crystals or crystalline powder. It is odorless.

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

It is affected by light.

Melting point: about 214°C (with decomposition).

**Identification** **(1)** To 5 mL of a solution of Homatropine Hydrobromide (1 in 20) add 2 to 3 drops of iodine TS: a brown precipitate is produced.

**(2)** Dissolve 0.05 g of Homatropine Hydrobromide in 5 mL of water, and add 3 mL of 2,4,6-trinitrophenol TS: a yellow precipitate is produced. Filter the precipitate, wash with five 10-mL portions of water, and dry at 105°C for 2 hours: it melts between 184°C and 187°C.

**(3)** A solution of Homatropine Hydrobromide (1 in 20) responds to the Qualitative Tests for bromide.

**Purity** **(1)** Acid—Dissolve 1.0 g of Homatropine Hydrobromide in 20 mL of water, and add 0.40 mL of 0.01 mol/L sodium hydroxide VS and 1 drop of methyl red-methylene blue TS: a green color develops.

**(2)** Atropine, hyoscyamine and scopolamine—To 0.010 g of Homatropine Hydrobromide add 5 drops of nitric acid, evaporate on a water bath to dryness, and cool. Dissolve the residue in 1 mL of *N,N*-dimethylformamide, and add 5 to 6 drops of tetraethylammonium hydroxide TS: no red-purple color is produced.

**(3)** Other alkaloids—Dissolve 0.15 g of Homatropine Hydrobromide in 3 mL of water, and use this solution as the sample solution.

(i) To 1 mL of the sample solution add 2 to 3 drops of tannic acid TS: no precipitate is produced.

(ii) To 1 mL of the sample solution add 2 to 3 drops each of dilute hydrochloric acid and platinic chloride TS: no precipitate is produced.

**Loss on drying** Not more than 1.5% (0.5 g, 105°C, 2 hours).

**Residue on ignition** Not more than 0.25% (0.2 g).

**Assay** Dissolve by warming about 0.4 g of Homatropine Hydrobromide in 60 mL of a mixture of acetic anhydride and acetic acid (100) (7:3). Cool, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination.

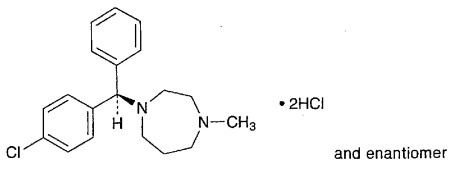
Each mL of 0.1 mol/L perchloric acid VS
= 35.626 mg of $C_{16}H_{21}NO_3.HBr$

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

Storage—Light-resistant.

# Homochlorcyclizine Hydrochloride

塩酸ホモクロルシクリジン




and enantiomer

$C_{19}H_{23}ClN_2.2HCl$: 387.77

1-[(*RS*)-(4-Chlorophenyl)(phenyl)methyl]-4-methyl-1,4-diazepine dihydrochloride [*1982-36-I*]

Homochlorcyclizine Hydrochloride, when dried, contains not less than 98.0% of $C_{19}H_{23}ClN_2.2HCl$.

**Description** Homochlorcyclizine Hydrochloride occurs as white to pale brown crystals or powder. It is odorless.

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

It is hygroscopic.

Melting point: about 227°C (with decomposition).

**Identification** **(1)** To 5 mL of a solution of Homochlorcyclizine Hydrochloride (1 in 100) add 5 drops of Reinecke salt TS: a light red precipitate is produced.

**(2)** Determine the absorption spectrum of a solution of Homochlorcyclizine Hydrochloride in 0.1 mol/L hydrochloric acid TS (1 in 4000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum 1: both spectra exhibit similar intensities of absorption at the same wavelengths. Separately, determine the absorption spectrum of a solution of Homochlorcyclizine Hydrochloride in 0.1 mol/L hydrochloric acid TS (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum 2: both spectra exhibit similar intensities of absorption at the same wavelengths.

**(3)** A solution of Homochlorcyclizine Hydrochloride (1 in 100) responds to the Qualitative Tests for chloride.

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

**(2)** Arsenic—Take 1.0 g of Homochlorcyclizine Hydrochloride, add 10 mL of a solution of magnesium nitrate hexahydrate in ethanol (95) (1 in 10), ignite the ethanol, and heat gradually to incinerate at 800°C. After cooling, add 3 mL of hydrochloric acid, heat on a water bath to dissolve the residue, use this solution as the test solution, and perform the test using Apparatus B (not more than 2 ppm).

