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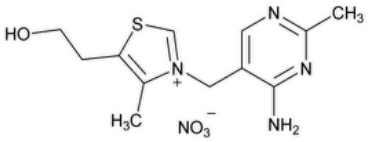
Thiamine Mononitrate



$C_{12}H_{17}N_5O_4S$ 327.36

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

Thiamine nitrate (salt) CAS RN®: 532-43-4; UNII: 8K0I04919X.

DEFINITION

Thiamine Mononitrate contains NLT 98.0% and NMT 102.0% of thiamine mononitrate ($C_{12}H_{17}N_5O_4S$), calculated on the dried basis.

IDENTIFICATION

• **A.**

Sample solution: 20 mg/mL of Thiamine Mononitrate

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: A brown ring is produced at the junction of the two liquids.

• **B.**

Sample: 5 mg

Analysis: Dissolve the *Sample* in a mixture of 1 mL of lead acetate TS and 1 mL of 2.5 N sodium hydroxide. Heat for several min on a steam bath.

Acceptance criteria: After dissolution of the *Sample*, a yellow color is produced. After heating the solution, the color changes to brown and on standing, a precipitate of lead sulfide separates.

• **C.** A solution of Thiamine Mononitrate 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.

• **D.**

Sample solution: Dissolve 5 mg in 5 mL of 0.5 N sodium hydroxide.

Analysis: To 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.

Acceptance criteria: 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.

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

Internal standard solution: 2.0% (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 solution of Thiamine Mononitrate 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 the thiamine peak area to the internal standard peak area

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of thiamine mononitrate ($C_{12}H_{17}N_5O_4S$) in the portion of Thiamine Mononitrate taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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 Mononitrate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of thiamine mononitrate, 327.36

M_{r2} = molecular weight of thiamine hydrochloride, 337.27

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

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.2%
- **Chloride and Sulfate,** *Chloride*⟨221⟩

Standard: 0.40 mL of 0.020 N hydrochloric acid

Sample: 500 mg of Thiamine Mononitrate

Acceptance criteria: NMT 0.06%

- **Related Compounds**

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

Sample solution: 1.0 mg/mL of Thiamine Mononitrate 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 Mononitrate 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: 20-mg/mL solution

  Acceptance criteria: 6.0–7.5

- **Loss on Drying** ⟨731⟩**:** Dry 500 mg at 105° for 2 h: it loses NMT 1.0% of its weight.

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 MONONITRATE	Fatkhulla K Tadjimukhamedov Associate 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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