

Alcohol Determination of Sanitizer Gel Using Nexis GC-2060

Hikaru Inada and Natsuko Kanno

User Benefits

- ◆ The newly developed FID on the Nexis GC-2060 provides excellent linearity for high-concentration samples.
- ◆ The Nexis GC-2060 enables rapid oven heating and cooling, allowing results to be obtained quickly.
- ◆ A special liner for aqueous solutions and an Xtra Life Microsyringe enable highly repeatable data acquisition.

Introduction

Methods for alcohol determination are specified in USP (United States Pharmacopeia) General Chapters <611> ALCOHOL DETERMINATION, which describes both a distillation and a gas chromatography method. In USP <611>, Method II (gas chromatography) includes a capillary column method (Method IIb).

For GC analysis of samples containing a large amount of water (e.g., sanitizing ethanol), sample vaporization may become unstable, resulting in abnormal peak shapes and poor repeatability. In addition, with a standard micro-syringe for AOC, the plunger may become stiff during aspiration and dispensing of aqueous solutions, which can degrade repeatability.

This article presents an example of alcohol determination in sanitizing ethanol using the Nexis GC-2060 equipped with a newly developed FID. The Nexis GC-2060 can be configured with a newly developed FID that has high sensitivity and excellent linearity. In addition, a special liner for aqueous solutions and an Xtra Life Microsyringe were used to achieve repeatable analysis.

Nexis GC-2060 and the Newly Developed FID

The Nexis GC-2060 is a gas chromatograph that combines world-class analytical performance with workflow optimization based on the latest technologies. Rapid oven heating and cooling shorten analysis cycle time and improve throughput.

The GC-2060 can also be equipped with a newly developed FID (Fig. 1). This FID offers world-class sensitivity and improved linearity.



Fig. 1 Appearance of the Nexis™ GC-2060 (Left) and the Newly Developed FID (Right)

Special Liner for Aqueous Solutions and Syringe

In this application, a special liner for aqueous solutions (P/N: 227-35015-01, Fig. 2, left) was used. This liner stabilizes sample vaporization, enabling good peak shapes and high repeatability for aqueous samples.

For sample introduction, an Xtra Life Microsyringe (P/N: 227-35400-01, Fig. 2 right) was used. The Xtra Life Microsyringe employs a flexible titanium alloy plunger, enabling stable introduction of aqueous samples.

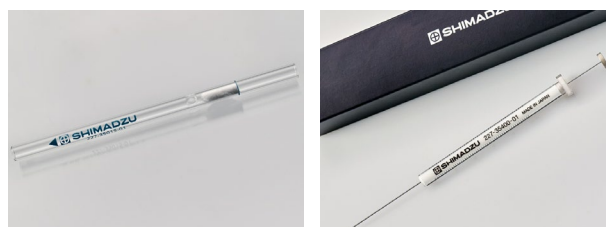


Fig. 2 The Special Liner for Aqueous Solutions (Left) and Xtra Life Microsyringe (Right)

Sample Preparation and Quantification Method

A standard solution was prepared by pipetting 5 mL each of 2 % (v/v) ethanol*1 and 2 % (v/v) acetonitrile*1 (internal standard), then diluting to 25 mL with water to obtain a 0.4 % (v/v) solution. As a sample, a commercially available sanitizing alcohol gel (ca. 80 % (v/v)) was diluted with water to ca. 2 % (v/v). Then, 5 mL each of the diluted sample and 2 % (v/v) acetonitrile was pipetted and diluted to 25 mL with water to obtain a ca. 0.4 % (v/v) sample solution.

*1 USP <611> states the use of USP Alcohol Determination–Alcohol RS (2 % (v/v) Ethanol) and USP Alcohol Determination–Acetonitrile RS (2 % (v/v) Acetonitrile) as standard solutions.

Analysis Conditions

Table 1 shows the instrument configuration used for analysis and the analysis conditions.

Table 1 Instrument Configuration and Analysis Conditions

Main Unit:	Nexis GC-2060 /AOC-30i
Column:	SH-I-624Si MS (0.53 mm I.D. × 30 m, d.f. = 3 μm)*1
Detector:	FID
Injection Volume:	0.2 μL
Injection Mode:	Split
Split Ratio:	1 : 5
Injection Unit Temp.:	210 °C
Carrier Gas:	He
Carrier Gas Control:	Linear velocity
Linear Velocity:	34 cm/sec
Column Temp.:	50 °C (5 min) – 10 °C/min – 200 °C (4 min)
Detector Temp.:	280 °C
Detector Gas:	Make up (N ₂) 30 mL/min H ₂ 40 mL/min Air 170 mL/min

*1 P/N: 227-36078-01

■ Chromatogram and Calibration Curve of the Standard Solution

The chromatogram of the standard solution is shown in Fig. 3, and the calibration curve is shown in Fig. 4. The peaks of ethanol and acetonitrile (IS) were completely separated.

