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Magnesium Oxide Capsules

DEFINITION

Magnesium Oxide Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of magnesium oxide (MgO).

IDENTIFICATION

• **A. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Magnesium***

Sample solution: Transfer the contents of 1 Capsule to a beaker. Add 10 mL of 3 N hydrochloric acid and 5 drops of methyl red TS, and heat to boiling. Add 6 N ammonium hydroxide until the color of the solution changes to deep yellow, then continue boiling for 2 min, and filter. Use the filtrate.

Acceptance criteria: Meet the requirements

Add the following:

▲• **B.** The retention time of the magnesium peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (Official 1-Jun-2021)

ASSAY

Change to read:

• **Procedure**

▲Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.

Mobile phase: 48 mM methanesulfonic acid

[Note—It is recommended to use suitable cation trapping techniques to ensure the *Mobile phase* is free of all cationic impurities.]

Diluent: 0.02 N hydrochloric acid

System suitability solution: 33 µg/mL of USP Magnesium Oxide RS and 5 µg/mL of USP Calcium Carbonate RS in *Diluent*

Standard stock solution: 3.3 mg/mL of USP Magnesium Oxide RS prepared as follows. Transfer an appropriate portion of USP Magnesium Oxide RS to a suitable volumetric flask. Add about 20% of the final volume of 6 N hydrochloric acid, and dissolve. Dilute with water to volume.

Standard solution: 33 µg/mL of USP Magnesium Oxide RS in water from the *Standard stock solution*

Sample stock solution: Nominally 3.3 mg/mL of magnesium oxide prepared as follows. Mix and finely powder the contents of NLT 30 Capsules and transfer an appropriate portion of the powder to a suitable container. Add about 20% of the final volume of 6 N hydrochloric acid. Heat to boiling with constant swirling for 10 min. Allow to cool to room temperature. Transfer the solution quantitatively to a suitable volumetric flask containing 10% of the flask volume of water. Dilute with water to volume. Pass through a suitable filter of 0.45-µm pore size.

Sample solution: Nominally 33 µg/mL of magnesium oxide in water from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: Conductivity with suppression

Columns

Guard: 5-mm × 5-cm; 5.5-µm packing L84

Analytical: 5-mm × 25-cm; 5.5-µm packing L84

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

Run time: NLT 2 times the retention time of magnesium

System suitability

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

[Note—The relative retention times for the magnesium and calcium ions are 1.0 and 1.3, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the magnesium and calcium ions, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of magnesium oxide (MgO) in the portion of Capsules taken:

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

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

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

C_S = concentration of USP Magnesium Oxide RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of magnesium oxide in the *Sample solution* (µg/mL)▲ (Official 1-Jun-2021)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Analysis: Using atomic absorption spectrophotometry at a wavelength of 285.2 nm, determine the amount of magnesium oxide (MgO) dissolved, using filtered portions of the solution under test, suitably diluted with *Medium* if necessary, in comparison with a standard solution having a known concentration of magnesium in the same *Medium*.

Tolerances: NLT 75% (*Q*) of the labeled amount of magnesium oxide (MgO) is dissolved.

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

SPECIFIC TESTS

• **Acid-Neutralizing Capacity** ⟨301⟩**:** NLT 5 mEq of acid is consumed by the minimum single dose recommended in the labeling, and NLT 85.0% of the expected mEq value calculated from the results of the *Assay* is obtained. Each mg of magnesium oxide (MgO) has an expected acid-neutralizing capacity value of 0.0492 mEq.

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in ▲tight▲ (Official 1-Jun-2021) containers.

Add the following:

▲• **USP Reference Standards** ⟨11⟩

USP Calcium Carbonate RS

USP Magnesium Oxide RS▲ (Official 1-Jun-2021)

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

Topic/Question	Contact	Expert Committee
MAGNESIUM OXIDE CAPSULES	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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