the solution of *n*-hexane prepared with 30 mL of water in the same manner as the blank: the absorbance is not more than 0.05.

(8) Readily carbonizable substances—Perform the test with 0.5 g of Citric Acid, provided that the solution is heated at 90°C for 1 hour: the solution has no more color than Matching Fluid K.

Residue on ignition Not more than 0.10% (2 g).

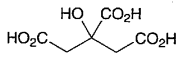
Assay Weigh accurately about 1.5 g of Citric Acid, dissolve in 25 mL of water, and titrate with 1 mol/L sodium hydroxide VS (indicator: 2 drops of phenolphthalein TS).

Each mL of 1 mol/L sodium hydroxide VS
= 70.05 mg of $C_6H_8O_7.H_2O$

Containers and storage Containers—Tight containers.

Anhydrous Citric Acid

無水クエン酸



$C_6H_8O_7$: 192.12
2-Hydroxypropane-1,2,3-tricarboxylic acid [*77-92-9*]

Anhydrous Citric Acid contains not less than 99.5% of $C_6H_8O_7$, calculated on the anhydrous basis.

Description Anhydrous Citric Acid occurs as colorless crystals, white granules or crystalline powder. It is odorless, and has a strong acid taste.

It is very soluble in water, freely soluble in methanol, in ethanol (95) and in acetone, and slightly soluble in diethyl ether.

Identification A solution of Anhydrous Citric Acid (1 in 20) changes the color of the blue litmus paper to red. The solution, made neutral with ammonia TS, responds to the Qualitative Tests for citrate.

Purity **(1)** Sulfate—Perform the test with 0.5 g of Anhydrous Citric Acid. Prepare the control solution with 0.50 mL of 0.005 mol/L sulfuric acid VS (not more than 0.048%).

(2) Oxalate—Dissolve 1.0 g of Anhydrous Citric Acid in 2 mL of dilute ethanol, neutralize with ammonia TS, add 0.2 mL of calcium chloride TS, and allow to stand for 1 hour: no turbidity is produced.

(3) Heavy metals—Proceed with 2.0 g of Anhydrous Citric Acid according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(4) Calcium—Dissolve 1.0 g of Anhydrous Citric Acid in 10 mL of water, neutralize with ammonia TS, and add 1 mL of ammonium oxalate TS: no turbidity is produced.

(5) Arsenic—Prepare the test solution with 2.0 g of Anhydrous Citric Acid according to Method 1, and perform the test using Apparatus B (not more than 1 ppm).

(6) Related substances—Dry 0.50 g of Anhydrous Citric Acid at 105°C for 3 hours. After cooling, dissolve the mass in exactly 10 mL of acetone, and use this solution as the sample solution. Perform the test with this solution as directed under the Paper Chromatography. Spot 5 μL of the sample solution on a filter paper. Develop the paper with the upper layer of a mixture of 1-butanol, formic acid and water (8:3:2) to a distance of about 25 cm, and air-dry the filter paper. Spray evenly bromophenol blue TS, pH 7.0, on the paper: any yellow spot other than the principal spot does not appear.

(7) Polycyclic aromatic hydrocarbon—Dissolve 25 g of Anhydrous Citric Acid in 30 mL of water by heating at about 50°C, cool, and extract with three 20-mL portions of hexane for ultraviolet-visible spectrophotometry. Each time separate the *n*-hexane layer by centrifuging between 2500 and 3000 revolutions per minute for 10 minutes. Combine the *n*-hexane extracts, and concentrate to 1 to 2 mL by evaporating. Cool, dilute with hexane for ultraviolet-visible spectrophotometry to make exactly 10 mL, and use this solution as the sample solution. Determine the absorbance between 260 nm and 350 nm as directed under the Ultraviolet-visible Spectrophotometry using the solution of *n*-hexane prepared with 30 mL of water in the same manner as the blank: the absorbance is not more than 0.05.

(8) Readily carbonizable substances—Perform the test with 0.5 g of Anhydrous Citric Acid, provided that the solution is heated at 90°C for 1 hour: the solution has no more color than Matching Fluid K.

Water Not more than 0.5% (2 g, direct titration).

Residue on ignition Not more than 0.10% (2 g).

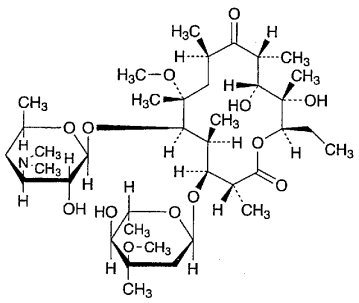
Assay Weigh accurately about 1.5 g of Anhydrous Citric Acid, dissolve in 25 mL of water, and titrate with 1 mol/L sodium hydroxide VS (indicator: 2 drops of phenolphthalein TS).

Each mL of 1 mol/L sodium hydroxide VS
= 64.04 mg of $C_6H_8O_7$

Containers and storage Containers—Tight containers.

Clarithromycin

クラリスロマイシン



$C_{38}H_{69}NO_{13}$: 747.95
(2*R*,3*S*,4*S*,5*R*,6*R*,8*R*,10*R*,11*R*,12*S*,13*R*)-5-(3,4,6-Trideoxy-3-dimethylamino-β-D-*xylo*-hexopyranosyloxy)-3-(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranosyloxy)-11,12-dihydroxy-6-methoxy-2,4,6,8,10,12-hexamethyl-9-oxopentadecan-13-olide
[*81103-11-9*]