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Propanediol



$C_3H_8O_2$

76.09

1,3-Propanediol;
1,3-Dihydroxypropane;
Propane, 1-3-diol;
Trimethylene glycol CAS RN®: 504-63-2.

DEFINITION
Propanediol contains NLT 99.7% of 1,3-propanediol ($C_3H_8O_2$). It may be of vegetable, other natural source, or synthetic origin.

IDENTIFICATION
Change to read:

- **A.**  [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy: 197F*  (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to the 1,3-propanediol peak of the *System suitability solution*, as obtained in the Assay.

ASSAY

- **PROCEDURE**
System suitability solution: Mix quantities of [USP Propylene Glycol RS](#) and [USP 1,3-Propanediol RS](#) to obtain a solution containing about 5% propylene glycol and 95% propanediol.
Sample solution: Propanediol (neat)
Chromatographic system
(See [Chromatography \(621\)](#), *System Suitability*.)
Mode: GC
Detector: Flame ionization
Column: 0.25-mm × 30-m capillary column; bonded with a 0.25-μm layer of phase G16
Temperatures
Detector: 250°
Injection port: 250°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
50	15	200	—
200	40	250	17

Carrier gas: Helium
Flow rate: 1.1 mL/min

Injection volume: 0.2 µL

Split type: Split ratio of 18:1

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for propylene glycol and propanediol are 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the peaks due to propylene glycol and propanediol

Analysis

Sample: *Sample solution*

Calculate the percentage of propanediol in the portion of sample taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for propanediol in the *Sample solution*

r_T = sum of all peak responses in the *Sample solution*

Acceptance criteria: NLT 99.7%

IMPURITIES

• LIMIT OF RELATED GLYCOL SUBSTANCES

System suitability solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Analysis

Sample: *Sample solution*

Calculate the percentage of each individual impurity in the portion of Propanediol taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each individual impurity in the *Sample solution*

r_T = sum of all peak responses in the *Sample solution*

Acceptance criteria

Each individual impurity: NMT 0.1%

Total impurities: NMT 0.3%

• LIMIT OF ALDEHYDES

Formaldehyde methanol solution:¹ A solution containing 37% (w/w) of formaldehyde and 10%–15% (w/w) of methanol in water

Phenolphthalein solution: Dissolve 0.1 g of phenolphthalein in 80 mL of alcohol, and dilute with water to 100 mL.

Quantification of Formaldehyde methanol solution: To 2.0 g of *Formaldehyde methanol solution*, add 100 mL of a freshly prepared 100 mg/mL solution of sodium sulfite in carbon-dioxide free water. Add 0.1 mL of *Phenolphthalein solution*, and titrate with 0.5 N sulfuric acid until the color changes from pink to colorless. Carry out a blank titration.

Calculate the percentage content of formaldehyde in *Formaldehyde methanol solution* using the following expression:

$$\text{Result } (P_{HCHO}) = \{[(V_S - V_B) \times N \times M_W \times F]/W\} \times 100$$

V_S = volume of 0.5 N sulfuric acid used in the assay (mL)

V_B = volume of 0.5 N sulfuric acid used in the blank (mL)

N = normality of the titrant (mEq/mL)

M_W = milliequivalent weight of formaldehyde, 30.03 mg/mEq

F = unit conversion factor, 10^{-3} g/mg

W = weight of sample (g)

Standard stock solution: 1.2 µg/mL of *Formaldehyde methanol solution* in carbon-dioxide free water, prepared from appropriately diluting *Formaldehyde methanol solution* in carbon-dioxide free water