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Thiamine Mononitrate Oral Solution

DEFINITION
Thiamine Mononitrate Oral Solution contains NLT 95.0% and NMT 115.0% of the labeled amount of thiamine mononitrate ($C_{12}H_{17}N_5O_4S$).

IDENTIFICATION

- **A.**

Sample solution: Dilute a portion of Oral Solution with water to a concentration of 10 mg/mL of thiamine mononitrate.

Analysis: To 0.5 mL of the *Sample 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 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: 5 mL of Oral Solution

Analysis: Add 2 mL of sulfuric acid to the *Sample*, cool, and superimpose 2 mL of ferrous sulfate TS.

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

ASSAY

- **Procedure**

Mobile phase: Methanol and 0.04 M aqueous monobasic potassium phosphate (45:55)

Internal standard solution: 100 µg/mL of methylparaben in *Mobile phase*

Standard stock solution: 500 µg/mL of USP Thiamine Hydrochloride RS in *Mobile phase*

Standard solution: Dilute a mixture of equal volumes of the *Standard stock solution* and *Internal standard solution* with *Mobile phase* to obtain a concentration of USP Thiamine Hydrochloride RS of 50 µg/mL.

Sample stock solution: Equivalent to 500 µg/mL of thiamine mononitrate in *Mobile phase* from an accurately measured volume of Oral Solution

Sample solution: Dilute a mixture of equal volumes of the *Sample stock solution* and *Internal standard solution* with *Mobile phase* to obtain a concentration of thiamine mononitrate of 50 µg/mL.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection size: 25 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for thiamine and methylparaben are about 0.35 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 6.0 between the thiamine and methylparaben

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of thiamine mononitrate ($C_{12}H_{17}N_5O_4S$) in the portion of Oral Solution taken:

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

R_U = peak area ratio of thiamine to methylparaben from the *Sample solution*

R_S = peak area ratio of thiamine to methylparaben from the *Standard solution*

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

C_U = nominal concentration of thiamine mononitrate in the *Sample stock solution* (µg/mL)

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

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

Acceptance criteria: 95.0%–115.0%

OTHER COMPONENTS

• **Alcohol Determination,** *Method II* ⟨611⟩**:** 90.0%–110.0% of the labeled quantity of C_2H_5OH, using acetone as the internal standard

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 ORAL SOLUTION	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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