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Calcium Carbonate Tablets

DEFINITION

Calcium Carbonate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of calcium carbonate ($CaCO_3$). For Tablets labeled for any indication other than, or in addition to, antacid use, the Tablets contain NLT 90.0% and NMT 115.0% of the labeled amount of calcium carbonate.

IDENTIFICATION

• **A. Identification Tests—General, *Calcium*⟨191⟩:** The addition of 6 N acetic acid to the Tablets produces effervescence, and the resulting solution, after being boiled to expel carbon dioxide and neutralized with 6 N ammonium hydroxide, meets the requirements.

ASSAY

• **Procedure**

Sample solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 200 mg of calcium carbonate, to a suitable crucible. Ignite to constant weight. Cool the crucible, add 10 mL of water, and dissolve the residue by adding sufficient 3 N hydrochloric acid, dropwise, to achieve complete solution.

Blank: 150 mL of water and 15 mL of 1 N sodium hydroxide

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Indicator: 300 mg of hydroxy naphthol blue

Endpoint detection: Visual, change to distinct blue

Analysis: Transfer the *Sample solution* completely to a suitable container, and dilute with water to 150 mL. Add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue. Titrate with the *Titrant*.

Calculate the percentage 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 = weight of calcium carbonate taken (mg)

Acceptance criteria: 90.0%–110.0% of the labeled amount of $CaCO_3$. For Tablets labeled for any indication other than, or in addition to, antacid use, 90.0%–115.0% of the labeled amount of $CaCO_3$

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

[Note—For Tablets labeled for any indication other than, or in addition to, antacid use.]

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Lanthanium chloride solution: 50 mg/mL of lanthanum chloride in 0.1 N hydrochloric acid

Standard stock solution: 100 µg/mL of calcium in 0.1 N hydrochloric acid

Standard solutions: Into separate 100-mL volumetric flasks containing 10.0 mL of *Lanthanium chloride solution* pipet 3-, 4-, 5-, and 6-mL portions of *Standard stock solution* and dilute each with 0.1 N hydrochloric acid to volume to obtain solutions with calcium concentrations of 3, 4, 5, and 6 µg/mL, respectively.

Sample solution: Filter a portion of the solution under test. Pipet a volume of the filtrate, estimated to contain 1 mg of calcium, into a 250-mL volumetric flask. Add 25.0 mL of *Lanthanium chloride solution*, and dilute with 0.1 N hydrochloric acid to volume.

Instrumental conditions

(See *Atomic Absorption Spectroscopy* ⟨852⟩.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 422.8 nm

Lamp: Calcium hollow-cathode

Flame: Air–acetylene

Blank: *Lanthanium chloride solution* and 0.1 N hydrochloric acid (1:9)

Analysis

Samples: *Standard solutions* and *Sample solution*

Concomitantly determine the absorbances of the *Standard solutions* and the *Sample solution* against the *Blank*. Construct a standard curve by plotting absorbances versus calcium concentrations of the *Standard solutions*, then from it obtain the concentration, *C*, in µg/mL of calcium, of the *Sample solution*.

Calculate the percentage of the labeled amount of calcium carbonate ($CaCO_3$) dissolved:

$$\text{Result} = (M_r/A_r) \times (C \times D \times V/L) \times 100$$

M_r = molecular weight of calcium carbonate, 100.09

A_r = atomic weight of calcium, 40.08

C = measured concentration of calcium in the *Sample solution* (mg/mL)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (*Q*) of the labeled amount of calcium carbonate ($CaCO_3$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

SPECIFIC TESTS

• **Acid-Neutralizing Capacity** ⟨301⟩**:** For Tablets labeled for antacid use

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:

$$\text{Result} = (C \times A_{NC}) \times F$$

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

A_{NC} = theoretical acid-neutralizing capacity of $CaCO_3$, 0.02 mEq/mg

F = acceptance factor for the lower limit of the required acid-neutralizing capacity, 0.9

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **Labeling:** Label it to indicate whether it is for use as an antacid, or as a dietary supplement, or both.

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

Topic/Question	Contact	Expert Committee
CALCIUM CARBONATE TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

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