

## Acetyltriethyl Citrate

Acetyltriethyl Citrate contains not less than 99.0 percent of C<sub>14</sub>H<sub>22</sub>O<sub>8</sub>, calculated on the anhydrous basis.

Packaging and storage— Preserve in tight containers.

### Identification—

A: [Infrared Absorption](#) [197F](#) .

B: The retention time for the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of a similar preparation of [USP Acetyltriethyl Citrate RS](#).

[Specific gravity](#) [841](#) : between 1.135 and 1.139.

[Refractive index](#) [831](#) : between 1.432 and 1.441.

**Acidity**— Dissolve 32.0 g 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: not more than 1.0 mL is required.

[Water, Method I](#) [921](#) : not more than 0.3%.

[Heavy metals, Method II](#) [231](#) : 0.001%.

### Assay—

System suitability solution— Prepare a solution in toluene containing about 30 mg each of [USP Acetyltriethyl Citrate RS](#) and [USP Triethyl Citrate RS](#) per mL.

Assay preparation— Transfer about 300 mg of Acetyltriethyl Citrate, accurately weighed, to a 10-mL volumetric flask, dissolve in and dilute with toluene to volume, and mix.

**Chromatographic system**— The gas chromatograph is equipped with an on-column, temperature-programmable injector, a flame-ionization detector maintained at about 275 °C, and a 0.32-mm × 30-m column bonded with a 0.5-µm layer of phase G42. The column temperature is programmed as follows. Initially the temperature of the column is maintained at about 80 °C for 0.5 minute, then increased at a rate of 20 °C per minute

to about 220 °C, and maintained at about 220 °C for 10 minutes. The injection port temperature is programmed as follows. Initially the temperature is maintained at about 85 °C for 0.5 minute, then increased at a rate of 20 °C per minute to about 225 °C, and maintained at about 225 °C for 10 minutes. The carrier gas is helium, flowing at a rate of about 2.3 mL per minute. Chromatograph the System suitability solution, and record the peak responses as directed for Procedure: the relative retention times are about 0.9 for triethyl citrate and 1.0 for acetyltriethyl citrate; the resolution, R, between triethyl citrate and acetyltriethyl citrate is not less than 1.5; and the relative standard deviation for replicate injections is not more than 2.0% determined from both the triethyl citrate and acetyltriethyl citrate peaks, based on area percent calculation.

**Procedure**— Inject 1 µL of the Assay preparation into the chromatograph, record the chromatogram, and measure all of the peak areas, excluding the solvent peak. Calculate the percentage of C<sub>14</sub>H<sub>22</sub>O<sub>8</sub> in the portion of Acetyltriethyl Citrate taken by the formula:

$$100(A/B)$$

in which A is the acetyltriethyl citrate peak area response; and B is the sum of the area responses of all the peaks.