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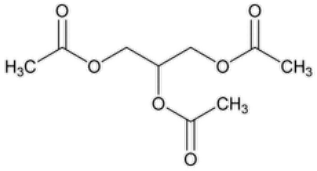
Triacetin



$C_9H_{14}O_6$ 218.21

1,2,3-Propanetriol triacetate;

Triacetin;

Glyceryl triacetate CAS RN®: 102-76-1.

DEFINITION

Triacetin contains NLT 97.0% and NMT 102.0% of triacetin ($C_9H_{14}O_6$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197F**▲ (CN 1-May-2020)

• **B.** The retention time of the triacetin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Internal standard solution: 0.1 mg/mL of benzyl alcohol in 2-propanol

Standard solution: 0.25 mg/mL of USP Triacetin RS in *Internal standard solution*

Sample solution: 0.25 mg/mL of Triacetin in *Internal standard solution*

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.25-mm × 30-m; coated with a 0.25-µm film of phase G46

Temperatures

Injection port: 200°

Detector: 250°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
100	—	100	1
100	30	230	1

Carrier gas: Hydrogen

Flow rate: 1.5 mL/min

Injection volume: 1 µL

Injection type: Split ratio, 40:1

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for benzyl alcohol and triacetin are 0.7 and 1.0, respectively.]

Suitability requirements

Tailing factor: NMT 2.0 for the triacetin peak

Relative standard deviation: NMT 1.0%, peak response ratio of triacetin to benzyl alcohol

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of triacetin ($C_9H_{14}O_6$) in the portion of Triacetin taken:

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

R_U = peak response ratio of triacetin to benzyl alcohol from the *Sample solution*

R_S = peak response ratio of triacetin to benzyl alcohol from the *Standard solution*

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

C_U = concentration of Triacetin in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0% on the anhydrous basis

IMPURITIES

- **ORGANIC IMPURITIES**

Internal standard solution: 0.02 mg/mL of benzyl alcohol in 2-propanol

Peak identification solution: 0.25 mg/mL each of glycerol, monoacetin, diacetin, and USP Triacetin RS in *Internal standard solution*

Standard solution: 0.02 mg/mL of USP Triacetin RS in *Internal standard solution*

Sample solution: 20 mg/mL of Triacetin in *Internal standard solution*

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.25-mm × 30-m; coated with a 0.25-µm film of phase G46

Temperatures

Injection port: 200°

Detector: 250°

Column: See *Table 2*.

Table 2

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
50	—	50	4
50	30	140	13
140	30	230	2

Carrier gas: Hydrogen

Flow rate: 1.5 mL/min

Injection volume: 1 µL

Injection type: Split ratio, 40:1

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for benzyl alcohol and triacetin are 0.62 and 1.0, respectively.]

Suitability requirements

Tailing factor: NMT 2.0 for the triacetin peak

Relative standard deviation: NMT 5.0%, peak response ratio of triacetin to benzyl alcohol

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Triacetin taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times (1/F) \times 100$$

R_U = peak response ratio of each impurity to benzyl alcohol from the *Sample solution*

R_S = peak response ratio of triacetin to benzyl alcohol from the *Standard solution*

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

C_U = concentration of Triacetin in the *Sample solution* (mg/mL)

F = relative response factor (see *Table 3*)

Acceptance criteria: See *Table 3*. Reporting threshold: 0.05%.

Table 3

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Acetic acid	0.24	0.62	0.1
Glycerol	0.65	0.54	0.1
1-Monoacetin	0.75	1.0	0.1
2-Monoacetin	0.82	1.0	0.1
1,3-Diacetin	0.90	1.0	0.1
1,2-Diacetin	0.92	0.73	0.1
Triacetin	1.0	—	—
Individual, unspecified impurity	—	1.0	0.1
Total impurities	—	—	0.2

SPECIFIC TESTS

- **WATER DETERMINATION ⟨921⟩, *Method I*:** NMT 0.2%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **USP REFERENCE STANDARDS ⟨11⟩**

USP Triacetin RS

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

Topic/Question	Contact	Expert Committee
TRIACETIN	Documentary Standards Support	SM12020 Small Molecules 1

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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