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Application News

No.G284

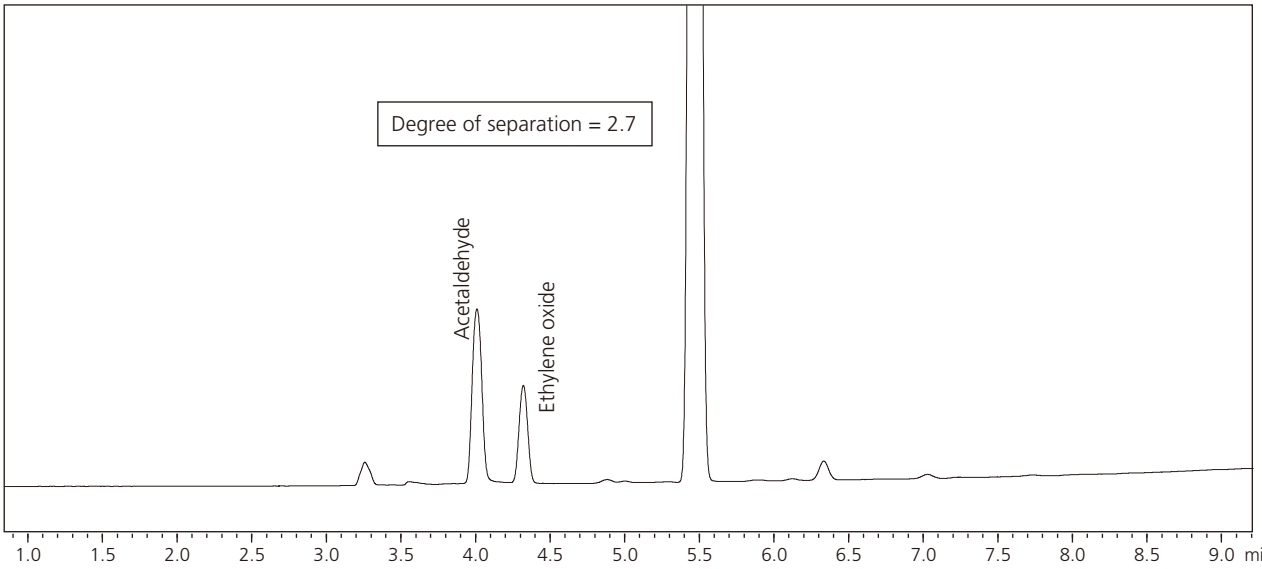
Gas Chromatography

Purity Testing of Polysorbate 80

Polysorbate 80 is a highly safe water soluble emulsifier that, in addition to its use in ointments (creams) as an emulsifier, is also used as an injectable solubilizing agent for oil-soluble vitamins as well as in health drinks. There was a partial revision of the Japanese Pharmacopoeia (2011 Japanese Ministry of Health, Labour and Welfare Notification No. 65) as reported by the Japanese Ministry of Health, Labour and Welfare in its Notification No. 47 (February 28, 2014), and which became effective that same day. In that Pharmacopoeia Supplement, the section "Purity (2)" was added to the Polysorbate 80 article of the official monographs. This Application News introduces the analyses described in Purity (2), Polysorbate 80 of the official monographs.

System Suitability Test

The system performance test specifies that when conducting analysis of the solution used for the system suitability test under the Table 1 conditions, acetaldehyde, ethylene oxide and 1,4-dioxane are eluted in this order, and the resolution between the peaks of acetaldehyde and ethylene oxide is not less than 2.0. The chromatogram obtained from analysis of this solution by the headspace method is shown in Fig. 1. The degree of separation of acetaldehyde and ethylene oxide was 2.0 or greater, as specified.



Note: Degree of separation is a reference value, and is not a guaranteed value.

Fig. 1 Chromatogram Obtained Using System Suitability Test Solution

Table 1 Analytical Conditions

Model	: GC-2010 Plus AF, HS-20	Inj. Volume	: 1.0 mL
Column	: BP5 (50 m × 0.53 mm I.D. df = 5.0 µm)	Sample Heating	: 80 ˚C, 30 min
Column Temp.	: 70 ˚C - 10 ˚C/min – 250 ˚C (5 min)	Sample Line Temp.	: 85 ˚C
Carrier Gas	: He, 4.0 mL/min at 70 ˚C	Transfer Line Temp.	: 85 ˚C
Det. Temp.	: 250 ˚C	HS Pressure	: 80 kPa
Split Ratio	: 1:3.5		

Purity Test

Both the sample solution and standard solution were prepared as specified in the head-space method under Gas Chromatography according to the Table 1 conditions. The amounts of ethylene oxide and 1,4-dioxane, calculated by the following equations, are not to be greater than 1 ppm and 10 ppm, respectively. The chromatograms of the standard solution and sample solution analyzed by the headspace method are shown in Fig. 2.

