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Calcium Carbonate and Magnesia Tablets

DEFINITION

Calcium Carbonate and Magnesia Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of calcium carbonate (CaCO_3) and NLT 90.0% and NMT 115.0% of the labeled amount of magnesium hydroxide $[\text{Mg}(\text{OH})_2]$.

IDENTIFICATION

• **A. IDENTIFICATION TESTS—GENERAL, [Calcium\(191\)](#):** The addition of 3 N hydrochloric acid to the Tablets produces effervescence. The resulting solution, after being boiled to expel carbon dioxide and neutralized with 6 N ammonium hydroxide, meets the requirements of the tests.

• **B. IDENTIFICATION TESTS—GENERAL, [Magnesium\(191\)](#):**

Sample solution: Heat 2 Tablets in 20 mL of 1 N sulfuric acid. Cool, add 20 mL of alcohol, mix, and allow to stand for 30 min. Filter this solution, and add 2 mL of 1 N hydrochloric acid to the filtrate.

Acceptance criteria: The solution meets the requirements.

ASSAY

• CALCIUM CARBONATE

Sample solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 400 mg of calcium carbonate, to a beaker with 25 mL of water. Add 40 mL of 1 N hydrochloric acid. Heat on a steam bath for 30 min, allow to cool, and transfer with the aid of water to a 100-mL volumetric flask. Dilute with water to volume, mix, filter, and use the filtrate. [NOTE—Reserve a portion of it for the test for *Magnesium Hydroxide*.]

Analysis: Transfer 20.0 mL of the *Sample solution* to a suitable container, dilute with water to 100 mL, and add 30 mL of 1 N sodium hydroxide, 5 mL of triethanolamine, and 100 mg of hydroxy naphthol blue. Titrate with 0.05 M edetate disodium VS until the solution is deep blue in color. Each mL of 0.05 M edetate disodium is equivalent to 5.004 mg of CaCO_3 .

Acceptance criteria: 90.0%–110.0%

• MAGNESIUM HYDROXIDE

Sample solution: Use the *Sample solution* from the test for *Calcium Carbonate*.

Analysis: Transfer a portion of the *Sample solution*, equivalent to 120 mg of calcium carbonate and magnesium hydroxide combined, to a suitable container. Dilute with water to 100 mL, and add 10 mL of ammonia–ammonium chloride buffer TS, 5 mL of triethanolamine, and 0.3 mL of eriochrome black TS. Titrate with 0.05 M edetate disodium VS to a blue endpoint. The volume, in mL, of 0.05 M edetate disodium consumed, less the volume of 0.05 M edetate disodium corresponding to the content of calcium carbonate in the volume, in mL, of the *Sample solution* taken, represents the volume, in mL, of 0.05 M edetate disodium equivalent to the quantity of magnesium hydroxide present. Each mL of 0.05 M edetate disodium is equivalent to 2.916 mg of $\text{Mg}(\text{OH})_2$.

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• **[UNIFORMITY OF DOSAGE UNITS \(905\)](#):** Meet the requirements for [Weight Variation](#) with respect to calcium carbonate and to magnesia

SPECIFIC TESTS

• **[ACID-NEUTRALIZING CAPACITY \(301\)](#):**

Analysis: NLT 5 mEq of acid is consumed by the minimum single dose recommended in the labeling, and NLT the number of mEq calculated by the formula:

$$\text{Result} = [0.8 \times (F_M \times M)] + [0.9 \times (F_C \times C)]$$

F_M = theoretical acid-neutralizing capacity of $\text{Mg}(\text{OH})_2$, 0.0343 mEq

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

F_C = theoretical acid-neutralizing capacity of CaCO_3 , 0.02 mEq

C = quantity of CaCO_3 in the sample tested (mg), based on the labeled quantity

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
CALCIUM CARBONATE AND MAGNESIA TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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