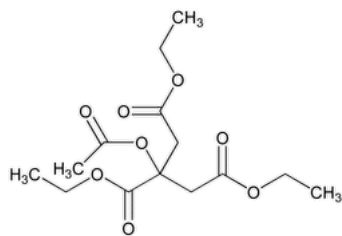


Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-May-2023
Document Type: NF Monographs
DocId: GUID-4CF097A8-66E5-4CE8-919D-669B5EEB1541_5_en-US
DOI: https://doi.org/10.31003/USPNF_M675_05_01
DOI Ref: j8h8u

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Acetyltriethyl Citrate



$C_{14}H_{22}O_8$ 318.32
Citric acid, O-acetyltriethyl ester;
Triethyl 2-acetoxypropane-1,2,3-tricarboxylate; CAS RN®: 77-89-4.

Change to read:

DEFINITION

Acetyltriethyl Citrate contains ▲NLT 98.0% and NMT 102.0%▲ (NF 1-May-2023) of acetyltriethyl citrate ($C_{14}H_{22}O_8$), calculated on the anhydrous basis.

IDENTIFICATION

• A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197F

Change to read:

• B. ▲CHROMATOGRAPHIC IDENTITY:▲ (NF 1-May-2023) The retention time of the major peak of the *Sample solution* corresponds to that of the ▲*Standard solution*,▲ (NF 1-May-2023) as obtained in the Assay.

ASSAY

Change to read:

• PROCEDURE

▲Diluent: [Methylene chloride](#)

Internal standard solution: 1 mg/mL of trimethyl citrate in *Diluent*

Standard solution: 1 mg/mL of [USP Acetyltriethyl Citrate RS](#) in *Internal standard solution*

Sample solution: 1 mg/mL of Acetyltriethyl Citrate in *Internal standard solution*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 30-m; 0.5-μm layer of phase [G42](#)

Temperatures

Injector: 225°

Detector: 275°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
50	—	50	
50	20	220	

Carrier gas: Helium**Flow rate:** 2.3 mL/min**Injection volume:** 1 µL**Injection type:** Split, split ratio 30:1**System suitability****Sample:** *Standard solution*

[NOTE—The retention time for acetyltriethyl citrate is about 15.4 min. The relative retention times for trimethyl citrate and acetyltriethyl citrate are 0.88 and 1.0, respectively.]

Suitability requirements**Tailing factor:** NMT 1.5 for the acetyltriethyl citrate and trimethyl citrate peaks**Relative standard deviation:** NMT 1.0% of the peak area ratio of acetyltriethyl citrate to trimethyl citrate**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of acetyltriethyl citrate ($C_{14}H_{22}O_8$) in the portion of Acetyltriethyl Citrate taken:

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

 R_U = peak area ratio of acetyltriethyl citrate to trimethyl citrate from the *Sample solution*
 R_S = peak area ratio of acetyltriethyl citrate to trimethyl citrate from the *Standard solution*
 C_S = concentration of [USP Acetyltriethyl Citrate RS](#) in the *Standard solution* (mg/mL)

 C_U = concentration of Acetyltriethyl Citrate in the *Sample solution* (mg/mL)
Acceptance criteria: 98.0%–102.0% on the anhydrous basis ▲ (NF 1-May-2023)

Add the following:

▲IMPURITIES**• ORGANIC IMPURITIES****Diluent** and **Chromatographic system:** Proceed as directed in the Assay.**Standard solution A:** 0.05 mg/mL of [USP Triethyl Aconitate RS](#) in *Diluent***Standard solution B:** 0.03 mg/mL of [USP Triethyl Citrate RS](#) in *Diluent***Standard solution C:** 0.03 mg/mL of [USP Acetyltriethyl Citrate RS](#) in *Diluent***Sample solution:** 10 mg/mL of Acetyltriethyl Citrate in *Diluent***System suitability****Samples:** *Standard solution A*, *Standard solution B*, and *Standard solution C***Suitability requirements****Relative standard deviation:** NMT 3.0% for the triethyl aconitate peak, *Standard solution A*; NMT 3.0% for the triethyl citrate peak, *Standard solution B*; NMT 3.0% for the acetyltriethyl citrate peak, *Standard solution C***Analysis****Samples:** *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Sample solution*[NOTE—See [Table 2](#) for the relative retention times.]**Table 2**

Compound Name	Relative Retention Time
Ethanol	0.11
Ethyl acetate	0.16
Triethyl aconitate ^a	0.93
Triethyl citrate	0.95
Triethyl isocitrate	0.97
Acetyltriethyl citrate	1.0
Any unidentified impurity	—

^a Triethyl (*E*)-prop-1-ene-1,2,3-tricarboxylate.