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Application News

Gas Chromatograph Brevis™ GC-2050

Analysis of Diethylene Glycol in Glycerin Using Brevis GC-2050 (with Reference to the Japanese Pharmacopoeia)

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User Benefits

- The compact Brevis GC-2050 allows for high-throughput analysis by increasing the number of operational units in the lab.
- Despite its small size, the Brevis GC-2050 achieves uncompromised analytical performance, enabling the analysis of concentrated glycerin in compliance with pharmacopeial standards.

■ Introduction

In response to the issue of contamination in pharmaceuticals and toothpaste with diethylene glycol, certain parts of the Japanese Pharmacopoeia were revised through Ministry of Health, Labour and Welfare Notification No. 32 (February 21, 2008). In Application News G259 "Analysis of Diethylene Glycol in Glycerin," a measurement example conforming to the pharmacopoeial requirements is introduced using GC-2010. While each country has its own official methods, this application conducted measurements on a Brevis GC-2050 under conditions where the Split/Splitless injection unit (SPL) temperature was set higher, taking into consideration that the sample component has a high boiling point, with reference to the Japanese Pharmacopoeia.

Fig. 1 AOC-30i and Brevis GC-2050

■ System Performance Verification

A solution was prepared by mixing 50 mg each of ethylene glycol, diethylene glycol, and glycerin in 100 mL of methanol. According to the Japanese Pharmacopoeia, when this solution was analyzed under the conditions specified in Table 1, the resolution between ethylene glycol and diethylene glycol was determined to be not less than 40, and the resolution between diethylene glycol and glycerin was determined to be not less than 10. the resolutions obtained were 67.3 and 19.7, respectively. In this measurement, the SPL temperature was set at 250 ˚C.

Table 1 Analysis Conditions

Model	: Brevis GC-2050AF+AOC-30i
Column	: SH-1701 (30 m x 0.32 mm (I.D.), df = 1.0 µm) (P/N : 221-75782-30)
Oven temp.	: 100 ˚C - 7.5 ˚C/min – 220 ˚C (13 min)
Carrier gas	: He, 38 cm/sec
INJ. Temp	: 250 ˚C
Det. Temp	: 250 ˚C
Split Ratio	: 1:20
INJ. Volume	: 1 µL

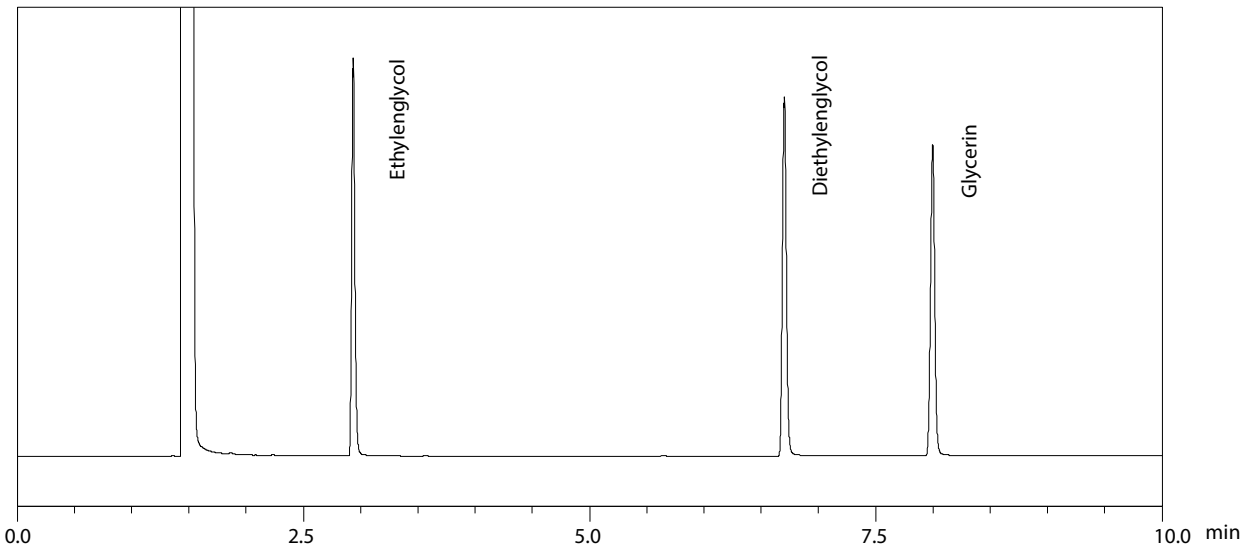

Fig. 2: Chromatogram of the System Performance Verification Solution

■ System Reproducibility

According to the Japanese Pharmacopoeia, it is specified that the Percent Relative Standard Deviation (%RSD) of the peak areas for ethylene glycol and diethylene glycol should be not more than 10% when analyzing a standard solution of 1 µL six times. The chromatogram obtained from injecting a 1 µL standard solution is shown in Fig. 3. The %RSD of the peak area values for ethylene glycol and diethylene glycol when analyzed six times consecutively is presented in Table 2. The %RSD values for diethylene glycol and glycerin were both below 10%. Fig. 4 shows the overlay of chromatograms from six measurements of the standard solution. Good reproducibility can be observed.

