

• **READILY OXIDIZABLE SUBSTANCES**

Analysis: Mix 20 mL with 0.10 mL of 0.10 N potassium permanganate in a glass-stoppered bottle.

Acceptance criteria: The permanganate color of the mixture does not completely disappear within 15 min.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers, remote from fire.

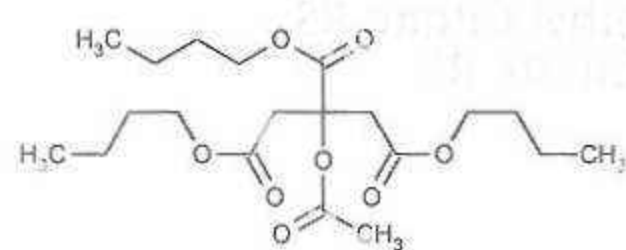
• **USP REFERENCE STANDARDS** (11)

USP Acetone RS

USP Methyl Alcohol RS

Acetylcysteine—see *Acetylcysteine General Monographs*

Acetyltributyl Citrate



$C_{20}H_{34}O_8$

402.48

DEFINITION

Acetyltributyl Citrate contains NLT 99.0% of $C_{20}H_{34}O_8$, calculated on the anhydrous basis.

IDENTIFICATION

• **A. INFRARED ABSORPTION** (197F)

• **B.** The retention time of the *Sample solution* corresponds to that of a similar preparation of USP Acetyltributyl Citrate RS, as obtained in the *Assay*.

ASSAY

• **PROCEDURE**

System suitability solution: 30 mg/mL each of USP Acetyltributyl Citrate RS and USP Tributyl Citrate RS in toluene

Sample solution: 30 mg/mL of Acetyltributyl Citrate in toluene

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.32-mm \times 30-m, bonded with a 0.5- μ m layer of phase G42

Temperature

Injector: 240°

Detector: 280°

Column: See the temperature program table below.

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
80	—	80	0
80	20	230	15

Flow rate: 1.9 mL/min

Carrier gas: Helium

Injection type: Split, 30:1

Injection size: 1 μ L

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for tributyl citrate and acetyl tributyl citrate are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between tributyl citrate and acetyl tributyl citrate

Relative standard deviation: NMT 2.0% determined from both the tributyl citrate and acetyl tributyl citrate peaks, based on area percent calculation

Analysis

Sample: *Sample solution*

[NOTE—Measure all of the peak areas, excluding the solvent peak.]

Calculate the percentage of $C_{20}H_{34}O_8$ in the portion of Acetyltributyl Citrate taken:

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

r_U = peak area of the *Sample solution*

r_T = sum of all the peak areas

Acceptance criteria: NLT 99.0% on the anhydrous basis

IMPURITIES

Inorganic Impurities

Delete the following:

• **HEAVY METALS, Method II (231):** NMT 10 ppm (Official 1-Jan-2018)

SPECIFIC TESTS

• **SPECIFIC GRAVITY (841):** 1.045–1.055

• **REFRACTIVE INDEX (831):** 1.4410–1.4425

• **ACIDITY**

Neutralized isopropyl alcohol: To a suitable quantity of isopropyl alcohol add 2–3 drops of bromothymol blue TS and just sufficient 0.10 N sodium hydroxide dropwise to produce a faint blue color. [NOTE—Prepare *Neutralized isopropyl alcohol* just before use.]

Sample solution: 32.0 g of Acetyltributyl Citrate in 30 mL of *Neutralized isopropyl alcohol*

Analysis: Add bromothymol blue TS. 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 0.25%

ADDITIONAL REQUIREMENTS

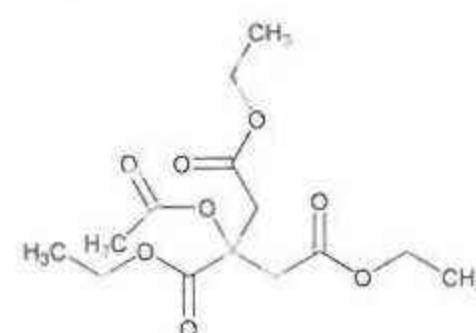
• **PACKAGING AND STORAGE:** Preserve in tight containers.

• **USP REFERENCE STANDARDS** (11)

USP Acetyltributyl Citrate RS

USP Tributyl Citrate RS

Acetyltriethyl Citrate



$C_{14}H_{22}O_8$

318.32