

roform. Filter the combined chloroform extracts into a conical flask, and wash the filter paper with three 5-mL portions of chloroform. Combine the filtrate and the washings, and add 10 mL of ethanol (95). Titrate with 0.1 mol/L potassium hydroxide-ethanol VS until the color of the solution changes from yellow through light blue to purple (indicator: 2 mL of alizarin yellow GG-thymolphthalein TS). Perform a blank determination with a mixture of 160 mL of chloroform and 30 mL of ethanol (95), and make any necessary correction.

Each mL of 0.1 mol/L potassium hydroxide-ethanol VS = 26.432 mg of  $C_{11}H_{17}N_2NaO_2S$

**Containers and storage** Containers—Tight containers.  
Storage—Light-resistant.

## Thiopental Sodium for Injeciton

注射用チオペンタールナトリウム

Thiopental Sodium for Injection is a preparation for injection which is dissolved before use. It contains not less than 93% and not more than 107% of the labeled amount of thiopental sodium ( $C_{11}H_{17}N_2NaO_2S$ ; 264.32).

**Method of preparation** Prepare as directed under Injections, with 100 parts of Thiopental Sodium and 6 parts of Dried Sodium Carbonate in mass.

**Description** Thiopental Sodium for Injection is a light yellow powder or mass, and has a slight, characteristic odor.

It is very soluble in water, and practically insoluble in dehydrated diethyl ether.

It is hygroscopic.

**Identification (1)** Dissolve 0.1 g of Thiopental Sodium for Injection in 10 mL of water, and add 0.5 mL of barium chloride TS: a white precipitate is formed. Collect the precipitate, and add dilute hydrochloric acid dropwise: the precipitate dissolves with effervescence.

(2) Proceed as directed in the Identification under Thiopental Sodium.

**pH** Dissolve 1 g of Thiopental Sodium for Injection in 40 mL of water: the pH of this solution is between 10.2 and 11.2.

**Purity** Proceed as directed in the Purity under Thiopental Sodium.

**Loss on drying** Not more than 2.0% (1 g, in vacuum, 80°C, 4 hours).

**Sterility** Perform the test according to the Membrane filtration method: it meets the requirements of the Sterility Test.

**Assay** Take 10 samples of Thiopental Sodium for Injection, and open each container carefully. Dissolve each content with water, wash each container with water, combine the washings with the former solution, and add water to make exactly 1000 mL. Pipet 10 mL of this solution, and add water to make exactly 100 mL. Measure exactly a volume ( $V$  mL) of this solution, equivalent to about 0.015 g of thiopental sodium ( $C_{11}H_{17}N_2NaO_2S$ ), and add water to

make exactly 1000 mL. Pipet 10 mL of this solution, add 15 mL of diluted dilute sodium hydroxide TS (1 in 100), add water to make exactly 30 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.046 g of thiopental for assay, previously dried at 105°C for 3 hours, dissolve in 50 mL of dilute sodium hydroxide TS, and add water to make exactly 200 mL. Pipet 2 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with the sample solution and the standard solution as directed under the Ultraviolet-visible Spectrophotometry, and determine the absorbances,  $A_T$  and  $A_S$ , at 304 nm.

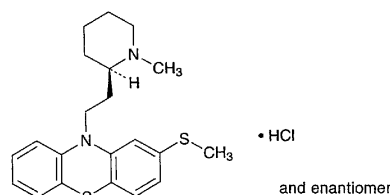
Amount (mg) of thiopental sodium ( $C_{11}H_{17}N_2NaO_2S$ ) in each sample of Thiopental Sodium for Injection = amount (mg) of thiopental sodium for assay

$$\times \frac{A_T}{A_S} \times \frac{300}{V} \times 1.0907$$

**Containers and storage** Containers—Hermetic containers.  
Storage—Light-resistant.

## Thioridazine Hydrochloride

塩酸チオリダジン



$C_{21}H_{26}N_2S_2 \cdot HCl$ : 407.04  
10- $\{2-[(1S)-1\text{-Methylpiperidin-2-yl}]ethyl\}$ -2-methylsulfonylphenothiazine monohydrochloride  
[130-61-0]

Thioridazine Hydrochloride, when dried, contains not less than 99.0% of  $C_{21}H_{26}N_2S_2 \cdot HCl$ .

**Description** Thioridazine Hydrochloride occurs as a white to pale yellow, crystalline powder. It is odorless, and has a bitter taste.

It is freely soluble in water, in methanol, in ethanol (95) and in acetic acid (100), sparingly soluble in acetic anhydride, and practically insoluble in diethyl ether.

The pH of a solution of Thioridazine Hydrochloride (1 in 100) is between 4.2 and 5.2.

It is gradually colored by light.

**Identification (1)** Dissolve 0.01 g of Thioridazine Hydrochloride in 2 mL of sulfuric acid: a deep blue color develops.

(2) Dissolve 0.01 g of Thioridazine Hydrochloride in 2 mL of water, and add 1 drop of cerium (IV) tetraammonium sulfate TS: a blue color develops, and the color disappears on the addition of excess of the reagent.

(3) Determine the infrared absorption spectrum of Thioridazine Hydrochloride, previously dried, as directed in the potassium chloride disk method under the Infrared Spectrophotometry, and compare the spectrum with the Refer-