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Meprobamate Tablets

DEFINITION
Meprobamate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of meprobamate ($C_9H_{18}N_2O_4$).

IDENTIFICATION

Change to read:

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

Sample: A portion of finely powdered Tablets, equivalent to 800 mg of meprobamate

Analysis: To the *Sample* add 5 mL of dehydrated alcohol, and heat to just below boiling for about 5 min, with occasional swirling. Cool, and filter into 15 mL of solvent hexane. With the aid of suction, filter the crystals that form, and dry at 60°.

Acceptance criteria: The IR absorption spectrum of a potassium bromide dispersion (about 1 mg in 200 mg) from a portion of crystals obtained from the *Sample* exhibits maxima only at the same wavelengths as that of a similar preparation of USP Meprobamate RS. If a difference appears, dissolve portions of both the *Sample* and the Reference Standard in acetone at a concentration of 8 mg/mL. Dilute 0.1-mL portions of the acetone solutions with 1 mL of *n*-heptane, and remove the solvents by evaporation under nitrogen at a temperature of about 30°. Dry the residues under vacuum at room temperature for 30 min, and repeat the test on the residues.

• **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 (30:70)

Phenacetin stock solution: 125 µg/mL of phenacetin in acetonitrile

Phenacetin solution: 25 µg/mL of phenacetin prepared as follows from the *Phenacetin stock solution*. Pipet a suitable volume of *Phenacetin stock solution* into a volumetric flask. Add acetonitrile to fill 30% of the final flask volume, and dilute with water to volume.

Standard solution: 5 mg/mL of USP Meprobamate RS prepared as follows. Transfer a suitable amount of the Reference Standard to a suitable volumetric flask. Dissolve in 30% of the final flask volume of acetonitrile, and dilute with water to volume.

System suitability solution: 5 mg/mL of USP Meprobamate RS and 5 µg/mL of phenacetin prepared as follows. Dissolve a weighed amount of USP Meprobamate RS, first in acetonitrile, using 20% final volume. Shake to dissolve. Add a suitable volume of *Phenacetin solution*, and dilute with water to volume.

Sample solution: Nominally equivalent to 5 mg/mL of meprobamate prepared as follows. Transfer an amount of meprobamate from a portion of finely powdered Tablets (NLT 20) to a suitable volumetric flask. Add acetonitrile to fill 30% of final volume, and shake to dissolve. Dilute with water to volume, and filter, discarding the first 10 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 200 nm

Column: 3.9–4.6-mm × 25–30-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for meprobamate and phenacetin are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the meprobamate and the phenacetin peaks, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of meprobamate ($C_9H_{18}N_2O_4$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Procedure for a pooled sample

Medium: Deaerated water; 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Standard solution, System suitability solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Calculate the percentage of the labeled amount of meprobamate ($C_9H_{18}N_2O_4$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

V = volume of the *Medium*, 900 mL

L = label claim (mg/Tablet)

Acceptance criteria: NLT 75% (Q) of the labeled amount of meprobamate ($C_9H_{18}N_2O_4$) is dissolved.

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards** ⟨11⟩

USP Meprobamate RS

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

Topic/Question	Contact	Expert Committee
MEPROBAMATE TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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