

low.

(2) To 1 mL of a solution of Pyridoxine Hydrochloride (1 in 10,000) add 2 mL of a freshly prepared solution of 2,6-dibromo-*N*-chloro-1,4-benzoquinone monoimine in ethanol (95) (1 in 4000) and 1 drop of ammonia TS: a blue color develops. To 1 mL of a solution of Pyridoxine Hydrochloride (1 in 10,000) add 1 mL of a saturated boric acid solution, and proceed as directed in the same manner: no blue color develops.

(3) Add 1 mL of water to 0.5 g of Pyridoxine Hydrochloride, warm to dissolve, cool, add 6 mL of 2,4,6-trinitrophenol TS, and allow to stand for 2 to 3 hours. Filter the crystals, wash with a small amount of ice-water, and dry at 105°C for 2 hours. The crystals so obtained melt between 156°C and 159°C (with decomposition).

(4) A solution of Pyridoxine Hydrochloride (1 in 10) responds to the Qualitative Tests for chloride.

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

(2) Heavy metals—Proceed with 1.0 g of Pyridoxine Hydrochloride according to Method 1, and perform the test. Prepare the control solution with 3.0 mL of Standard Lead Solution (not more than 30 ppm).

Loss on drying Not more than 0.30% (1 g, in vacuum, silica gel, 4 hours).

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

Assay Weigh accurately about 0.2 g of Pyridoxine Hydrochloride, previously dried, add 5 mL of acetic acid (100) and 5 mL of acetic anhydride, dissolve by gentle boiling, cool, add 30 mL of acetic anhydride, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

$$\begin{aligned} \text{Each mL of 0.1 mol/L perchloric acid VS} \\ = 20.564 \text{ mg of } C_8H_{11}NO_3 \cdot HCl \end{aligned}$$

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Pyridoxine Hydrochloride Injection

Vitamin B₆ Injection

塩酸ピリドキシン注射液

Pyridoxine Hydrochloride Injection is an aqueous solution for injection. It contains not less than 95% and not more than 115% of the labeled amount of pyridoxine hydrochloride ($C_8H_{11}NO_3 \cdot HCl$: 205.64).

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

Description Pyridoxine Hydrochloride Injection is a colorless or pale yellow, clear liquid.

It is gradually affected by light.

pH: 3.0 – 6.0

Identification (1) To a volume of Pyridoxine Hydrochloride Injection, equivalent to 0.01 g of Pyridoxine Hydrochloride according to the labeled amount, add water to make 10 mL, and use this solution as the sample solution. Proceed with 1 mL of the sample solution as directed in the Identification (1) under Pyridoxine Hydrochloride.

(2) Dilute 1 mL of the sample solution obtained in (1) with water to make 10 mL. Proceed with 1 mL of this solution as directed in the Identification (2) under Pyridoxine Hydrochloride.

(3) Add 0.5 mL of phosphotungstic acid TS to 1 mL of the sample solution obtained in (1): a white turbidity is produced.

Assay Measure exactly a volume of Pyridoxine Hydrochloride Injection, equivalent to about 0.02 g of pyridoxine hydrochloride ($C_8H_{11}NO_3 \cdot HCl$), dilute with water, if necessary, and add water to make exactly 100 mL. Pipet 25 mL of this solution, add water to make exactly 200 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.1 g of Pyridoxine Hydrochloride Reference Standard, previously dried in a desiccator (in vacuum, silica gel) for 4 hours, and dissolve in water to make exactly 100 mL. Pipet 5 mL of this solution, add water to make exactly 200 mL, and use this solution as the standard solution. Pipet 1 mL each of the sample solution and the standard solution, add 2.0 mL of barbital buffer solution, 9.0 mL of 2-propanol and 2.0 mL of a freshly prepared solution of 2,6-dibromo-*N*-chloro-1,4-benzoquinone monoimine in ethanol (95) (1 in 4000), shake well, add 2-propanol to make exactly 25 mL, and allow to stand for 90 minutes. Determine the absorbances, A_T and A_S , of the subsequent sample solution and the subsequent standard solution, respectively, at 650 nm as directed under the Ultraviolet-visible Spectrophotometry, using a solution, prepared in the same manner with 1 mL of water, as the blank.

$$\begin{aligned} \text{Amount (mg) of pyridoxine hydrochloride} \\ (C_8H_{11}NO_3 \cdot HCl) \\ = \text{amount (mg) of Pyridoxine Hydrochloride} \\ \text{Reference Standard} \\ \times \frac{A_T}{A_S} \times \frac{1}{5} \end{aligned}$$

Containers and storage Containers—Hermetic containers, and colored containers may be used.

Storage—Light-resistant.

Quinidine Sulfate

硫酸キニジン