**(3)** Related substances—Dissolve 0.20 g of Homochlorcyclizine Hydrochloride in 10 mL of methanol, and use this solution as the sample solution. Measure exactly 5 mL of the sample solution, and add methanol to make exactly 100 mL. Measure exactly 5 mL of this solution, add methanol 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 10 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 chloroform, methanol and formic acid (13:5:2) to a distance of about 15 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 2.0% (1 g, 110°C, 4 hours).

**Residue on ignition** Not more than 0.20% (1 g).

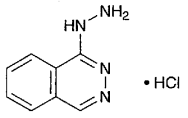
**Assay** Weigh accurately about 0.3 g of Homochlorcyclizine Hydrochloride, previously dried, dissolve in 50 mL of a mixture of acetic anhydride and acetic acid (100) (7:3), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination.

Each mL of 0.1 mol/L perchloric acid VS
= 19.389 mg of $C_{19}H_{23}ClN_2.2HCl$

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

# Hydralazine Hydrochloride

塩酸ヒドララジン



$C_8H_8N_4.HCl$: 196.64
Phthalazin-1-ylhydrazine monohydrochloride [*304-20-I*]

Hydralazine Hydrochloride, when dried, contains not less than 98.0% of $C_8H_8N_4.HCl$.

**Description** Hydralazine Hydrochloride occurs as a white, crystalline powder. It is odorless, and has a bitter taste.

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

Melting point: about 275°C (with decomposition).

**Identification** (1) Determine the absorption spectrum of a solution of Hydralazine Hydrochloride (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectrum of Hydralazine Hydrochloride, previously dried, as directed in the potassium bromide disk 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.

(3) A solution of Hydralazine Hydrochloride (1 in 4000) responds to the Qualitative Tests for chloride.

**pH** Dissolve 1.0 g of Hydralazine Hydrochloride in 50 mL of water: the pH of the solution is between 3.5 and 4.5.

**Purity** (1) Clarity and color of solution—Dissolve 1.0 g of Hydralazine Hydrochloride in 50 mL of water: the solution is clear, and colorless or pale yellow.

(2) Heavy metals—Proceed with 1.0 g of Hydralazine 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% (0.5 g, in vacuum, phosphorus (V) oxide, 8 hours).

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

**Assay** Weigh accurately about 0.15 g of Hydralazine Hydrochloride, previously dried, transfer it to a glass-stoppered flask, dissolve in 25 mL of water, add 25 mL of hydrochloric acid, cool to room temperature, add 5 mL of chloroform, and titrate with 0.05 mol/L potassium iodate VS while shaking until the purple color of the chloroform layer disappears. The end point is reached when the red-purple color no more reappears in the chloroform layer within 5 minutes after the layer has been decolorized.

Each mL of 0.05 mol/L potassium iodate VS
= 9.832 mg of $C_8H_8N_4.HCl$

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

# Hydralazine Hydrochloride for Injection

注射用塩酸ヒドララジン

Hydralazine Hydrochloride for Injection is a preparation for injection which is dissolved before use. It contains not less than 99% and not more than 113% of the labeled amount of hydralazine hydrochloride ($C_8H_8N_4.HCl$: 196.64).

**Method of preparation** Prepare as directed under Injections, with Hydralazine Hydrochloride.

**Description** Hydralazine Hydrochloride for Injection occurs as a white to pale yellow powder or mass. It is odorless, and has a bitter taste.

**Identification** Determine the absorption spectrum of a solution of Hydralazine Hydrochloride for Injection (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry: it exhibits maxima between 238 nm and 242 nm, between 258 nm and 262 nm, between 301 nm and 305 nm, and between 313 nm and 317 nm.

**pH** Dissolve 1.0 g of Hydralazine Hydrochloride for Injection in 50 mL of water: the pH of this solution is between 3.5 and 4.5.

**Assay** Weigh accurately the contents of not less than 10 samples of Hydralazine Hydrochloride for Injection. Weigh accurately about 0.15 g of the contents, transfer it to a glass-stoppered flask, dissolve in 25 mL of water, add 25 mL of hydrochloric acid, cool to room temperature, and proceed as directed in the Assay under Hydralazine Hydrochloride.

Each mL of 0.05 mol/L potassium iodate VS
= 9.832 mg of $C_8H_8N_4.HCl$

**Containers and storage** Containers—Hermetic containers.

# Hydralazine Hydrochloride Powder

塩酸ヒドララジン散

Hydralazine Hydrochloride Powder contains not less than 95% and not more than 105% of the labeled