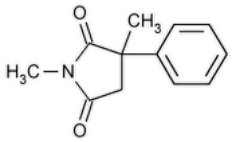
Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Sep-2022
Document Type: USP Monographs
DocId: GUID-8DFA3D57-5555-4562-BA5D-9E136D3337C7_3_en-US
DOI: https://doi.org/10.31003/USPNF_M51880_03_01
DOI Ref: fjq28

Methsuximide



$C_{12}H_{13}NO_2$ 203.24

2,5-Pyrrolidinedione,1,3-dimethyl-3-phenyl-, (±)-;

(±)-*N*,2-Dimethyl-2-phenylsuccinimide CAS RN®: 77-41-8; UNII: 0G76K8X6C0.

DEFINITION

Methsuximide contains NLT 97.0% and NMT 103.0% of methsuximide ($C_{12}H_{13}NO_2$), calculated on the dried basis.

IDENTIFICATION

• **A.** **Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**

• **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 (9:11)

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

Sample solution: 0.6 mg/mL of Methsuximide in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; 10-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 5800 theoretical plates

Tailing factor: NMT 1.3

Relative standard deviation: NMT 0.6%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.2%

Change to read:

• **Organic Impurities**

Mobile phase and **Chromatographic system:** Proceed as directed in the *Assay*.

System suitability solution: 0.6 mg/mL of Methsuximide in *Mobile phase*

Standard solution: 0.006 mg/mL of USP Methsuximide RS in *Mobile phase*

Sample solution: 6.0 mg/mL of Methsuximide in *Mobile phase*

System suitability

Sample: *System suitability solution*

Suitability requirements

Column efficiency: ▲NLT▲ (ERR 1-Sep-2022) 5800 theoretical plates

Tailing factor: NMT 1.3

Relative standard deviation: NMT 0.6%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Methsuximide taken:

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

r_U = peak response for each impurity from the *Sample solution*

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

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

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

Acceptance criteria

Any individual impurity: NMT 0.1%

Total impurities: NMT 2.0%

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry a sample over phosphorus pentoxide for 16 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **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	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 39(3)

Current DocID: GUID-8DFA3D57-5555-4562-BA5D-9E136D3337C7_3_en-US

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