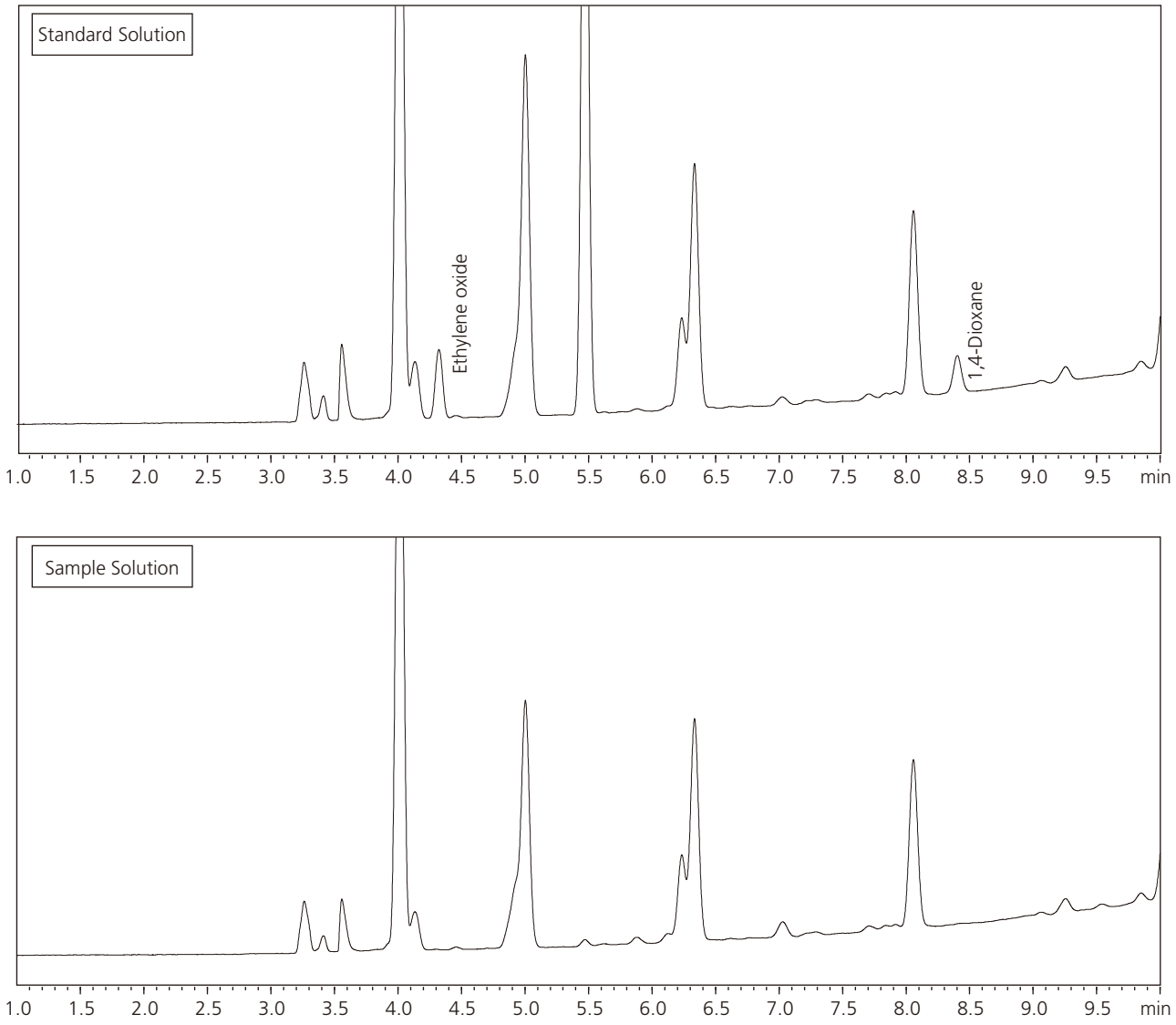


Fig. 2 Chromatograms of Standard Solution and Sample Solution

[References]
Ministry of Health, Labor and Welfare Notification No. 47 (February 28, 2014)

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