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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 10² 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:

Result = 0.8 × (F_M × M)

F_M = theoretical acid-neutralizing capacity of magnesium hydroxide [Mg(OH)₂], 0.0343 mEq/mg

M = quantity of magnesium hydroxide [Mg(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	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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