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Magnesium Silicate

DEFINITION

Magnesium Silicate is a compound of magnesium oxide and silicon dioxide. It contains NLT 15.0% of magnesium oxide (MgO) and NLT 67.0% of silicon dioxide (SiO₂), calculated on the ignited basis.

IDENTIFICATION

- A. IDENTIFICATION TESTS—GENERAL, *Magnesium* (191).**
Sample: 500 mg
Analysis: Mix the *Sample* with 10 mL of 3 N hydrochloric acid. Filter, and neutralize the filtrate to litmus paper with 6 N ammonium hydroxide.
Acceptance criteria: The neutralized filtrate meets the requirements.
- B.**
Analysis: Prepare a bead by fusing a few crystals of sodium ammonium phosphate on a platinum loop in the flame of a Bunsen burner. Place the hot, transparent bead in contact with Magnesium Silicate, and again fuse.
Acceptance criteria: Silica floats about in the bead, producing, upon cooling, an opaque bead with a web-like structure.

ASSAY

- MAGNESIUM OXIDE**
Sample: 1.5 g
Titrimetric system
Mode: Residual titration
Titrant: 1 N sodium hydroxide VS
Endpoint detection: Visual
Analysis: Dissolve the *Sample* in 50.0 mL of 1 N sulfuric acid VS. Digest on a steam bath for 1 h, cool to room temperature, and add methyl orange TS. Titrate the excess acid in the sample with *Titrant*. Each mL of 1 N sulfuric acid is equivalent to 20.15 mg of MgO.
Acceptance criteria: NLT 15.0% on the ignited basis
- SILICON DIOXIDE**
Sample: 700 mg
Analysis: Transfer the *Sample* to a small platinum dish. Add 10 mL of 1 N sulfuric acid, and heat on a steam bath to dryness, leaving the dish uncovered. Treat the residue with 25 mL of water, and digest on a steam bath for 15 min. Decant the supernatant through an ashless filter paper, with the aid of suction, and wash the residue, by decantation, three times with hot water, passing the washings through the filter paper. Finally, transfer the residue to the filter, and wash thoroughly with hot water. Transfer the filter paper and its contents to the platinum dish previously used. Heat to dryness, incinerate, ignite strongly for 30 min, cool, and weigh. Moisten the residue with water, and add 6 mL of hydrofluoric acid and 3 drops of sulfuric acid. Evaporate to dryness, ignite for 5 min, cool, and weigh. The loss in weight represents the weight of SiO₂.
Acceptance criteria: NLT 67.0% on the ignited basis

IMPURITIES

- FLUORIDE**
Indicator solution: 100 mg/mL of lanthanum alizarin complexan mixture in 60% isopropyl alcohol. Filter the solution if it is not clear.
Standard solution: 2.21 µg/mL of sodium fluoride in 0.1 N hydrochloric acid
Sample solution: Prepare a slurry consisting of 5.0 g of Magnesium Silicate and 45 mL of 0.1 N hydrochloric acid. Stir at room temperature for 15 min, and pass through a filter of 0.45-µm pore size into a 50-mL volumetric flask. Wash the filter with five 1-mL portions of 0.1 N hydrochloric acid, collecting the washings in the flask. Dilute with 0.1 N hydrochloric acid to volume.
Instrumental conditions
Mode: Vis
Analytical wavelength: About 620 nm
Cell: 1 cm
Blank: 0.1 N hydrochloric acid, *Indicator solution*, and water (5:5:15)

Analysis: Transfer 5.0 mL of the *Standard solution* and *Sample solution* to separate 25-mL volumetric flasks, add 5.0 mL of *Indicator solution*, dilute with water to volume, and allow to stand for 1 h in diffuse light at ambient temperature. Determine the absorbance of the solutions against the *Blank*.

Acceptance criteria: 10 µg/g; the absorbance of the *Sample solution* is NMT than that of the *Standard solution*.

• SOLUBLE SALTS

Sample: 10.0 g

Analysis: Boil the *Sample* with 150 mL of water for 15 min. Cool to room temperature, and allow the mixture to stand for 15 min. Filter with the aid of suction, transfer the filtrate to a 200-mL volumetric flask, and dilute with water to volume. Evaporate 50.0 mL of this solution, representing 2.5 g of the Silicate, in a tared platinum dish to dryness. Ignite gently to constant weight. Retain the remaining diluted solution for the test for *Free Alkali*.

Acceptance criteria: 3.0%; NMT 75.0 mg

• FREE ALKALI

Sample: 20 mL of the retained diluted filtrate prepared in the test for *Soluble Salts*

Analysis: Add 2 drops of phenolphthalein TS to the *Sample*, representing 1 g of Magnesium Silicate.

Acceptance criteria: If a pink color is produced, NMT 2.5 mL of 0.1 N hydrochloric acid is required to discharge it.

Change to read:

- ▲ [LEAD \(251\), Procedures, Procedure 1](#) ▲ (CN 1-JUN-2023)

Test preparation: Dissolve 1.0 g of Magnesium Silicate in 20 mL of 3 N hydrochloric acid, evaporate on a steam bath to 10 mL, dilute with water to 20 mL, and cool.

Acceptance criteria: NMT 10 µg/g

SPECIFIC TESTS

• RATIO OF SiO₂ TO MgO

Analysis: Divide the percentage of SiO₂ obtained in the *Assay for Silicon Dioxide* by the percentage of MgO obtained in the *Assay for Magnesium Oxide*.

Acceptance criteria: 2.50–4.50

• [LOSS ON DRYING \(731\)](#)

[NOTE—Retain the dried specimen for the test for *Loss on Ignition*.]

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 15.0%

• [LOSS ON IGNITION \(733\)](#)

Sample: The specimen retained from the test for *Loss on Drying*

Analysis: Ignite the *Sample* at 900°–1000° for 20 min.

Acceptance criteria: NMT 15%, previously dried

• [pH \(791\)](#)

Sample solution: A well-mixed aqueous suspension (1 in 10)

Acceptance criteria: 7.0–10.8

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
MAGNESIUM SILICATE	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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