

through blue-green to green (indicator: 3 drops of crystal violet TS). Perform a blank determination, and make any necessary correction.

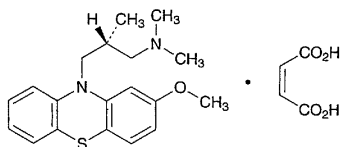
Each mL of 0.1 mol/L perchloric acid  
= 19.719 mg of  $C_9H_{11}NO_4$

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

Storage—Light-resistant.

## Levomepromazine Maleate

マレイン酸レボメプロマジン



$C_{19}H_{24}N_2OS \cdot C_4H_4O_4$ : 444.54

*N*-[(2*R*)-3-(2-Methoxyphenothiazin-10-yl)-2-methylpropyl]-*N,N*-dimethylamine monomaleate [7104-38-3]

Levomepromazine Maleate, when dried, contains not less than 98.0% of  $C_{19}H_{24}N_2OS \cdot C_4H_4O_4$ .

**Description** Levomepromazine Maleate occurs as white crystals or crystalline powder. It is odorless, and has a slightly bitter taste.

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

Melting point: 184 – 190°C (with decomposition).

**Identification (1)** Dissolve 5 mg of Levomepromazine Maleate in 5 mL of sulfuric acid: a red-purple color develops, which slowly becomes deep red-purple. To this solution add 1 drop of potassium dichromate TS: a brownish yellow-red color is produced.

(2) To 0.2 g of Levomepromazine Maleate add 5 mL of sodium hydroxide TS and 20 mL of diethyl ether, and shake well. Separate the diethyl ether layer, wash twice with 10-mL portions of water, add 0.5 g of anhydrous sodium sulfate, filter, evaporate the diethyl ether on a water bath, and dry the residue at 105°C for 2 hours: the residue melts between 124°C and 128°C.

(3) To 0.5 g of Levomepromazine Maleate add 5 mL of water and 2 mL of ammonia solution (28), extract with three 5-mL portions of chloroform, separate and evaporate the water layer to dryness. To the residue add 2 to 3 drops of dilute sulfuric acid and 5 mL of water, and extract with four 25-mL portions of diethyl ether. Combine all the diethyl ether extracts, evaporate the diethyl ether in a water bath at a temperature of about 35°C with the aid of a current of air: the residue melts between 128°C and 136°C.

**Optical rotation**  $[\alpha]_D^{20}$ : –13.5 – –16.5° (after drying, 0.5 g, chloroform, 20 mL, 200 mm).

**Purity (1)** Clarity and color of solution—To 0.5 g of Levomepromazine Maleate add 10 mL of methanol, and dis-

solve by warming: the solution is clear and colorless to pale yellow.

(2) Chloride—Dissolve 0.5 g of Levomepromazine Maleate in 40 mL of methanol, and add 6 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.40 mL of 0.01 mol/L hydrochloric acid VS, 40 mL of methanol, 6 mL of dilute nitric acid and water to make 50 mL (not more than 0.028%).

(3) Heavy metals—Proceed with 2.0 g of Levomepromazine Maleate according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

**Loss on drying** Not more than 0.5% (2 g, 105°C, 3 hours).

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

**Assay** Weigh accurately about 1 g of Levomepromazine Maleate, previously dried, and dissolve in a mixture of 40 mL of acetic acid (100) and 20 mL of acetone for nonaqueous titration. Titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from red-purple through blue-purple to blue (indicator: 5 drops of bromocresol green-methylrosaniline chloride TS). Perform a blank determination, and make any necessary correction.

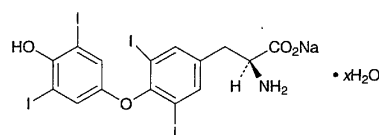
Each mL of 0.1 mol/L perchloric acid VS  
= 44.46 mg of  $C_{19}H_{24}N_2OS \cdot C_4H_4O_4$

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

Storage—Light-resistant.

## Levothyroxine Sodium

レボチロキシナトリウム



$C_{15}H_{10}I_4NNaO_4 \cdot xH_2O$

Monosodium *O*-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-*L*-tyrosinate hydrate [25416-65-3]

Levothyroxine Sodium contains not less than 97.0% of  $C_{15}H_{10}I_4NNaO_4$  (mol. wt.: 798.85), calculated on the dried basis.

**Description** Levothyroxine Sodium occurs as a pale yellowish white to light yellow-brown powder. It is odorless.

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

It dissolves in sodium hydroxide TS.

It is gradually colored by light.

**Identification (1)** Heat 0.1 g of Levothyroxine Sodium over a flame: a purple gas evolves.

(2) To 0.5 mg of Levothyroxine Sodium add 8 mL of a mixture of water, ethanol (95), hydrochloric acid and sodium hydroxide TS (6:5:2:2), warm in a water bath for 2 minutes, cool, and add 0.1 mL of sodium nitrite TS. Allow