■ Conclusion

A sample was prepared for the analysis of concentrated glycerin as described in the Japanese Pharmacopoeia, and the analysis was conducted by the condition specified in the Japanese Pharmacopoeia.

Good separation and reproducibility were confirmed.

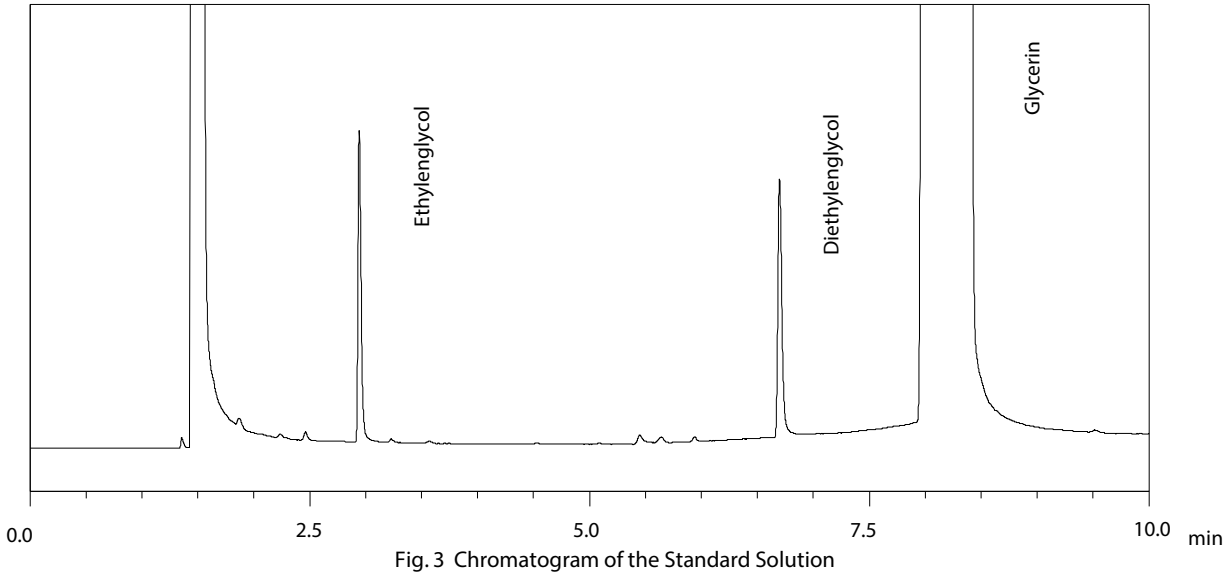

Fig. 3 Chromatogram of the Standard Solution

Table 2 Reproducibility of Peak Area Values for Diethylene Glycol and Glycerin (n=6)

	1st Run	2nd Run	3rd Run	4th Run	5th Run	6th Run	Average	%RSD
Diethylenglycol	14303	14362	14709	14394	14630	14466	14477	1.10
Glycerin	17596103	17555935	17853551	17575346	17960351	17528343	17678272	1.03

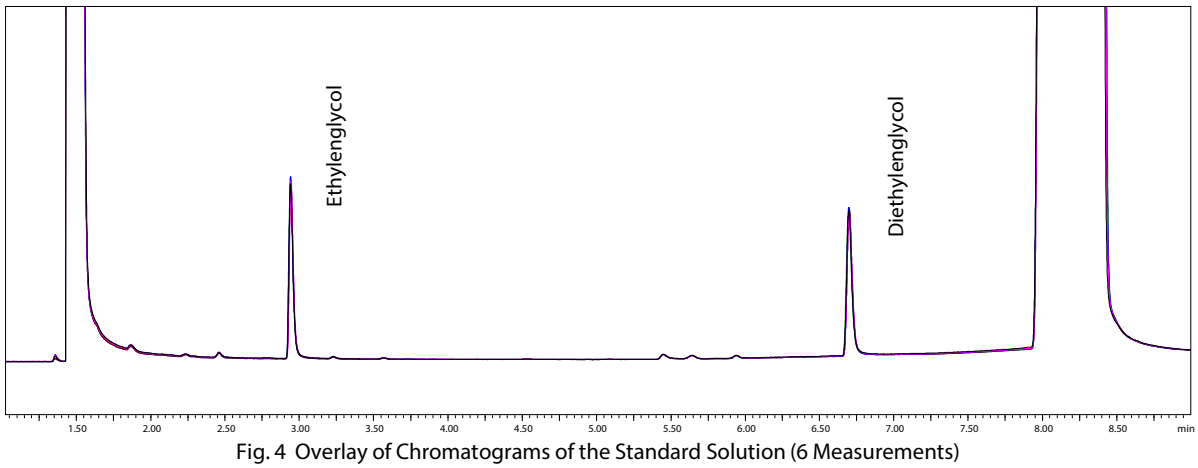

Fig. 4 Overlay of Chromatograms of the Standard Solution (6 Measurements)

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