

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.

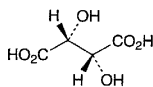
(4) Arsenic—To 0.5 g of Talc add 5 mL of dilute sulfuric acid, and heat gently to boiling with shaking. Cool immediately, filter, and wash the residue with 5 mL of dilute sulfuric acid, then with 10 mL of water. Combine the filtrate and the washings, evaporate to 5 mL on a water bath, and perform the 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.

nus Antitoxin, Equine, in the Minimum Requirements for Biological Products.

**Description** Freeze-dried Tetanus Antitoxin, Equine, becomes a clear, colorless to light yellow-brown liquid or slightly white-turbid liquid on addition of solvent.

## Thianthol

チアントール

Thianthol consists of dimethylthianthrene and ditoluene disulfide. It contains not less than 23.5% and not more than 26.5% of sulfur (S: 32.07).

**Description** Thianthol is a yellowish, viscous liquid. It has a faint, agreeable odor.

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

It, when cold, may separate crystals, which melt on warming.

Specific gravity  $d_{20}^{20}$ : 1.19 – 1.23

**Identification** To 0.1 g of Thianthol add cautiously 5 mL of sulfuric acid: a blue-purple color develops. Add 5 to 6 drops of nitric acid to the solution: the color of the solution changes to yellow-red with evolution of gas.

**Purity (1)** Acidity or alkalinity—Shake 10 g of Thianthol with 20 mL of water, allow to stand, and separate the water layer. The solution is neutral.

(2) Sulfate—To 10 mL of the water layer obtained in (1) add 2 to 3 drops of barium chloride TS: no opalescence is produced.

**Residue on ignition** Not more than 0.10% (1 g).

**Assay** Weigh accurately about 0.01 g of Thianthol, and proceed as directed in the sulfur determination of the Oxygen Flask Combustion Method, using a mixture of 5 mL of diluted sodium hydroxide TS (1 in 10) and 1.0 mL of hydrogen peroxide TS as an absorbing liquid.

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

## Compound Thianthol and Salicylic Acid Solution

複方チアントール・サリチル酸液

Compound Thianthol and Salicylic Acid Solution contains not less than 1.8 w/v% and not more than 2.2 w/v% of salicylic acid ( $C_7H_6O_3$ : 138.12), and not less than 1.8 w/v% and not more than 2.2 w/v% of phenol ( $C_6H_6O$ : 94.11).

### Method of preparation

Thianthol	200 mL
Salicylic Acid	20 g
Phenol	20 g

Olive Oil	50 mL
Ether	100 mL
Petroleum Benzin	a sufficient quantity
To make 1000 mL	

Dissolve Salicylic Acid and Phenol in Ether, add Thianthol, Olive Oil and Petroleum Benzin to this solution, mix and dissolve to make 1000 mL.

**Description** Compound Thianthol and Salicylic Acid Solution is a light yellow liquid, having a characteristic odor.

**Identification (1)** Place 1 mL of Compound Thianthol and Salicylic Acid Solution to a porcelain dish, and evaporate on a water bath to dryness. To the residue add cautiously 5 mL of sulfuric acid: the color of the solution changes to yellow-red with evolution of gas (thianthol).

(2) Shake 10 mL of Compound Thianthol and Salicylic Acid Solution with 10 mL of sodium hydrogen carbonate TS, and separate the water layer. To 0.5 mL of the water layer add hydrochloric acid-potassium chloride buffer solution, pH 2.0, to make 50 mL, and to 5 mL of this solution add 5 mL of a solution of iron (III) nitrate enneahydrate (1 in 200): a red-purple color is produced (salicylic acid).

(3) Wash the upper phase obtained in (2) with 10 mL of sodium hydrogen carbonate TS, and extract with 10 mL of dilute sodium hydroxide TS. Shake 1 mL of the extract with 1 mL of sodium nitrate TS and 1 mL of dilute hydrochloric acid, and add 3 mL of sodium hydroxide TS: a yellow color is produced (phenol).

(4) To 1 mL of Compound Thianthol and Salicylic Acid Solution add 10 mL of ethanol (95), mix, and use this solution as the sample solution. Dissolve 0.01 g each of salicylic acid, phenol and thianthol in 5 mL each of ethanol (95), and use each solution as standard solutions (1), (2) and (3). Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5  $\mu$ L each of the sample solution and the standard solutions on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform, acetone and acetic acid (100) (45:5:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): three spots obtained from the sample solution and the corresponding spots of standard solutions (1), (2) and (3) show the same  $R_f$  value. Spray evenly iron (III) chloride TS on the plate: the spot from standard solution (1) and the corresponding spot from the sample solution reveal a purple color.

**Assay** Measure exactly 2 mL of Compound Thianthol and Salicylic Acid Solution, add exactly 10 mL of the internal standard solution, then add 70 mL of diluted methanol (1 in 2), mix well, and add diluted methanol (1 in 2) to make 100 mL. Filter, discard the first 10 mL of the filtrate, and use the subsequent filtrate as the sample solution. Weigh accurately about 0.2 g of salicylic acid for assay, previously dried in a desiccator (silica gel) for 3 hours, and about 0.2 g of phenol for assay, dissolve in diluted methanol (1 in 2) to make exactly 50 mL. Pipet 10 mL of this solution, add exactly 10 mL of the internal standard solution and diluted methanol (1 in 2) to make 100 mL, and use this solution as the standard solution. With 5  $\mu$ L each of the sample solution and the standard solution, perform the test as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios,  $Q_{Ta}$  and  $Q_{Tb}$ , of the peak area of salicylic