

ence Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

(4) To 5 mL of a solution of Thioridazine Hydrochloride (1 in 100) add 2 mL of ammonia TS, and heat on a water bath for 5 minutes. After cooling, filter, and acidify the filtrate with dilute nitric acid: the solution responds to the Qualitative Tests (2) for chloride.

**Melting point** 159 – 164°C

**Purity (1) Heavy metals**—Proceed with 1.0 g of Thioridazine Hydrochloride according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(2) **Arsenic**—Prepare the test solution with 1.0 g of Thioridazine Hydrochloride, according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(3) **Related substances**—Conduct this procedure under the protection from the sunlight. Dissolve 0.10 g of Thioridazine Hydrochloride in 10 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, and add methanol to make exactly 20 mL. Pipet 2 mL of this solution, add methanol to make exactly 10 mL, and use this solution as the standard solution. 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 solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform, 2-propanol and ammonia solution (28) (74:25:1) to a distance of about 10 cm, and air-dry the plate. Examine the plate under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

**Loss on drying** Not more than 0.5% (1 g, 105°C, 4 hours).

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

**Assay** Weigh accurately about 0.35 g of Thioridazine Hydrochloride, previously dried, dissolve in 80 mL of a mixture of acetic anhydride and acetic acid (100) (1:1), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

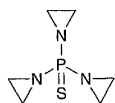
Each mL of 0.1 mol/L perchloric acid VS  
= 40.70 mg of  $C_{21}H_{26}N_2S_2 \cdot HCl$

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

Storage—Light-resistant.

## Thiotepa

チオテパ



$C_6H_{12}N_3PS$ : 189.22

Tris(aziridin-1-yl)phosphine sulfate [52-24-4]

Thiotepa, when dried, contains not less than 98.0% of  $C_6H_{12}N_3PS$ .

**Description** Thiotepa occurs as colorless or white crystals, or white, crystalline powder. It is odorless.

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

A solution of Thiotepa (1 in 10) is neutral.

**Identification (1)** To 5 mL of a solution of Thiotepa (1 in 100) add 1 mL of hexaammonium heptamolybdate TS, and allow to stand: a dark blue color develops slowly when the solution is cold, or quickly when warm.

(2) To 5 mL of a solution of Thiotepa (1 in 100) add 1 mL of nitric acid: this solution responds to the Qualitative Tests (2) for phosphate.

(3) Dissolve 0.1 g of Thiotepa in a mixture of 1 mL of lead (II) acetate TS and 10 mL of sodium hydroxide TS, and boil: the gas evolved changes moistened red litmus paper to blue, and the solution shows a grayish red color.

**Melting point** 52 – 57°C

**Purity (1) Clarity and color of solution**—Dissolve 1.0 g of Thiotepa in 20 mL of water: the solution is clear and colorless.

(2) **Heavy metals**—Proceed with 1.0 g of Thiotepa in a platinum crucible according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(3) **Arsenic**—Dissolve 0.20 g of Thiotepa in 5 mL of water, and add 1 mL of nitric acid and 1 mL of sulfuric acid. Take this solution, prepare the test solution according to Method 2, and perform the test using Apparatus B (not more than 10 ppm).

**Loss on drying** Not more than 0.20% (1 g, in vacuum, silica gel, 4 hours).

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

**Assay** Weigh accurately about 0.1 g of Thiotepa, previously dried, dissolve in 50 mL of a solution of potassium thiocyanate (3 in 20), add 25 mL of 0.05 mol/L sulfuric acid VS, exactly measured, and allow to stand for 20 minutes with occasional shaking. Titrate the excess sulfuric acid with 0.1 mol/L sodium hydroxide VS until the color of the solution changes from red to light yellow (indicator: 3 drops of methyl red TS). Perform a blank determination.

Each mL of 0.05 mol/L sulfuric acid VS  
= 6.307 mg of  $C_6H_{12}N_3PS$

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

Storage—Light-resistant, and in a cold place.

## L-Threonine

L-トレオニン

