

EUROPEAN PHARMACOPOEIA

ELEVENTH EDITION

Supplement 11.6

# EUROPEAN PHARMACOPOEIA

Propylene glycol

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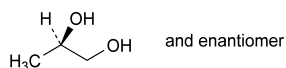
The following monograph is given for information only. The official version will appear in Ph. Eur. supplement 11.6.



**01/2025:0430** *Reference solution (b).* Weigh 200.0 mg of *propylene glycol R1* and dilute to about 75 mL with *methanol R*, add 5.0 mL of the internal standard solution and 5.0 mL of reference solution (a) and dilute to 100.0 mL with *methanol R*.

## PROPYLENE GLYCOL

### Propylenglycolum



C<sub>3</sub>H<sub>8</sub>O<sub>2</sub>  
[57-55-6]

M<sub>r</sub> 76.1

#### DEFINITION

(2*RS*)-Propane-1,2-diol.

#### CHARACTERS

*Appearance*: clear, colourless, viscous, hygroscopic liquid.

*Solubility*: miscible with water and with ethanol (96 per cent).

#### IDENTIFICATION

*First identification*: D.

*Second identification*: A, B, C.

A. Relative density (see Tests).

B. Refractive index (see Tests).

C. Boiling point (2.2.12): 184 °C to 189 °C.

D. Infrared absorption spectrophotometry (2.2.24).

*Comparison*: *propylene glycol for identification CRS*.

#### TESTS

**Appearance.** The substance to be examined is clear (2.2.1) and not more intensely coloured than reference solution B<sub>1</sub> (2.2.2, *Method II*).

**Relative density** (2.2.5): 1.035 to 1.040.

**Refractive index** (2.2.6): 1.431 to 1.433.

**Acidity.** To 50 mL of *water R* add 1 mL of *phenolphthalein solution R*, and then add 0.01 M *sodium hydroxide* until the pink colour persists for 30 s. Add 50.0 mL of the substance to be examined and titrate with 0.01 M *sodium hydroxide* until the colour reverts to pink and remains for more than 30 s. Not more than 8.3 mL of 0.01 M *sodium hydroxide* is required to change the colour of the indicator.

1 mL of 0.01 M *sodium hydroxide* is equivalent to 0.6 mg of C<sub>2</sub>H<sub>4</sub>O<sub>2</sub>.

**Oxidising substances.** To 10 mL add 5 mL of *water R*, 2 mL of *potassium iodide solution R* and 2 mL of *dilute sulfuric acid R* and allow to stand in a ground-glass-stoppered flask protected from light for 15 min. Titrate with 0.05 M *sodium thiosulfate*, using 1 mL of *starch solution R* as indicator. Not more than 0.2 mL of 0.05 M *sodium thiosulfate* is required (equivalent to a maximum of 17 ppm, calculated as H<sub>2</sub>O<sub>2</sub>).

**Ethylene glycol and diethylene glycol.** Gas chromatography (2.2.28).

*Internal standard solution.* Weigh 200.0 mg of 2,2,2-trichloroethanol *R* and dilute to 100.00 mL with *methanol R*.

*Test solution.* Weigh 5.0 g of the substance to be examined and dilute to about 75 mL with *methanol R*, add 5.0 mL of the internal standard solution and dilute to 100.0 mL with *methanol R*.

*Reference solution (a).* Weigh 62.0 mg of *ethylene glycol R* and 100.0 mg of *diethylene glycol R* and dilute to 100.0 mL with *methanol R*.

#### Column:

- *material*: fused silica;
- *size*: *l* = 30 m, Ø = 0.53 mm;
- *stationary phase*: cyanopropyl(3)phenyl(3)methyl(94)polysiloxane *R* (film thickness 3 µm).

*Carrier gas*: helium for chromatography *R*.

*Flow rate*: 4.5 mL/min.

*Split ratio*: 1:10.

*Temperature*:

|                | Time<br>(min) | Temperature<br>(°C) |
|----------------|---------------|---------------------|
| Column         | 0 - 4         | 100                 |
|                | 4 - 4.4       | 100 → 120           |
|                | 4.4 - 14.4    | 120                 |
|                | 14.4 - 16.4   | 120 → 220           |
| Injection port | 16.4 - 22.4   | 220                 |
|                |               | 220                 |
| Detector       |               | 250                 |

*Detection*: flame ionisation.

*Injection*: 1 µL of the test solution and reference solution (b).

*Injection liner*:

- packed with deactivated glass wool.

*Relative retention* with reference to propylene glycol (retention time = about 4 min): ethylene glycol = about 0.8; internal standard = about 1.7; diethylene glycol = about 2.4.

*System suitability*: reference solution (b):

- *resolution*: minimum 4.0 between the peaks due to ethylene glycol and propylene glycol;
- *symmetry factor*: maximum 5.0 for the peaks due to ethylene glycol and diethylene glycol.

*Limits*:

- ethylene glycol: calculate the ratio (*R*<sub>1</sub>) of the area of the peak due to ethylene glycol to the area of the peak due to the internal standard from the chromatogram obtained with reference solution (b); from the chromatogram obtained with the test solution, calculate the ratio of the area of the peak due to ethylene glycol to the area of the peak due to the internal standard: this ratio is not greater than *R*<sub>1</sub> (620 ppm);
- diethylene glycol: calculate the ratio (*R*<sub>2</sub>) of the area of the peak due to diethylene glycol to the area of the peak due to the internal standard from the chromatogram obtained with reference solution (b); from the chromatogram obtained with the test solution, calculate the ratio of the area of the peak due to diethylene glycol to the area of the peak due to the internal standard: this ratio is not greater than *R*<sub>2</sub> (0.10 per cent).

**Reducing substances.** To 1 mL add 1 mL of *dilute ammonia R1* and heat in a water-bath at 60 °C for 5 min. The solution is not yellow. Immediately add 0.15 mL of 0.1 M *silver nitrate* and allow to stand for 5 min. The solution does not change its appearance.

**Water** (2.5.12): maximum 0.2 per cent, determined on at least 5.00 g.

**Sulfated ash** (2.4.14): heat 50 g until it burns and ignite. Allow to cool. Moisten the residue with *sulfuric acid R* and ignite; repeat the operations. The residue weighs not more than 5 mg (0.01 per cent).

#### STORAGE

Store in an airtight container.

**2,2,2-Trichloroethanol.**  $C_2H_3Cl_3O$ . ( $M_r$  149.4). 1222400.  
[115-20-8]. 2,2,2-Trichloroethan-1-ol.

bp: about 152 °C.

mp: about 17.8 °C.

**Propylene glycol R1.** 1072901.

Complies with the requirements prescribed for the monograph *Propylene glycol (0430)* and free from diethylene glycol and ethylene glycol when examined as prescribed in the test for ethylene glycol and diethylene glycol in that monograph.

FOR INFORMATION