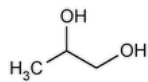


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Propylene Glycol



$C_3H_8O_2$ 76.09
1,2-Propanediol;
Propane-1,2-diol CAS RN®: 57-55-6.

DEFINITION
Propylene Glycol contains NLT 99.5% of $C_3H_8O_2$.

IDENTIFICATION
[NOTE—Compliance is determined by meeting the requirements of *Identification* tests A, B, and C.]
Change to read:

- A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS 〈197〉, Infrared Spectroscopy: 197F](#) ▲ (CN 1-MAY-2020)

[NOTE—Undried specimen.]

- B. LIMIT OF DIETHYLENE GLYCOL AND ETHYLENE GLYCOL

Diluent: Methanol

Standard solution: 2.0 mg/mL of [USP Propylene Glycol RS](#), 0.050 mg/mL of [USP Ethylene Glycol RS](#), 0.050 mg/mL of [USP Diethylene Glycol RS](#), and 0.10 mg/mL of 2,2,2-trichloroethanol (internal standard) in methanol

Sample solution: 50 mg/mL of Propylene Glycol and 0.10 mg/mL of 2,2,2-trichloroethanol (internal standard) in methanol

Chromatographic system

(See [Chromatography 〈621〉, System Suitability](#).)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m fused-silica coated with 3.0-μm G43 stationary phase, and a deactivated split liner with glass wool

Temperature

Injector: 220°

Detector: 250°

Column: See the temperature program table below.

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
100	—	100	4
100	50	120	10
120	50	220	6

Carrier gas: Helium

Injection size: 1.0 μL

Flow rate: 4.5 mL/min

Injection type: The split flow ratio is about 10:1.

System suitability

Sample: *Standard solution*

[NOTE—For informational purposes only. See [Impurity Table 1](#) for relative retention times for ethylene glycol, internal standard, and diethylene glycol. The retention time for propylene glycol is 4 min.]

Impurity Table 1

Component	Relative Retention Time
Ethylene glycol	0.8
Propylene glycol	1.0
Internal standard	1.7
Diethylene glycol	2.4

Suitability requirements

Resolution: NLT 5 between ethylene glycol and propylene glycol

Analysis

Sample: *Sample solution*

Acceptance criteria

Diethylene glycol: If a peak at the retention time for diethylene glycol is present in the *Sample solution*, the peak response ratio relative to 2,2,2-trichloroethanol is NMT the peak response ratio for diethylene glycol relative to 2,2,2-trichloroethanol in the *Standard solution*: NMT 0.10% for diethylene glycol.

Ethylene glycol: If a peak at the retention times for ethylene glycol is present in the *Sample solution*, the peak response ratio relative to 2,2,2-trichloroethanol is not more than the peak response ratio for ethylene glycol relative to 2,2,2-trichloroethanol in the *Standard solution*: NMT 0.10% for ethylene glycol is found.

- **C.** Examine the chromatograms obtained in *Identification* test B. The retention time of the propylene glycol peak of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

PROCEDURE

Sample: Propylene Glycol

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: GC

Detector: Thermal conductivity

Column: 1-m × 4-mm; 5% phase G16; support S5

Temperature

Injector: 240°

Detector: 250°

Column: Increase from 120° to 200° at a rate of 5°/min.

Carrier gas: Helium

Injection size: 10 µL

[NOTE—The approximate retention time for propylene glycol is 5.7 min, and the approximate retention times for the three isomers of dipropylene glycol, when present, are 8.2, 9.0, and 10.2 min, respectively.]

Analysis: Calculate the percentage of C₃H₈O₂ in the *Sample* by dividing the area under the propylene glycol peak by the sum of the areas under all of the peaks, excluding those due to air and water, and multiplying by 100:

$$\text{Result} = [r_U / (r_U + \Sigma r_U)] \times 100$$

r_U = peak response for Propylene Glycol from the *Sample*

Σr_U = sum of individual impurity peak responses, excluding those due to air and water, from the *Sample*

Acceptance criteria: NLT 99.5%

IMPURITIES

INORGANIC IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#).

Sample: 50 g

Analysis: Heat the *Sample* in a tared 100-mL shallow dish until it ignites, and allow it to burn without further application of heat in a place free from drafts. Cool, moisten the residue with 0.5 mL of sulfuric acid, and ignite to constant weight.

Acceptance criteria: The weight of the residue is NMT 3.5 mg.

- [CHLORIDE AND SULFATE, Chloride \(221\)](#): A 1-mL portion shows no more chloride than corresponds to 0.10 mL of 0.020 N hydrochloric acid (70 ppm).
- [CHLORIDE AND SULFATE, Sulfate \(221\)](#): A 5.0-mL portion shows no more sulfate than corresponds to 0.30 mL of 0.020 N sulfuric acid (60 ppm).

SPECIFIC TESTS

- **SPECIFIC GRAVITY** (841): 1.035–1.037
- **ACIDITY**
Sample: 10 mL of Propylene Glycol
Analysis: Add 1 mL of phenolphthalein TS to 50 mL of water, then add 0.1 N sodium hydroxide until the solution remains pink for 30 s. Add the **Sample**, and titrate with 0.10 N sodium hydroxide until the original pink color returns and remains for 30 s.
Acceptance criteria: NMT 0.20 mL of 0.10 N sodium hydroxide
- **WATER DETERMINATION, Method I** (921): NMT 0.2%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **USP REFERENCE STANDARDS** (11).
[USP Diethylene Glycol RS](#)
[USP Ethylene Glycol RS](#)
[USP Propylene Glycol RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PROPYLENE GLYCOL	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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