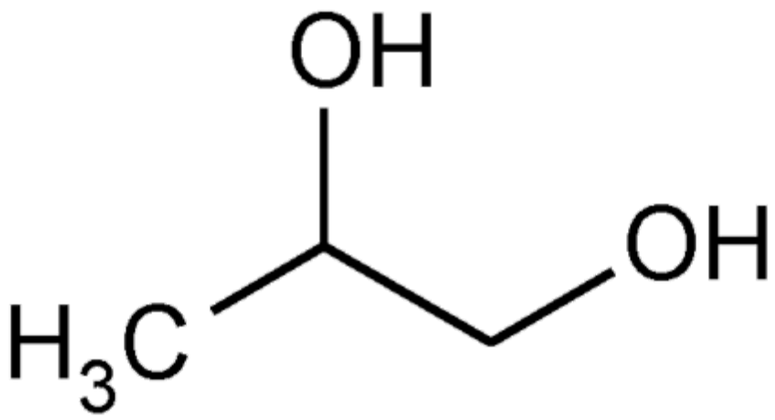
U.S. PHARMACOPEIA

Search USP29 Go

Propylene Glycol



$C_3H_8O_2$ 76.09

1,2-Propanediol.
1,2-Propanediol [*57-55-6*].

» Propylene Glycol contains not less than 99.5 percent of $C_3H_8O_2$.

Packaging and storage— Preserve in tight containers.

USP Reference standards ⟨ 11 ⟩ **—** *USP Propylene Glycol RS*.

Identification, *Infrared Absorption* ⟨ 197F ⟩ on undried specimen.

Specific gravity ⟨ 841 ⟩ : between 1.035 and 1.037.

Acidity— 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 seconds. Then add 10 mL of Propylene Glycol, accurately measured, and titrate with 0.10 N sodium hydroxide until the original pink color returns and remains for 30 seconds: not more than 0.20 mL of 0.10 N sodium hydroxide is required.

Water, *Method I* ⟨ 921 ⟩ : not more than 0.2%.

Residue on ignition— Heat 50 g 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: the weight of the residue does not exceed 3.5 mg.

Chloride ⟨ 221 ⟩ **—** A 1-mL portion shows no more chloride than corresponds to 0.10 mL of 0.020 N hydrochloric acid (0.007%).

Sulfate ⟨ 221 ⟩ **—** A 5.0-mL portion shows no more sulfate than corresponds to 0.30 mL of 0.020 N sulfuric acid (0.006%).

Heavy metals ⟨ 231 ⟩ **—** Mix 4.0 mL with water to make 25 mL: the limit is 5 ppm.

Organic volatile impurities, *Method IV* ⟨ 467 ⟩ : meets the requirements.

Residual solvents ⟨ 467 ⟩ **:** meets the requirements.
(Official January 1, 2007)

Assay—

Chromatographic system (see *Chromatography* ⟨ 621 ⟩)— The gas chromatograph is equipped with a thermal conductivity detector, and contains a 1-m × 4-mm column packed with 5% G16 on support S5. The injection port temperature is 240°, the detector temperature is 250°, and the column temperature is programmed at a rate of 5° per minute from 120° to 200°, and helium is used as the carrier gas. The approximate retention time for propylene glycol is 5.7 minutes, and the approximate retention times for the 3 isomers of dipropylene glycol, when present, are 8.2, 9.0, and 10.2 minutes, respectively.

Procedure— Inject a suitable volume, typically about 10 µL, of Propylene Glycol into a suitable gas chromatograph, and record the chromatogram. Calculate the percentage of $C_3H_8O_2$ in the Propylene Glycol 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.

Auxiliary Information— *Staff Liaison* : Catherine Sheehan, B.Sc., Scientist
Expert Committee : (EM105) Excipient Monographs 1
USP29–NF24 Page 1850
Phone Number : 1-301-816-8262