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# Propylene Glycol Solution

## [General Notices](#)

*Propylene Glycol* Cutaneous Solution

*NOTE: This monograph has been developed to cover unlicensed formulations.*

## Action and use

Excipient; emollient.

## DEFINITION

*Propylene Glycol* Solution is a *cutaneous solution*. It contains *Propylene Glycol* in Purified Water.

*The solution complies with the requirements stated under Liquids for Cutaneous Application and with the following requirements. Where appropriate, the solution also complies with the requirements stated under Unlicensed Medicines.*

## Content of *propylene glycol*, C<sub>3</sub>H<sub>8</sub>O<sub>2</sub>

95.0 to 105.0% of the stated amount.

## IDENTIFICATION

- A. The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of *propylene glycol* ([RS 437](#)).
- B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).

## TESTS

### Acidity

To 10 mL of the solution add 40 mL of [water](#) and 0.1 mL of [bromothymol blue solution R1](#); the solution is greenish-yellow. Not more than 0.1 mL of 0.1M [sodium hydroxide](#) is required to change the colour of the solution to blue.

### Related substances

Carry out the method for [gas chromatography](#), [Appendix III B](#), using the following solutions.

- (1) Dilute a quantity of the solution with sufficient [water](#) to contain 5% w/v of *Propylene Glycol*.
- (2) 1% w/v of [diethylene glycol](#) in [water](#).
- (3) Dilute 1 volume of solution (2) to 10 volumes with solution (1) and further dilute 1 volume of this solution to 20 volumes with

solution (1).

(4) Dilute 1 volume of a 40% w/v solution of [propylene glycol BPCRS](#) in [water](#) and 5 volumes of solution (2) to 100 volumes with [water](#); further dilute 1 volume to 10 volumes with [water](#).

(5) 0.05% w/v of [diethylene glycol](#) in [water](#).

#### CHROMATOGRAPHIC CONDITIONS

(a) Use a fused silica capillary column (30 m × 0.53 mm) bonded with a film (3 µm) of 6% cyanopropylphenyl siloxane and 94% polydimethylsiloxane (DB-624 is suitable).

(b) Use [helium](#) as the carrier gas at 4.5 mL per minute.

(c) Use an oven maintained at an initial temperature of 100°, increasing linearly to 220° at a rate of 7.5° per minute, then maintained at 220° for 4 minutes.

(d) Use an inlet temperature of 220°.

(e) Use a flame ionisation detector maintained at a temperature of 250°.

(f) Use a split ratio of 1:10.

(g) Inject 0.5 µL of each solution.

#### SYSTEM SUITABILITY

The chromatogram obtained with solution (4) shows a peak due to *propylene glycol* (retention time about 4.2 minutes) and a peak due to diethylene glycol with a retention relative to *propylene glycol* of about 1.8. The test is not valid unless the [symmetry factor](#) of both peaks is not less than 0.8 and not more than 1.2.

#### LIMITS

In the chromatogram obtained with solution (1):

the area of any peak due to diethylene glycol is not greater than the area of the corresponding peak in the chromatogram obtained with solution (3) (0.1%);

the area of any other [secondary peak](#) is not greater than five times the area of the peak due to diethylene glycol in the chromatogram obtained with solution (3) (0.5%);

the sum of the areas of all the peaks is not greater than 10 times the area of the peak due to diethylene glycol in the chromatogram obtained with solution (3) (1%).

Disregard any peak with an area less than 0.05 times the area of the peak in the chromatogram obtained with solution (5) (0.05%).

## ASSAY

Carry out the method for [gas chromatography](#), [Appendix III B](#), using the following solutions.

(1) Dilute a quantity of the solution with sufficient [water](#) to contain 0.04% w/v of *Propylene Glycol*.

(2) 0.04% w/v of [propylene glycol BPCRS](#) in [water](#).

#### CHROMATOGRAPHIC CONDITIONS

- (a) Use a fused silica capillary column (30 m × 0.53 mm) bonded with a film (3 µm) of 6% cyanopropylphenyl siloxane and 94% polydimethylsiloxane (DB-624 is suitable).
- (b) Use [helium](#) as the carrier gas at 4.5 mL per minute.
- (c) Use an oven maintained at an initial temperature of 100°, increasing linearly to 220° at a rate of 7.5° per minute, then maintained at 220° for 4 minutes.
- (d) Use an inlet temperature of 220°.
- (e) Use a flame ionisation detector maintained at a temperature of 250°.
- (f) Use a split ratio of 1:10.
- (g) Inject 0.5 µL of each solution.

#### DETERMINATION OF CONTENT

Calculate the content of C<sub>3</sub>H<sub>8</sub>O<sub>2</sub> in the solution using the declared content of C<sub>3</sub>H<sub>8</sub>O<sub>2</sub> in [propylene glycol BPCRS](#).

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