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Methsuximide Capsules

DEFINITION
Methsuximide Capsules contain NLT 92.0% and NMT 108.0% of the labeled amount of methsuximide ($C_{12}H_{13}NO_2$).

IDENTIFICATION

Change to read:

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

Sample: Mix a portion of the content of Capsules, equivalent to 200 mg of methsuximide with 25 mL of water in a separator, extract with 50 mL of ether, and discard the aqueous layer. Wash the ether extract with 25 mL of water, and discard the water. Filter the extract, evaporate with the aid of a current of warm air to dryness, and dry the methsuximide over phosphorus pentoxide for 16 h.

Acceptance criteria: Meet the requirements

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution,* as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (45:55). Filter, and degas.

Standard solution: 0.6 mg/mL of USP Methsuximide RS in *Mobile phase*

Sample stock solution: Place 10 Capsules in a 500-mL volumetric flask, and add 280 mL of water. Sonicate in a water bath at 40°–50°, with occasional shaking, until the Capsules have broken, and cool to room temperature. Dilute with acetonitrile to volume, mix, and filter.

Sample solution: Nominally 0.6 mg/mL of methsuximide prepared from *Sample stock solution* in *Mobile phase*

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 volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 2100 theoretical plates

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of methsuximide ($C_{12}H_{13}NO_2$) in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of methsuximide from the *Sample solution*

r_S = peak response of methsuximide from the *Standard solution*

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

C_U = nominal concentration of methsuximide in the *Sample solution* (mg/mL)

Acceptance criteria: 92.0%–108.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 120 min

Analysis: Determine the percentage of the labeled amount of methsuximide ($C_{12}H_{13}NO_2$) dissolved by using the procedure set forth in the *Assay*, making any necessary adjustments.

Tolerances: NLT 75% (*Q*) of the labeled amount of methsuximide ($C_{12}H_{13}NO_2$) is dissolved.

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

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and avoid exposure to excessive heat.
- **USP Reference Standards ⟨11⟩**
  USP Methsuximide RS

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

Topic/Question	Contact	Expert Committee
METHSUXIMIDE CAPSULES	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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