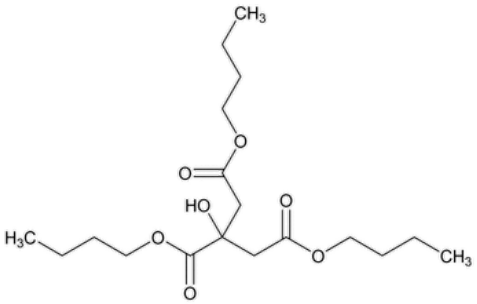
Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: NF Monographs
DocId: GUID-7B1DACCD-A57F-41EA-B3D3-002ABD94B72D_4_en-US
DOI: https://doi.org/10.31003/USPNF_M84970_04_01
DOI Ref: uz8wy

Tributyl Citrate



$C_{18}H_{32}O_7$ 360.44

DEFINITION

Tributyl Citrate contains NLT 99.0% of tributyl citrate ($C_{18}H_{32}O_7$), 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 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 Tributyl Citrate RS and USP Acetyltributyl Citrate RS in toluene

Sample solution: 30 mg/mL of Tributyl Citrate 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

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
85	—	85	0.5
85	20	225	10

Table 2

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
80	—	80	0.5
80	20	220	10

Carrier gas: Helium

Flow rate: 2.3 mL/min

Injection volume: 1 µL

System suitability

Sample: *System suitability solution*

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

Suitability requirements

Resolution: NLT 1.5 between tributyl citrate and acetyltributyl citrate

Relative standard deviation: NMT 2.0%, determined from both the tributyl citrate and acetyltributyl citrate peaks

Analysis

Sample: *Sample solution*

Calculate the percentage of tributyl citrate ($C_{18}H_{32}O_7$) in the portion of sample taken:

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

r_U = peak area of tributyl citrate from the *Sample solution*

r_T = sum of all peaks excluding the solvent peak

Acceptance criteria: NLT 99.0% on the anhydrous basis

SPECIFIC TESTS

- **SPECIFIC GRAVITY ⟨841⟩:** 1.037–1.045
- **REFRACTIVE INDEX ⟨831⟩:** 1.443–1.445
- **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 0.2%

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
TRIBUTYL CITRATE	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 49(4)
Current DocID: GUID-7B1DACCD-A57F-41EA-B3D3-002ABD94B72D_4_en-US
DOI: https://doi.org/10.31003/USPNF_M84970_04_01
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