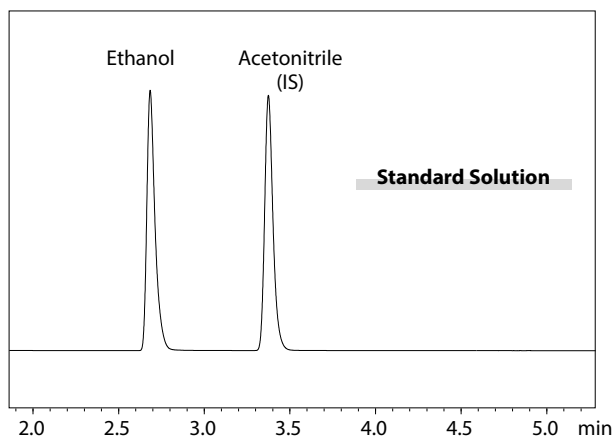


Fig. 3 Chromatograms of the Standard Samples

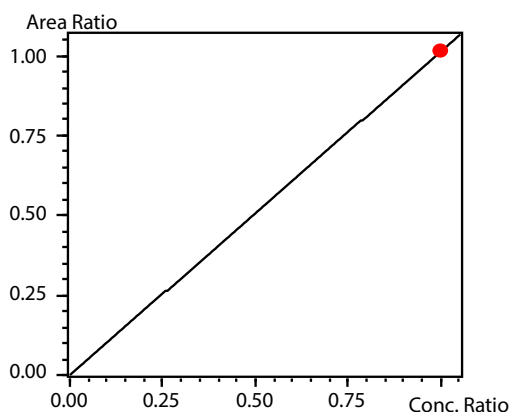


Fig. 4 Calibration Curve

USP <611> Method IIb defines the following three criteria for the system suitability test (SST):

- The tailing factor of the alcohol peak should not exceed **2.0**.
- The resolution factor, R, between alcohol and the internal standard is at least **4**.
- Six replicate injections of the standard solution show a relative standard deviation of not more than **4.0** % in the ratio of the peak of alcohol to the peak of the internal standard.

Table 2 summarizes the SST results for the standard solution. The specified SST items are highlighted in the original document. The results satisfied all SST criteria, confirming good repeatability of the area ratio.

Table 2 System Suitability of Standard Solution (n = 6)

Compound	Peak Area	Area ratio	Area ratio %RSD	Symmetry (tailing) factor	Resolution (USP)
Ethanol	929,184	1.013	0.432	1.510	—
Acetonitrile (IS)	917,152	—	—	1.291	8.213

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

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■ Chromatogram of the Sample Solution and Quantitative Results for Ethanol

The chromatogram of the sample solution is shown in Fig. 5. The alcohol concentration (v/v%) quantified for the sanitizing ethanol, along with the repeatability of the quantitative values (%RSD, n = 3), is listed in Table 3. The %RSD was 0.259, indicating good repeatability. Although repeatability often deteriorates in aqueous solution analysis, high repeatability was achieved in this application by using a liner and a micro-syringe suitable for aqueous samples.

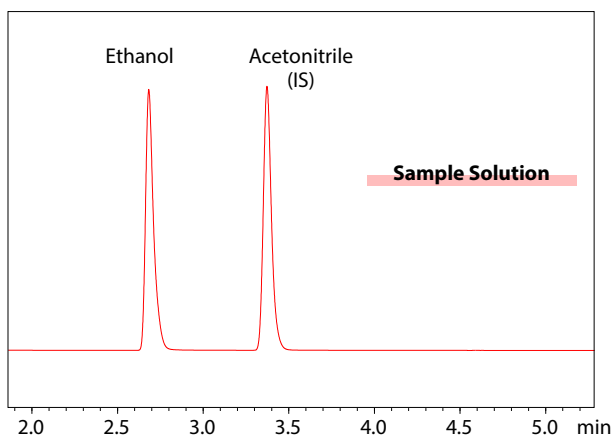


Fig. 5 Chromatograms of the Sample Solution

Table 3 Quantitative Results and Repeatability for the Sample Solution (n = 3)

Data	Area Ratio	Quantitative Value (v/v%)
1	0.975	77.0
2	0.978	77.2
3	0.981	77.4
Average	0.978	77.2
%RSD	0.314	0.259

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

■ Conclusion

The alcohol concentration in a commercially available sanitizing gel was determined using the Nexis GC-2060 equipped with the newly developed FID.

The results met the system suitability requirements of USP <611> Method IIb, confirming the effectiveness of the Nexis GC-2060 equipped with the new FID, along with the special liner for aqueous solutions, and the Xtra Life Microsyringe for repeatable analysis of aqueous samples.

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