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Calcium and Magnesium Carbonates Oral Suspension

DEFINITION

Calcium and Magnesium Carbonates Oral Suspension contains 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 3 N hydrochloric acid to a quantity of Oral Suspension, equivalent to 500 mg of calcium carbonate, produces effervescence, and the resulting solution, after having been filtered, meets the requirements.

• **B. Identification Tests—General, *Magnesium* ⟨191⟩**

Sample solution: Heat a quantity of Oral Suspension, equivalent to 800 mg of magnesium carbonate, with 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: Meets the requirements

ASSAY

• **Calcium Carbonate**

Sample solution: Transfer a portion of Oral Suspension equivalent to 400 mg of calcium carbonate, previously well shaken in its original container and free of air bubbles, to a beaker, with the aid of 20 mL of water, and add 10 mL of 1 N hydrochloric acid. Heat on a steam bath for 30 min, allow to cool, transfer with the aid of water to a 100-mL volumetric flask, dilute with water to volume, 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

• **Deliverable Volume ⟨698⟩:** Meets the requirements

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count is NMT 100 cfu/mL, and it meets the requirements of the tests for absence of *Escherichia coli* and *Pseudomonas aeruginosa*.

• **pH ⟨791⟩:** 7.0–8.6

• **Acid-Neutralizing Capacity ⟨301⟩:** 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 tight containers, and avoid freezing.

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

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