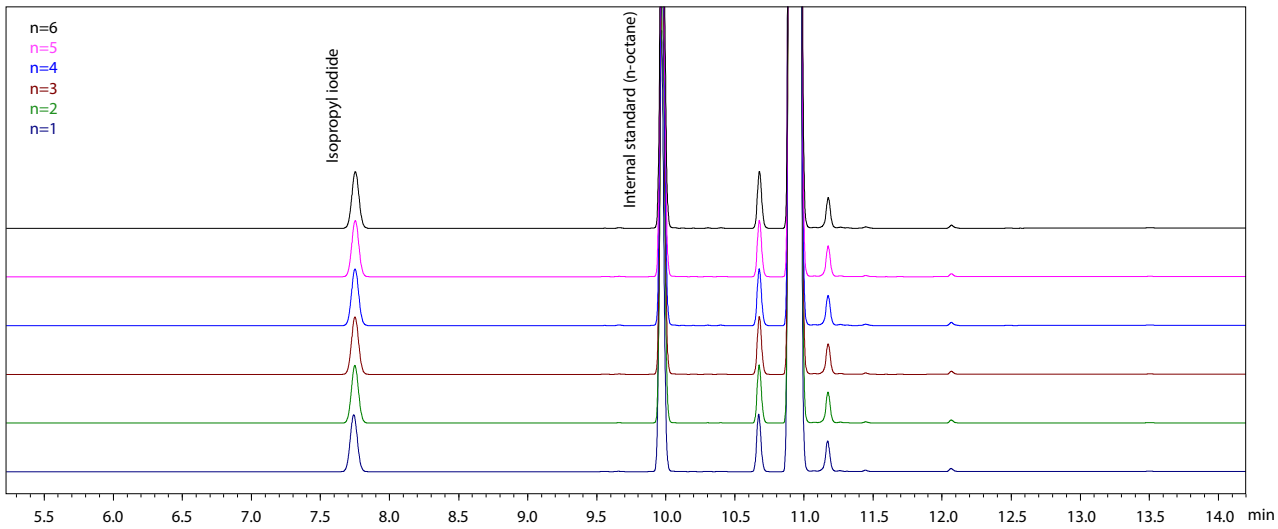

Fig. 2 Comparison of Chromatograms of Standard Solution (n = 6)

Table 2 Peak Areas of Isopropyl Iodide and Internal Standard (n-Octane)

	Isopropyl iodide	Internal standard (n-octane)	Peak area ratio
	Peak area μV・s	Peak area μV・s	
n=1	1657971	7972428	0.207
n=2	1678243	8056098	0.208
n=3	1673697	8034163	0.208
n=4	1656798	7948074	0.208
n=5	1643823	7893254	0.208
n=6	1649018	7912827	0.208
Repeatability RSD%	0.816	0.817	0.083

Conclusion

System suitability test of low-substituted hydroxypropyl cellulose for the United States Pharmacopeia (USP) 42-NF37 was performed with Shimadzu Nexis GC-2030.

As a standard solution, isopropyl iodide was diluted in a mixed solution of o-xylene and hydroiodic acid with n-octane also added as an internal standard in accordance with the USP method.

In this experiment, satisfactory results were obtained for both resolution and repeatability, confirming that Shimadzu Nexis GC-2030 satisfies system suitability required by USP42-NF37.

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