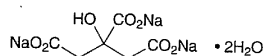


## Sodium Citrate

クエン酸ナトリウム

C<sub>6</sub>H<sub>5</sub>Na<sub>3</sub>O<sub>7</sub>·2H<sub>2</sub>O: 294.10

Trisodium 2-hydroxypropane-1,2,3-tricarboxylate dihydrate [6132-04-3]

Sodium Citrate, when dried, contains not less than 99.0% of C<sub>6</sub>H<sub>5</sub>Na<sub>3</sub>O<sub>7</sub>: 258.07.

**Description** Sodium Citrate occurs as colorless crystals, or a white, crystalline powder. It is odorless, and has a cooling, saline taste.

It is freely soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.

**Identification** A solution of Sodium Citrate (1 in 20) responds to the Qualitative Tests for citrate and for sodium salt.

**pH** Dissolve 1.0 g of Sodium Citrate in 20 mL of water: the pH of this solution is between 7.5 and 8.5.

**Purity (1)** Clarity and color of solution—A solution of 1.0 g of Sodium Citrate in 10 mL of water is clear and colorless.

(2) Chloride—Take 0.6 g of Sodium Citrate, and perform the test. Prepare the control solution with 0.25 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.015%).

(3) Sulfate—To 0.5 g of Sodium Citrate add water to make 40 mL, then add 3.0 mL of dilute hydrochloric acid and water to make 50 mL, and perform the test. Prepare the control solution with 0.50 mL of 0.005 mol/L sulfuric acid VS (not more than 0.048%).

(4) Heavy metals—Proceed with 2.5 g of Sodium Citrate according to Method 2, and perform the test. Prepare the control solution with 2.5 mL of Standard Lead Solution (not more than 10 ppm).

(5) Arsenic—Prepare the test solution with 1.0 g of Sodium Citrate according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

(6) Tartrate—To a solution of 1.0 g of Sodium Citrate in 2 mL of water add 1 mL of acetic acid (31): no crystalline precipitate is formed after the sides of the tube have been rubbed with a glass rod.

(7) Oxalate—Dissolve 1.0 g of Sodium Citrate in a mixture of 1 mL of water and 3 mL of dilute hydrochloric acid, add 4 mL of ethanol (95) and 0.2 mL of calcium chloride TS, and allow to stand for 1 hour: the solution is clear.

(8) Readily carbonizable substances—Take 0.5 g of Sodium Citrate, and perform the test by heating at 90°C for 1 hour: the solution has no more color than Matching Fluid K.

**Loss on drying** 10.0 – 13.0% (1 g, 180°C, 2 hours).

**Assay** Weigh accurately between  $3.434 \text{ g} \times f$  and  $3.475 \text{ g} \times f$  of Sodium Citrate, previously dried ( $f$  is the normality factor of 2 mol/L hydrochloric acid VS added in the next procedure). Dissolve in exactly 20 mL of 2 mol/L hydrochloric acid VS, and add exactly 25 mL of ethanol

(99.5). Then add 1 mL of dilute thymol blue TS and water to make exactly 50 mL. Perform the test with this solution as directed under the Absorbance Ratio Method. Determine the absorbances,  $A_1$  and  $A_2$ , of this solution at 440 nm and at 550 nm, using water as the blank. Calculate the value of  $r$  by the following formula:  $r = A_2/(A_1 + A_2)$ . Estimate the value of  $x$ , using the above value of  $r$  and the  $x - r$  curve obtained from the following table showing the relationship between  $x$  and  $r$ .

$$\text{Amount (g) of sodium citrate (C}_6\text{H}_5\text{Na}_3\text{O}_7) = 3.4409 \times f \times x$$

The table showing the relationship between  $x$  and  $r$ .

$x$	0.960	0.965	0.970	0.975	0.980	0.985	0.990	0.995	1.000
$r$	0.731	0.721	0.708	0.691	0.670	0.646	0.617	0.585	0.551
$x$	1.005	1.010	1.015	1.020	1.025	1.030	1.035	1.040	
$r$	0.516	0.482	0.444	0.409	0.379	0.358	0.346	0.345	

**Containers and storage** Containers—Tight containers.

## Sodium Citrate Injection for Transfusion

輸血用クエン酸ナトリウム注射液

Sodium Citrate Injection for Transfusion is an aqueous solution for injection. It contains not less than 9.5 w/v% and not more than 10.5 w/v% of sodium citrate (C<sub>6</sub>H<sub>5</sub>Na<sub>3</sub>O<sub>7</sub>·2H<sub>2</sub>O: 294.10).

### Method of preparation

Sodium Citrate	100 g
Water for Injection	a sufficient quantity
To make 1000 mL	

Prepare as directed under Injections, with the above ingredients.

No preservatives may be added.

**Description** Sodium Citrate Injection for Transfusion is a clear, colorless liquid.

**Identification** Sodium Citrate Injection for Transfusion responds to the Qualitative Tests for sodium salt and citrate.

**pH** 7.0 – 8.5

**Bacterial endotoxins** Less than 5.6 EU/mL.

**Assay** Pipet 5 mL of Sodium Citrate Injection for Transfusion, and add water to make exactly 25 mL. Evaporate 10 mL of this solution, exactly measured, on a water bath to dryness, dry the residue at 180°C for 2 hours, and dissolve in 30 mL of acetic acid (100) by warming. Cool, titrate with 0.1 mol/L perchloric acid VS (indicator: 3 drops of crystal violet TS). Perform a blank determination, and make any necessary correction.

$$\text{Each mL of 0.1 mol/L perchloric acid VS} = 9.803 \text{ mg of C}_6\text{H}_5\text{Na}_3\text{O}_7 \cdot 2\text{H}_2\text{O}$$

**Containers and storage** Containers—Hermetic containers.