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Thiamine Hydrochloride Injection

» Thiamine Hydrochloride Injection is a sterile solution of Thiamine Hydrochloride in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of thiamine hydrochloride ($C_{12}H_{17}ClN_4OS \cdot HCl$).

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

USP Reference standards ⟨11⟩—
USP Thiamine Hydrochloride RS

Identification—

A: It yields a white precipitate with mercuric chloride TS, and a red-brown precipitate with iodine TS. It also yields a precipitate with mercuric-potassium iodide TS, and with trinitrophenol TS.

B: Dilute a portion of Injection with water to a concentration of about 10 mg of thiamine hydrochloride per mL. To 0.5 mL of this solution add 5 mL of 0.5 N sodium hydroxide, then add 0.5 mL of potassium ferricyanide TS and 5 mL of isobutyl alcohol, shake the mixture vigorously for 2 minutes, and allow the liquid layers to separate: when illuminated from above by a vertical beam of UV light and viewed at a right angle to this beam, the air-liquid meniscus shows a vivid blue fluorescence, which disappears when the mixture is slightly acidified, but reappears when it is again made alkaline.

C: It responds to the tests for *Chloride* ⟨191⟩.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 3.5 USP Endotoxin Units per mg of thiamine hydrochloride.

pH ⟨791⟩**:** between 2.5 and 4.5.

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

Assay—

Mobile phase, Internal standard solution, Standard preparation, and *Chromatographic system*—Prepare as directed in the *Assay* under *Thiamine Hydrochloride Oral Solution*.

Assay preparation—Quantitatively dilute an accurately measured volume of Injection with *Mobile phase* to obtain a solution containing about 500 µg of thiamine hydrochloride per mL. Pipet 10 mL of the resulting solution and 10 mL of *Internal standard solution* into a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Thiamine Hydrochloride Oral Solution*. Calculate the quantity, in mg, of thiamine hydrochloride ($C_{12}H_{17}ClN_4OS \cdot HCl$) in each mL of the Injection taken by the formula:

$$C(L/D)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Thiamine Hydrochloride RS in the *Standard preparation*; L is the labeled quantity, in mg per mL, of thiamine hydrochloride in the Injection; D is the concentration, in mg per mL, of thisamine hydrochloride in the *Assay preparation* on the basis of the labeled quantity and the extent of dilution; and R_U and R_S are the ratios of the peak responses of thiamine to methylparaben obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
THIAMINE 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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