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Calcium and Magnesium Carbonates Tablets

DEFINITION

Calcium and Magnesium Carbonates Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of calcium carbonate ($CaCO_3$) and NLT 85.0% and NMT 115.0% of the labeled amount of magnesium carbonate ($MgCO_3$).

IDENTIFICATION

• **A. Identification Tests—General, *Calcium*⟨191⟩:** The addition of 1 N hydrochloric acid to 1 Tablet produces effervescence, and the resulting solution, after having been filtered, 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: Meet 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 the aid of 25 mL of water, and add 10 mL of 1 N hydrochloric acid. Heat on a steam bath for 30 min, allow to cool, and transfer to a 100-mL volumetric flask with the aid of water. Dilute with water to volume, mix, filter, and use the filtrate. [Note—Reserve a portion of the filtrate for the *Sample solution* in the *Magnesium Carbonate* test.]

Analysis: Transfer 20.0 mL of *Sample solution* to a suitable container. Dilute with water to 100 mL, and add 15 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. Each mL of 0.05 M edetate disodium is equivalent to 5.004 mg of $CaCO_3$.

Acceptance criteria: 90.0%–110.0%

• **Magnesium Carbonate**

Sample solution: Use a portion of the filtrate from the *Sample solution* in the *Calcium Carbonate* test.

Analysis: Transfer the *Sample solution* equivalent to 120 mg of calcium carbonate and magnesium carbonate 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. From the volume of 0.05 M edetate disodium consumed, subtract the volume of 0.05 M edetate disodium corresponding to the content of calcium carbonate in the portion of the *Sample solution* taken. The difference is the volume of 0.05 M edetate disodium equivalent to the quantity of magnesium carbonate present. Each mL of 0.05 M edetate disodium is equivalent to 4.216 mg of $MgCO_3$.

Acceptance criteria: 85.0%–115.0%

PERFORMANCE TESTS

• **Disintegration ⟨701⟩**

Time: NMT 10 min, except that where Tablets are labeled as gelatin-coated, the time is NMT 30 min, simulated gastric fluid TS being substituted for water in the test

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements for *Weight Variation* with respect to calcium carbonate and to magnesium carbonate

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:

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

F_M = theoretical acid-neutralizing capacity of $MgCO_3$, 0.024 mEq

M = quantity of $MgCO_3$ in the specimen tested, based on the labeled quantity (mg)

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

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

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **Labeling:** Tablets that are gelatin-coated are so labeled.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CALCIUM AND MAGNESIUM CARBONATES TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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