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Magnesium Oxide Tablets

DEFINITION

Magnesium Oxide Tablets 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: Finely powder 1 Tablet. Transfer the powder 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. Finely powder NLT 30 Tablets 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 Tablets 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 2: 75 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 \(301\)](#) (where Tablets are labeled as intended for antacid use): 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 milligram 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 TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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