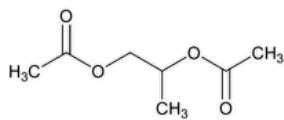


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Propylene Glycol Diacetate



$C_7H_{12}O_4$ 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	

