and shake: a red-orange precipitate is produced.

(2) Dissolve 0.5 g of *d*-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 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 *d*-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 $E^{1\%}_{1\,cm}$(265 nm): 210 - 220 (after drying, 5 mg, 0.25 mol/L sulfuric acid TS, 250 mL).

Optical rotation $[\alpha]_D^{20}$: + 39.5 - + 43.0° (after drying, 0.5 g, *N,N*-dimethylformamide, 10 mL, 100 mm).

pH Dissolve 1.0 g of *d*-Chlorpheniramine Maleate in 100 mL of freshly boiled and cooled water: the pH of this solution is between 4.0 and 5.0.

Melting point 111 - 115°C

Purity Clarity and color of solution—Dissolve 1.0 g of *d*-Chlorpheniramine Maleate in 50 mL of water: the solution is clear and colorless.

Loss on drying Not more than 0.5% (1 g, 65°C, 4 hours).

Residue on ignition Not more than 0.15% (1 g).

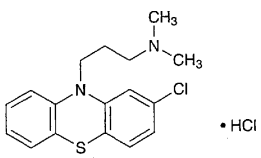
Assay Weigh accurately about 0.3 g of *d*-Chlorpheniramine Maleate, previously dried, and dissolve in 20 mL of acetic acid (100). Titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from purple through blue-green to green (indicator: 2 drops of crystal violet TS). Perform 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.

Chlorpromazine Hydrochloride

塩酸クロルプロマジン



$C_{17}H_{19}ClN_2S.HCl$: 355.33
N-[3-(2-Chlorophenothiazin-10-yl)propyl]-*N,N*-dimethylamine monohydrochloride [*69-09-0*]

Chlorpromazine Hydrochloride, when dried, contains not less than 99.0% of $C_{17}H_{19}ClN_2S.HCl$.

Description Chlorpromazine Hydrochloride occurs as a white to pale yellow, crystalline powder. It is odorless, or has a faint, characteristic odor.

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

It is gradually colored by light.

Identification **(1)** To 5 mL of a solution of Chlorpromazine Hydrochloride (1 in 1000) add 1 drop of iron (III) chloride TS: a red color develops.

(2) Dissolve 0.1 g of Chlorpromazine Hydrochloride in 20 mL of water and 3 drops of dilute hydrochloric acid, add 10 mL of 2,4,6-trinitrophenol TS, and allow to stand for 5 hours. Collect the resulting precipitate, wash with water, recrystallize from a small portion of acetone, and dry at 105°C for 1 hour: the crystals so obtained melt between 175°C and 179°C.

(3) Dissolve 0.5 g of Chlorpromazine Hydrochloride in 5 mL of water, add 2 mL of ammonia TS, and heat on a water bath for 5 minutes. Cool, filter, and render the filtrate acidic with dilute nitric acid: the solution responds to the Qualitative Tests (2) for chloride.

Melting point 194 - 198°C

pH Dissolve 1.0 g of Chlorpromazine Hydrochloride in 20 mL of freshly boiled and cooled water, and measure within 10 minutes: the pH of this solution is between 4.0 and 5.0.

Purity **(1)** Clarity and color of solution—A solution of 1.0 g of Chlorpromazine Hydrochloride in 20 mL of water, when observed within 10 minutes, is clear and colorless to pale yellow.

(2) Heavy metals—Proceed with 1.0 g of Chlorpromazine 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).

Loss on drying Not more than 0.5% (1 g, 105°C, 2 hours).

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

Assay Weigh accurately about 0.7 g of Chlorpromazine Hydrochloride, previously dried, dissolve in 50 mL of a mixture of acetic anhydride and acetic acid (100) (7:3), 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
= 35.533 mg of $C_{17}H_{19}ClN_2S.HCl$

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