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Pyridoxine Hydrochloride Injection

» Pyridoxine Hydrochloride Injection is a sterile solution of Pyridoxine Hydrochloride in Water for Injection. It contains not less than 95.0 percent and not more than 115.0 percent of the labeled amount of Pyridoxine Hydrochloride ($C_8H_{11}NO_3 \cdot HCl$).

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light.

USP Reference standards ⟨11⟩—
USP Pyridoxine Hydrochloride RS

Identification—Evaporate a volume of Injection, equivalent to about 50 mg of pyridoxine hydrochloride, on a steam bath to dryness. Add 5 mL of dehydrated alcohol, and again evaporate to dryness. Dry the residue at 105° for 3 hours: the residue so obtained responds to *Identification* tests *A* and *B* under *Pyridoxine Hydrochloride*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.4 USP Endotoxin Unit per mg of pyridoxine hydrochloride.

pH ⟨791⟩**:** between 2.0 and 3.8.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay—

Ammonium chloride–ammonium hydroxide buffer—Dissolve 16 g of ammonium chloride in 70 mL of water, add 16 mL of ammonium hydroxide, dilute with water to 100 mL, mix, and filter.

Chlorimide solution—Dissolve 40 mg of 2,6-dichloroquinone-chlorimide in 100 mL of isopropyl alcohol. Store the solution in a refrigerator, and use within 1 month. Do not use the solution if it has become pink.

Standard stock solution—Dissolve a suitable quantity of USP Pyridoxine Hydrochloride RS, accurately weighed, in 0.1 N hydrochloric acid, quantitatively dilute with the same solvent to obtain a solution having a known concentration of about 0.1 mg per mL, and mix. Keep the solution in an amber bottle, in a cool place.

Standard preparation—In a 100-mL volumetric flask dilute 10.0 mL of the *Standard stock solution* with water to volume, and mix. Prepare this solution daily as needed.

Assay preparation—Dilute an accurately measured volume of Injection, equivalent to about 100 mg of pyridoxine hydrochloride, quantitatively and stepwise with water to a concentration of about 10 µg of pyridoxine hydrochloride per mL.

Procedure—

(a) Pipet 5 mL of the clear *Assay preparation* into a flask, add 25.0 mL of isopropyl alcohol, and mix. Pipet 5 mL of the isopropyl alcohol dilution into a glass-stoppered, 25-mL graduated cylinder or test tube; and add in succession, mixing after each addition, 1.0 mL of *Ammonium chloride–ammonium hydroxide buffer,* 1.0 mL of sodium acetate solution (1 in 5), and 1.0 mL of water. Cool to about 25°, then add 1.0 mL of *Chlorimide solution,* and shake vigorously for 10 seconds, accurately timed. Ninety seconds, accurately timed, after the addition of the *Chlorimide solution,* determine the absorbance at the wavelength of maximum absorbance at about 650 nm, with a suitable spectrophotometer, using water as the blank. [Note—Make the reading promptly to avoid errors due to fading of the color.] Designate the absorbance as A_U.

(b) Repeat procedure *(a),* but substitute 1.0 mL of boric acid solution (1 in 20) for the 1.0 mL of water. Designate the absorbance as A_U'.

(c) Repeat procedure *(a),* but substitute 5.0 mL of the *Standard preparation* for the 5.0 mL of the *Assay preparation.* Designate the absorbance as A_S.

(d) Repeat procedure *(c),* but substitute 1.0 mL of boric acid solution (1 in 20) for the 1.0 mL of water. Designate the absorbance as A_S'.

Calculate the quantity, in mg, of pyridoxine hydrochloride ($C_8H_{11}NO_3 \cdot HCl$) in each mL of the Injection taken by the formula:

$$10(C/V)(A_U - A_U')/(A_S - A_S')$$

in which C is the concentration, in µg per mL, of USP Pyridoxine Hydrochloride RS in the *Standard preparation; V* is the volume, in mL, of Injection taken; and the other terms are as defined above.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PYRIDOXINE HYDROCHLORIDE INJECTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

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