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Calcium Carbonate Oral Suspension

DEFINITION

Calcium Carbonate Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of calcium carbonate ($CaCO_3$).

IDENTIFICATION

• **A. Identification Tests—General, *Calcium*⟨191⟩:** The addition of acetic acid to it produces effervescence (presence of carbonate). The resulting solution, after boiling, meets the requirements.

ASSAY

• **Procedure**

Sample solution: Transfer a portion of Oral Suspension, equivalent to 1 g of calcium carbonate, previously well shaken in its original container, to a beaker with the aid of 25 mL of water. Add 20 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, and filter.

Blank: 100 mL of water, 15 mL of 1 N sodium hydroxide, and 5 mL of triethanolamine

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Indicator: 100 mg of hydroxy naphthol blue

Endpoint detection: Visual, change to distinct blue

Analysis: Transfer 20.0 mL of the *Sample solution* to a suitable container. Dilute with water to 100 mL. Add 15 mL of 1 N sodium hydroxide, 5 mL of triethanolamine, and 100 mg of hydroxy naphthol blue. Titrate with the *Titrant*.

Calculate the percentage of the labeled amount of calcium carbonate ($CaCO_3$) in the sample taken:

$$\text{Result} = [(V_S - V_B) \times M \times F \times 100]/W$$

V_S = volume of the *Titrant* consumed by the *Sample solution* (mL)

V_B = volume of the *Titrant* consumed by the *Blank* (mL)

M = *Titrant* molarity (mmol/mL)

F = equivalency factor, 100.09 mg/mmol

W = nominal amount of calcium carbonate taken for the *Analysis* (mg)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Limit of Fluoride**

[Note—Prepare and store all solutions in plastic containers.]

Solution A: 294 mg/mL of sodium citrate dihydrate in water

Standard stock solution: 1.1 mg/mL of USP Sodium Fluoride RS in water

Standard solution: Combine 20.0 mL of the *Standard stock solution* with 50.0 mL of *Solution A*, and dilute with water to 100.0 mL. [Note—Each mL of this solution contains 100 µg of fluoride ion.]

Sample solution: Transfer a portion of Oral Suspension, equivalent to 2.0 g of calcium carbonate, to a beaker containing a plastic-coated stirring bar. Add 20 mL of water and 4.0 mL of hydrochloric acid. Stir until dissolved. Add 50.0 mL of *Solution A* and sufficient water to make 100.0 mL.

Electrode system: Use a fluoride-specific ion-indicating electrode and a silver–silver chloride reference electrode connected to a pH meter capable of measuring potentials with a minimum reproducibility of ±0.2 mV (see *pH* ⟨791⟩).

Standard response line: Transfer 50.0 mL of *Solution A* and 4.0 mL of hydrochloric acid to a beaker. Add water to make 100.0 mL. Add a plastic-coated stirring bar, insert the electrodes into the solution, and stir for 15 min. Read the potential, in mV. Continue stirring, and at 5-min intervals add 100, 100, 300, and 500 µL of the *Standard solution*, reading the potential 5 min after each addition. Plot the logarithms of the cumulative fluoride ion concentrations (0.1, 0.2, 0.5, and 1.0 µg/mL) versus potential, in mV.

Analysis: Rinse and dry the electrodes, and insert them into the *Sample solution*. Stir for 5 min, and read the potential, in mV. From the measured potential and the *Standard response line*, determine the concentration, *C*, in µg/mL, of fluoride ion in the *Sample solution*. Calculate the content of fluoride in the sample taken:

$$\text{Result} = (V \times C)/W$$

V = volume of the *Sample solution* (mL)

C = determined concentration of fluoride in the *Sample solution* (µg/mL)

W = nominal weight of calcium carbonate taken (g)

Acceptance criteria: 50 µg/g, with respect to the labeled amount of calcium carbonate

Change to read:

• ▲**Arsenic ⟨211⟩, *Procedures, Procedure 1*** ▲ (CN 1-Jun-2023)

Test preparation: Slowly dissolve a portion of Oral Suspension equivalent to 1.0 g of calcium carbonate in 15 mL of hydrochloric acid. Dilute with water to 55 mL.

Analysis: Proceed as directed in the chapter, except omit the addition of 20 mL of 7 N sulfuric acid specified under *Procedure*.

Acceptance criteria: NMT 3 µg/g, with respect to the labeled amount of calcium carbonate

Change to read:

• ▲**Lead ⟨251⟩, *Procedures, Procedure 1*** ▲ (CN 1-Jun-2023)

Test preparation: Mix a portion of Oral Suspension equivalent to 1.0 g of calcium carbonate in 5 mL of water.

Analysis: To the *Test preparation* slowly add 8 mL of 3 N hydrochloric acid. Evaporate on a steam bath to dryness, and dissolve the residue in 5 mL of water.

Acceptance criteria: NMT 3 µg/g, with respect to the labeled amount of calcium carbonate

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count is NMT 10^2 cfu/mL. It meets the requirements of the tests for absence of *Escherichia coli* and *Pseudomonas aeruginosa*.

• **pH ⟨791⟩:** 7.5–8.7

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and avoid freezing.

• **USP Reference Standards ⟨11⟩**

USP Sodium Fluoride RS

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

Topic/Question	Contact	Expert Committee
CALCIUM CARBONATE ORAL SUSPENSION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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