DEFINITION
Acetyltriethyl Citrate contains NLT 99.0% of acetyltriethyl citrate ($C_{14}H_{22}O_8$), calculated on the anhydrous basis.

IDENTIFICATION
- **A. Infrared Absorption** ⟨197F⟩
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *System suitability solution*, as obtained in the *Assay*.

ASSAY
- **Procedure**

System suitability solution: 30 mg/mL each of USP Acetyltriethyl Citrate RS and USP Triethyl Citrate RS in toluene
Sample solution: 30 mg/mL in toluene
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: GC, equipped with an on-column, temperature-programmable injector
Detector: Flame ionization
Column: 0.32-mm × 30-m, bonded with a 0.5-µm layer of phase G42
Temperatures
Injector: See *Table 1*.
Detector: 275°
Column: See *Table 2*.

Table 1

Start Temperature (°)	Ramp (°)	End Temperature (°)	Hold Time (min)
85	—	85	0.5
85	20	225	10

Table 2

Start Temperature (°)	Ramp (°)	End Temperature (°)	Hold Time (min)
80	—	80	0.5
80	20	220	10

Flow rate: 2.3 mL/min
Carrier gas: Helium
Injection volume: 1 µL
System suitability
Sample: *System suitability solution*
[NOTE—The relative retention times of triethyl citrate and acetyltriethyl citrate are 0.9 and 1.0, respectively.]
Suitability requirements
Resolution: NLT 1.5 between triethyl citrate and acetyltriethyl citrate
Relative standard deviation: NMT 2.0% determined from both the triethyl citrate and acetyltriethyl citrate peaks
Analysis
Sample: *Sample solution*
Calculate the percentage of acetyltriethyl citrate ($C_{14}H_{22}O_8$) in the portion of sample taken:

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

r_U = peak area of acetyltriethyl citrate from the *Sample solution*
r_T = sum of all the peaks excluding the solvent peak
Acceptance criteria: NLT 99.0% on the anhydrous basis

IMPURITIES

Delete the following:

•• **Heavy Metals,** *Method II* ⟨231⟩**:** NMT 10 µg/g •• (Official 1-Jan-2018)

SPECIFIC TESTS
- **Specific Gravity** ⟨841⟩**:** 1.135–1.139
- **Refractive Index** ⟨831⟩**:** 1.432–1.441
- **Acidity**

Sample: 32.0 g
Analysis: Dissolve the *Sample* in 30 mL of isopropyl alcohol, previously neutralized to bromothymol blue. Add bromothymol blue TS, and titrate with 0.10 N sodium hydroxide to a faint blue endpoint.
Acceptance criteria: NMT 1.0 mL of 0.10 N sodium hydroxide is required.

- **Water Determination,** *Method I* ⟨921⟩**:** NMT 0.3%

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

USP Acetyltriethyl Citrate RS
USP Triethyl Citrate RS

Activated Charcoal—*see Activated Charcoal General Monographs*

Adipic Acid

$C_6H_{10}O_4$ 146.14
Hexanedioic acid;
1,4-Butanedicarboxylic acid [124-04-9].

DEFINITION
Adipic Acid contains NLT 99.0% and NMT 101.0% of $C_6H_{10}O_4$, calculated on the dried basis.

IDENTIFICATION
- **A. Infrared Absorption** ⟨197K⟩

ASSAY
- **Procedure**

Sample: 60 mg
Titrimetric system
(See *Titrimetry* ⟨541⟩.)
Mode: Direct titration
Titrant: 0.1 N sodium hydroxide VS
Blank: 50.0 mL of water
Endpoint detection: Colorimetric
Analysis: Dissolve the *Sample* in 50 mL of water. Add 0.2 mL of phenolphthalein TS, and titrate with 0.1 N sodium hydroxide VS to a permanent pale pink endpoint. Perform a blank determination. Calculate the percentage of adipic acid ($C_6H_{10}O_4$) in the *Sample* taken:

$$\text{Result} = [(V - B) \times N \times F \times 100]/W$$

V = titrant volume consumed by the *Sample* (mL)
B = titrant volume consumed by the *Blank* (mL)
N = titrant actual normality (mEq/mL)
F = equivalency factor, 73.1 mg/mEq
W = weight of the *Sample* (mg)

NF Monographs