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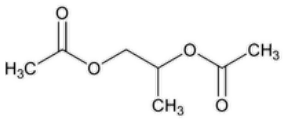
Propylene Glycol Diacetate



$C_7H_{12}O_4$ 160.17

1,2-Propanediol, 1,2-diacetate;

Propane-1,2-diyl diacetate CAS RN®: 623-84-7.

DEFINITION

Propylene Glycol Diacetate contains NLT 98.0% and NMT 102.0% of propylene glycol diacetate ($C_7H_{12}O_4$).

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197F**

- **B. Chromatographic Identity**

Analysis: Proceed as directed in the *Assay*.

Acceptance criteria: The retention time of the major peak of the *Sample solution*, excluding the solvent and internal standard peaks, corresponds to the propylene glycol diacetate peak of the *Standard solution*.

ASSAY

- **Procedure**

Internal standard solution: 20 mg/mL of triacetin in methanol

System suitability solution: 20 mg/mL each of USP Propylene Glycol Diacetate RS and USP Benzyl Alcohol RS in *Internal standard solution*

Standard solution: 20.0 mg/mL of USP Propylene Glycol Diacetate RS in *Internal standard solution*

Sample solution: 20.0 mg/mL of Propylene Glycol Diacetate in *Internal standard solution*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m fused silica; coated with a 1.0-µm film of phase G46

Temperatures

Injection port: 280°

Detector: 280°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
80	—	80	2
80	25	250	2

Carrier gas: Hydrogen

Flow rate: 5.0 mL/min

Injection volume: 1 µL

Injection type: Split ratio, 60:1

Run time: 10.8 min

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for propylene glycol diacetate, benzyl alcohol, and triacetin are 1.0, 1.1, and 1.4, respectively.]

Suitability requirements

Resolution: NLT 10 between the propylene glycol diacetate and benzyl alcohol peaks, *System suitability solution*

Tailing factor: NMT 1.5 for the propylene glycol diacetate and triacetin peaks, *Standard solution*

Relative standard deviation: NMT 1.0% for the peak area ratio of propylene glycol diacetate to the internal standard, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of propylene glycol diacetate in the portion of Propylene Glycol Diacetate taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times P \times 100$$

R_U = peak area ratio of propylene glycol diacetate to the internal standard from the *Sample solution*

R_S = peak area ratio of propylene glycol diacetate to the internal standard from the *Standard solution*

C_S = concentration of USP Propylene Glycol Diacetate RS in the *Standard solution* (mg/mL)

C_U = concentration of Propylene Glycol Diacetate in the *Sample solution* (mg/mL)

P = labeled purity of USP Propylene Glycol Diacetate RS

Acceptance criteria: 98.0%–102.0%

IMPURITIES

Change to read:

• **ORGANIC IMPURITIES**

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

Sensitivity solution: 0.2 mg/mL of USP Propylene Glycol Diacetate RS in methanol

Sample solution: 20.0 mg/mL of Propylene Glycol Diacetate in methanol

System suitability

Samples: *System suitability solution* and *Sensitivity solution*

[NOTE—The relative retention times for propylene glycol diacetate, benzyl alcohol, and triacetin are 1.0, 1.1, and 1.4, respectively.]

Suitability requirements

Resolution: NLT 10 between the propylene glycol diacetate and benzyl alcohol peaks, *System suitability solution*

Signal-to-noise ratio: NLT 20 for the propylene glycol diacetate peak, *Sensitivity solution*

Analysis

Sample: *Sample solution*

Identify the impurities in the *Sample solution* by comparing with those listed in *Table 2*.

Calculate the percentage of any individual impurity in the portion of Propylene Glycol Diacetate taken:

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

r_U = peak area of any individual impurity from the *Sample solution*

r_S = sum of all the peak areas, excluding the solvent peaks from the ▲*Sample*▲ *(ERR 1-Mar-2022) solution*

Table 2

Name	Relative Retention Time
Propylene glycol	0.67

Name	Relative Retention Time
Propylene glycol monoacetate, isomer 1	0.85
Propylene glycol monoacetate, isomer 2	0.88
Propylene glycol diacetate	1.0
Propylene glycol monoacetate monopropionate	1.11

Acceptance criteria

Individual impurity: NMT 0.1%

Total impurities: NMT 0.5%

- **Acetic Acid**

Sample: 10 g

Analysis: Dissolve the *Sample* in 30 mL of a mixture of alcohol and water (1:1), previously neutralized to phenolphthalein. Titrate with 0.1 N sodium hydroxide VS to a phenolphthalein endpoint. Each milliliter of 0.1 N sodium hydroxide is equivalent to 6.005 mg of acetic acid ($C_2H_4O_2$).

Acceptance criteria: NMT 0.2%

SPECIFIC TESTS

- **pH** ⟨791⟩

Sample: 1 in 20 solution

Acceptance criteria: 4.0–6.0

- **Specific Gravity** ⟨841⟩**:** 1.040–1.060
- **Refractive Index** ⟨831⟩**:** 1.4130–1.4150 at 20°
- **Water Determination** ⟨921⟩, *Method I, Method Ic*: NMT 0.1%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩

USP Benzyl Alcohol RS

USP Propylene Glycol Diacetate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PROPYLENE GLYCOL DIACETATE	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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