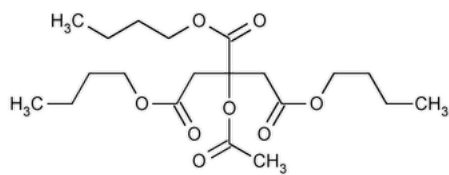


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Acetyltributyl Citrate



C₂₀H₃₄O₈ 402.48

DEFINITION

Acetyltributyl Citrate contains NLT 99.0% of C₂₀H₃₄O₈, 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 *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 × 30-m, bonded with a 0.5-μm 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 μL

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

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](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ACETYLTRIBUTYL CITRATE	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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