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## Milk of Magnesia

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click

<https://www.uspnf.com/rb-milk-of-magnesia-20211119>.

### Change to read:

$Mg(OH)_2$  58.32

Magnesium hydroxide CAS RN®: 1309-42-8; ▲UNII: NBZ3QY004S.▲ (RB 1-Dec-2022)

### DEFINITION

Milk of Magnesia is a suspension of Magnesium Hydroxide. Milk of Magnesia, Double-Strength Milk of Magnesia, and Triple-Strength Milk of Magnesia contain NLT 90.0% and NMT 115.0% of the labeled amount of magnesium hydroxide  $[Mg(OH)_2]$ , the labeled amount being 80, 160, and 240 mg/mL of magnesium hydroxide  $[Mg(OH)_2]$ , respectively. It may contain NMT 0.05% of a volatile oil or a blend of volatile oils, suitable for flavoring purposes.

### IDENTIFICATION

#### • A. [IDENTIFICATION TESTS—GENERAL \(191\), Chemical Identification Tests, Magnesium](#)

**Sample:** A solution of the equivalent of 1 g of regular-strength Milk of Magnesia in 2 mL of 3 N [hydrochloric acid](#)

**Acceptance criteria:** Meets the requirements

#### Delete 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.▲ (RB 1-Dec-2022)

### ASSAY

#### Change to read:

#### • PROCEDURE

▲ **Sample:** A portion of Milk of Magnesia, previously shaken in its original container, equivalent to about 800 mg of magnesium hydroxide

#### Titrimetric system

**Mode:** Direct titration

**Titrant:** [0.05 M edetate disodium VS](#)

**Endpoint detection:** Visual

**Analysis:** Transfer the *Sample* to a 250-mL volumetric flask. Dissolve in 30 mL of 3 N [hydrochloric acid](#) and dilute with [water](#) to volume. Filter, if necessary, and transfer 25.0 mL of the filtrate to a beaker containing 75 mL of [water](#). Adjust the reaction of the solution to a pH of 7 (using pH indicator paper; see [Reagents, Indicators, and Solutions—Indicator and Test Papers](#)) with 1 N [sodium hydroxide](#), and add 5 mL of [ammonia–ammonium chloride buffer TS](#) and 0.15 mL of [eriochrome black TS](#). Titrate with the *Titrant* to a blue endpoint. Each milliliter of the *Titrant* is equivalent to 2.916 mg of magnesium hydroxide  $[Mg(OH)_2]$ .▲ (RB 1-Dec-2022)

**Acceptance criteria:** 90.0%–115.0%

### IMPURITIES

#### • SOLUBLE ALKALIES

**Sample solution:** Centrifuge 50 mL of Milk of Magnesia. Dilute 5.0 mL of the clear supernatant with 40 mL of [water](#).

#### Titrimetric system

**Mode:** Direct titration

**Titrant:** 0.10 N [sulfuric acid](#)

**Endpoint detection:** Visual

**Analysis:** Add 1 drop of [methyl red TS](#), and titrate with *Titrant* to the production of a persistent pink color.

**Acceptance criteria:** NMT 1.0 mL of *Titrant* is required. Where the specimen is Double- or Triple-Strength Milk of Magnesia, NMT 2.0 or 3.0 mL of *Titrant* is required, respectively.

#### • CARBONATE AND ACID-INSOLUBLE MATTER

**Sample solution:** To the equivalent of 1 g of regular-strength Milk of Magnesia, add 2 mL of 3 N [hydrochloric acid](#).

**Acceptance criteria:** NMT a slight effervescence occurs, and the solution is NMT slightly turbid.

**SPECIFIC TESTS**

- **MICROBIAL ENUMERATION TESTS (61)** and **TESTS FOR SPECIFIED MICROORGANISMS (62)**: The total aerobic microbial count does not exceed  $10^2$  cfu/mL, and it meets the requirements of the test for absence of *Escherichia coli*.

- **ACID-NEUTRALIZING CAPACITY (301)**.

**Analysis:** Proceed as directed in the chapter.

**Acceptance criteria:** NLT 5 mEq of acid is consumed by the minimum single dose recommended in the labeling, and NLT the number of mEq calculated as follows:

$$\text{Result} = 0.8 \times (F_M \times M)$$

$F_M$  = theoretical acid-neutralizing capacity of magnesium hydroxide  $[\text{Mg}(\text{OH})_2]$ , 0.0343 mEq/mg

$M$  = quantity of magnesium hydroxide  $[\text{Mg}(\text{OH})_2]$  in the sample tested, based on the labeled quantity (mg)

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in tight containers, preferably at a temperature NMT 35°. Avoid freezing.
- **LABELING:** Double- or Triple-Strength Milk of Magnesia is so labeled, or may be labeled as 2× or 3× Concentrated Milk of Magnesia, respectively.

**Delete the following:**

- ▲ **USP REFERENCE STANDARDS (11)**.

USP Calcium Carbonate RS

USP Magnesium Hydroxide RS ▲ (RB 1-Dec-2022)

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

Topic/Question	Contact	Expert Committee
MILK OF MAGNESIA	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

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