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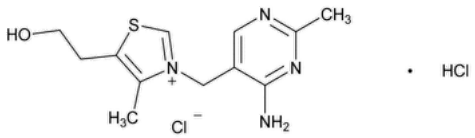
Thiamine Hydrochloride



$C_{12}H_{17}ClN_4OS \cdot HCl$ 337.27

Thiazolium, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methyl-, chloride, monohydrochloride;

Thiamine monohydrochloride CAS RN®: 67-03-8; UNII: M572600E5P.

DEFINITION

Thiamine Hydrochloride contains NLT 98.0% and NMT 102.0% of thiamine hydrochloride ($C_{12}H_{17}ClN_4OS \cdot HCl$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

  Analysis: Dry specimens at 105° for 2 h.

  Acceptance criteria: Meets the requirements

- **B.** **Identification Tests—General, *Chloride*⟨191⟩:** A 20-mg/mL solution meets the requirements.

ASSAY

- **Procedure**

  Solution A: 0.005 M sodium 1-octanesulfonate in dilute glacial acetic acid (1 in 100)

  Solution B: Methanol and acetonitrile (3:2)

  Mobile phase: *Solution B* and *Solution A* (40:60)

  Internal standard solution: 2% (v/v) of methylbenzoate in methanol

  Standard solution: Prepare a 1-mg/mL solution of USP Thiamine Hydrochloride RS in *Mobile phase*. Transfer 20.0 mL of this solution and 5.0 mL of *Internal standard solution* to a 50-mL volumetric flask, and dilute with *Mobile phase* to volume. The *Standard solution* contains 400 µg/mL of thiamine hydrochloride.

  Sample solution: Prepare a 2-mg/mL of Thiamine Hydrochloride in *Mobile phase*. Transfer 10.0 mL of this solution and 5.0 mL of *Internal standard solution* to a 50-mL volumetric flask, and dilute with *Mobile phase* to volume.

  Chromatographic system

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

  Mode: LC

  Detector: UV 254 nm

  Column: 4-mm × 30-cm; packing L1

  Flow rate: 1 mL/min

  [Note—The flow rate may be adjusted as needed to obtain a retention time of about 12 min for thiamine hydrochloride.]

  Injection size: 10 µL

  System suitability

  Sample: *Standard solution*

  Suitability requirements

  Resolution: NLT 4.0 between the thiamine and methylbenzoate peaks

  Tailing factor: NMT 2.0 for the thiamine peak

  Column efficiency: NLT 1500 theoretical plates for the thiamine peak

  Relative standard deviation: NMT 2.0% for the ratios of thiamine peak areas to the internal standard peak area

  Analysis

  Samples: *Standard solution* and *Sample solution*

  Calculate the percentage of thiamine hydrochloride ($C_{12}H_{17}ClN_4OS \cdot HCl$) in the portion of Thiamine Hydrochloride taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = internal standard ratio (peak area of thiamine/peak area of the internal standard) from the *Sample solution*

R_S = internal standard ratio (peak area of thiamine/peak area of the internal standard) from the *Standard solution*

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

C_U = concentration of Thiamine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.2%
- **Limit of Nitrate**

Sample solution: 20 mg/mL of Thiamine Hydrochloride

Analysis: To 2 mL of the *Sample solution* add 2 mL of sulfuric acid. Cool, and superimpose 2 mL of ferrous sulfate TS.

Acceptance criteria: No brown ring is produced at the junction of the two layers.

- **Related Compounds**

Solution A, Solution B, and **Mobile phase:** Proceed as directed in the *Assay*.

Sample solution: 1.0 mg/mL of Thiamine Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.0-mm × 15-cm; packing L1

Flow rate: 0.75 mL/min

Injection size: 10 µL

Analysis

Sample: *Sample solution*

Allow the *Sample solution* to elute for NLT three times the retention time of the main peak.

Calculate the percentage of total secondary peaks in the portion of Thiamine Hydrochloride taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = sum of the areas of all the peaks, except that of the thiamine peak

r_T = sum of the areas of all the peaks

Acceptance criteria: NMT 1.0%

SPECIFIC TESTS

- **pH ⟨791⟩**

Sample solution: 10-mg/mL solution

Acceptance criteria: 2.7–3.4

- **Water Determination, *Method I*⟨921⟩:** NMT 5.0%
- **Absorbance of Solution**

Sample solution: 100 mg/mL in water. Filter through a fine-porosity, sintered-glass funnel.

Blank: Water

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩.*)

Mode: UV-Vis

Analytical wavelength: 400 nm

Cell: 1 cm

Analysis

Samples: *Sample solution* and *Blank*

Determine the absorbance of the *Sample solution* against that of the *Blank*.

Acceptance criteria: NMT 0.025

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers.
- **USP Reference Standards ⟨11⟩**

USP Thiamine Hydrochloride RS

Topic/Question	Contact	Expert Committee
THIAMINE HYDROCHLORIDE	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

Most Recently Appeared In:
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