

and add disodium hydrogenphosphate TS: a white, crystalline precipitate is produced.

**Purity (1) Acid-soluble substances**—Weigh accurately about 1 g of Talc, heat with 20 mL of dilute hydrochloric acid at 50°C for 15 minutes with stirring. Cool, add water to make exactly 50 mL, and filter. Centrifuge, if necessary, until the filtrate becomes clear. To 25 mL of this filtrate add 1 mL of dilute sulfuric acid, evaporate to dryness, and ignite to constant mass at  $800 \pm 25^\circ\text{C}$ : the amount of the residue is not more than 2.0%.

(2) Acid or alkali, and water-soluble substances—To 10.0 g of Talc, add 50 mL of water, weigh, and boil for 30 minutes, supplying water lost by evaporation. Cool, add water to restore the original mass, and filter. Centrifuge, if necessary, until the filtrate becomes clear: the filtrate is neutral. Evaporate 20 mL of the filtrate to dryness, and dry the residue at 105°C for 1 hour: the mass of the residue is not more than 4.0 mg.

(3) Water-soluble iron—Make 10 mL of the filtrate obtained in (2) weakly acidic with hydrochloric acid, and add dropwise potassium hexacyanoferrate (II) TS: the liquid does not acquire a blue color.

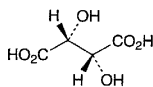
(4) Arsenic—To 0.5 g of Talc add 5 mL of dilute sulfuric acid, and heat gently to boiling with shaking. Cool immediately, filter, and wash the residue with 5 mL of dilute sulfuric acid, then with 10 mL of water. Combine the filtrate and the washings, evaporate to 5 mL on a water bath, and perform the test using apparatus B with this solution as the test solution (not more than 4 ppm).

**Loss on drying** Not more than 5.0% (1 g, 450 – 550°C, 3 hours).

**Containers and storage** Containers—Well-closed containers.

## Tartaric Acid

酒石酸



$\text{C}_4\text{H}_6\text{O}_6$ : 150.09  
(2*R*,3*R*)-2,3-Dihydroxybutanedioic acid [87-69-4]

Tartaric Acid, when dried, contains not less than 99.7% of  $\text{C}_4\text{H}_6\text{O}_6$ .

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

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

A solution of Tartaric Acid (1 in 10) is dextrorotatory.

**Identification (1)** Ignite Tartaric Acid gradually: it decomposes and an odor of burning sugar is perceptible.

(2) A solution of Tartaric Acid (1 in 10) changes blue litmus paper to red, and responds to the Qualitative Tests for tartrate.

**Purity (1) Sulfate**—Perform the test with 0.5 g of Tartaric 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 Tartaric Acid in 10 mL of water, and add 2 mL of calcium chloride TS: no turbidity is produced.

(3) Heavy metals—Proceed with 2.0 g of Tartaric Acid according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(4) Calcium—Neutralize a solution of 1.0 g of Tartaric Acid in 10 mL of water 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 Tartaric Acid according to Method 1, and perform the test using Apparatus B (not more than 1 ppm).

**Loss on drying** Not more than 0.5% (3 g, silica gel, 3 hours).

**Residue on ignition** Not more than 0.05% (1 g).

**Assay** Weigh accurately about 1.5 g of Tartaric Acid, previously dried, dissolve in 40 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  
= 75.04 mg of  $\text{C}_4\text{H}_6\text{O}_6$

**Containers and storage** Containers—Well-closed containers.

## Adsorbed Tetanus Toxoid

沈降破傷風トキソイド

Adsorbed Tetanus Toxoid is a liquid for injection containing tetanus toxoid prepared by treating tetanus toxin with formaldehyde by a method involving no appreciable loss of the immunogenicity and rendered insoluble by the addition of aluminum salt.

It conforms to the requirements of Adsorbed Tetanus Toxoid in the Minimum Requirements for Biological Products.

**Description** Adsorbed Tetanus Toxoid becomes a uniform white-turbid liquid on shaking.

## Freeze-dried Tetanus Antitoxin, Equine

乾燥破傷風ウマ抗毒素

Freeze-dried Tetanus Antitoxin, Equine, is a preparation for injection which is dissolved before use. It contains tetanus antitoxin in immunoglobulin of horse origin.

It conforms to the requirements of Freeze-dried Tetanus Antitoxin, Equine.