Hydralazine Hydrochloride Powder

Hydralazine Hydrochloride for Injection

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 (C₈H₈N₄.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 (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 C₈H₈N₄.HCl

Containers and storage

Containers—Hermetic containers.

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