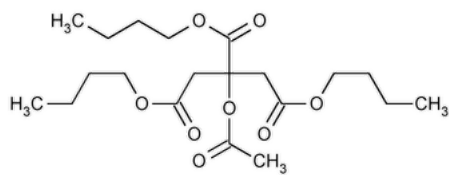


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# Acetyltributyl Citrate



C<sub>20</sub>H<sub>34</sub>O<sub>8</sub> 402.48

## DEFINITION

Acetyltributyl Citrate contains NLT 99.0% of C<sub>20</sub>H<sub>34</sub>O<sub>8</sub>, 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 | <a href="#">Documentary Standards Support</a> | SE2020 Simple Excipients |

**Chromatographic Database Information:** [Chromatographic Database](#)**Most Recently Appeared In:**

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