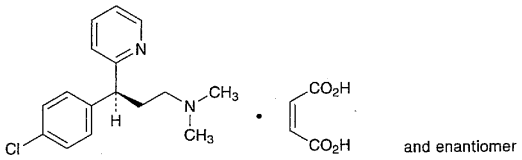
TS, and warm at 70°C for 40 minutes. After cooling, add 100 mL of ethanol (95), and titrate the excess potassium hydroxide with 0.1 mol/L hydrochloric acid VS until the color of the solution changes from blue through blue-green to yellow (indicator: 1 mL of thymol blue TS). Perform a blank determination.

Each mL of 0.1 mol/L potassium hydroxide-ethanol TS
= 24.566 mg of $C_{10}H_{12}ClNO_4$

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

# Chlorpheniramine Maleate

マレイン酸クロルフェニラミン




and enantiomer

$C_{16}H_{19}ClN_2.C_4H_4O_4$: 390.86
*N*-[(*RS*)-3-(4-Chlorophenyl)-3-pyridin-2-ylpropyl]-*N*,*N*-dimethylamine monomaleate [*113-92-8*]

Chlorpheniramine Maleate, when dried, contains not less than 98.0% of *dl*-chlorpheniramine maleate ($C_{16}H_{19}ClN_2.C_4H_4O_4$).

**Description** Chlorpheniramine Maleate occurs as white, fine crystals. It is odorless, and has a bitter taste.

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

**Identification** (1) Dissolve 1 mg of Chlorpheniramine Maleate in 5 mL of water, add 2 mL of Dragendorff's TS, and shake: a red-orange precipitate is produced.

(2) Dissolve 0.5 g of Chlorpheniramine Maleate in 5 mL of water, add 2 mL of ammonia solution (28), and extract with three 5-mL portions of chloroform. Separate the water layer, evaporate to dryness, add about 1.5 mL of dilute sulfuric acid and 5 mL of water, and extract with four 25-mL portions of diethyl ether. Combine the diethyl ether extracts, and evaporate on 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.

(3) Determine the infrared absorption spectrum of Chlorpheniramine Maleate, previously dried, as directed in the paste method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

**Absorbance** $E^{1\%}_{1cm}$ (265 nm): 210 - 220 (after drying, 5 mg, 0.25 mol/L sulfuric acid TS, 250 mL).

**pH** Dissolve 1.0 g of Chlorpheniramine Maleate in 100 mL of water: the pH of this solution is between 4.0 and 5.5.

**Melting point** 130 - 135°C

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

(2) Readily carbonizable substances—Weigh 0.025 g of Chlorpheniramine Maleate, and perform the test: no color develops.

(3) Related substances—Dissolve 0.10 g of Chlorpheniramine maleate in 2 mL of chloroform, and use this solution as the sample solution. Pipet 1 mL of the sample solution, and add chloroform to make exactly 10 mL. Pipet 1 mL of this solution, add chloroform again to make exactly 50 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 2 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, methanol and dilute acetic acid (31) (5:3:2) to a distance of about 10 cm, and air-dry the plate. Spray evenly Dragendorff's TS for spraying on the plate: 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, 3 hours).

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

**Assay** Dissolve about 0.4 g of Chlorpheniramine Maleate, previously dried and accurately weighed, in 20 mL of acetic acid (100). Titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from purple through blue-green to green (indicator: 2 drops of crystal violet TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 19.543 mg of $C_{16}H_{19}ClN_2.C_4H_4O_4$

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

# Chlorpheniramine Maleate Injection

マレイン酸クロルフェニラミン注射液

Chlorpheniramine Maleate Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of *dl*-chlorpheniramine maleate ($C_{16}H_{19}ClN_2.C_4H_4O_4$: 390.86).

**Method of preparation** Prepare as directed under Injections, with Chlorpheniramine Maleate.

**Description** Chlorpheniramine Maleate Injection is a clear, colorless liquid.
pH: 4.5 - 7.0

**Identification** (1) Take a volume of Chlorpheniramine Maleate Injection, equivalent to 1 mg of Chlorpheniramine Maleate According to the labeled amount, add 5 mL of water and 2 mL of Dragendorff's TS, and shake: a red-orange precipitate is produced.

(2) Transfer a volume of Chlorpheniramine Maleate In-