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Thiamine Hydrochloride Tablets

DEFINITION
Thiamine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of thiamine hydrochloride ($C_{12}H_{17}ClN_4OS \cdot HCl$).

IDENTIFICATION

- **A.**

  Sample solution: Triturate a quantity of powdered Tablets, equivalent to 10 mg of thiamine hydrochloride, with 10 mL of 0.5 N sodium hydroxide, and filter.

  Analysis: To 5 mL of the *Sample solution* add 0.5 mL of potassium ferricyanide TS and 5 mL of isobutyl alcohol, shake the mixture vigorously for 2 min, and allow the liquid layers to separate. Illuminate from above by a vertical beam of UV light, and observe the air–liquid meniscus at a right angle to this beam.

  Acceptance criteria: 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.

- **B.**

  Sample solution: Triturate a quantity of powdered Tablets, equivalent to 10 mg of thiamine hydrochloride, with 10 mL of water, and filter.

  Analysis 1: To 2 mL of the *Sample solution* add iodine TS.

  Acceptance criteria 1: A red-brown precipitate is formed.

  Analysis 2: To 2 mL of the *Sample solution* add mercuric chloride TS.

  Acceptance criteria 2: A white precipitate is formed.

  Analysis 3: *Identification Tests—General ⟨191⟩, Chloride*

  Acceptance criteria 3: Meet the requirements

- **C.**

  Sample solution: Use the remainder of the *Sample solution* from *IdentificationB*.

  Analysis: Add 1 mL of lead acetate TS and 1 mL of 2.5 N sodium hydroxide.

  Acceptance criteria: A yellow color is produced. Heat the mixture for several minutes on a steam bath: the color changes to brown, and, on standing, a precipitate of lead sulfide separates.

ASSAY

- **Thiamine Assay ⟨531⟩, *Chemical Methods, Procedure 1***

  Sample solution: Place NLT 20 Tablets in a flask of suitable size, half fill the flask with 0.2 N hydrochloric acid, and heat on a steam bath, with frequent agitation, until the Tablets have dissolved or have disintegrated so that a uniform dispersion is obtained. Cool, transfer the contents of the flask to a volumetric flask, and dilute with 0.2 N hydrochloric acid to volume. If the mixture is not clear, either centrifuge it or filter it through paper known not to adsorb thiamine. Dilute a portion of the clear solution with 0.2 N hydrochloric acid to obtain a 0.2-µg/mL solution of thiamine hydrochloride.

  Analysis: Proceed as directed in the chapter.

  Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- **Dissolution ⟨711⟩, *Procedure, Apparatus 1 and 2, Immediate-Release Dosage Forms, Procedure for a pooled sample for immediate-release dosage forms***

  Medium: Water; 900 mL

  Apparatus 2: 50 rpm

  Time: 45 min

  Standard solution: A known concentration of USP Thiamine Hydrochloride RS in *Medium*

  Sample solution: Filtered portion of the solution under test, suitably diluted with the *Medium* if necessary

  Mobile phase: A mixture of methanol, glacial acetic acid, and water (27:1:73) containing 1.40 mg/mL of sodium 1-hexanesulfonate

  Chromatographic system

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(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of thiamine hydrochloride ($C_{12}H_{17}ClN_4OS \cdot HCl$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S \times D \times V/L) \times 100$$

r_U = peak area of thiamine from the *Sample solution*

r_S = peak area of thiamine from the *Standard solution*

C_S = concentration of USP Thiamine Hydrochloride RS in the *Standard solution* (mg/mL)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = labeled claim of thiamine hydrochloride (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of thiamine hydrochloride ($C_{12}H_{17}ClN_4OS \cdot HCl$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Thiamine Hydrochloride RS

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

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

Chromatographic Database Information: Chromatographic Database

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