

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

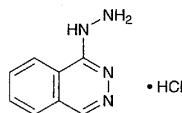
**Assay** Weigh accurately about 0.3 g of Homochlorcyclazine Hydrochloride, previously dried, dissolve in 50 mL of a mixture of acetic anhydride and acetic acid (100) (7:3), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination.

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

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

## Hydralazine Hydrochloride

塩酸ヒドララジン



$C_8H_8N_4 \cdot HCl$ : 196.64

Phthalazin-1-ylhydrazine monohydrochloride [304-20-1]

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

**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  $C_8H_8N_4 \cdot HCl$

**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 ( $C_8H_8N_4 \cdot HCl$ : 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  $C_8H_8N_4 \cdot HCl$

**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