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Calcium Carbonate Lozenges

DEFINITION

Calcium Carbonate Lozenges contain 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 6 N hydrochloric acid to a Lozenge produces effervescence, and the resulting solution, after being boiled to expel carbon dioxide and then neutralized with 6 N ammonium hydroxide, meets the requirements of the tests.

ASSAY

• **Procedure**

[Note—The *Standard solutions* and the *Sample solution* may be modified, if necessary, to obtain solutions of suitable concentrations adaptable to the linear or working range of the instrument.]

Lanthanum chloride solution: Transfer 10 g of potassium chloride and 20 g of lanthanum chloride to a 2000-mL volumetric flask. Add 1000 mL of water and 40 mL of hydrochloric acid, mix, and allow to cool. Dilute with water to volume.

Standard stock solution: Transfer 250 mg of chelometric standard calcium carbonate, previously dried at 110° for 2 h and then cooled in a desiccator, to a 500-mL volumetric flask. Add 100 mL of water and 12 mL of 1 N hydrochloric acid, swirl to dissolve the calcium carbonate, and allow to cool. Dilute with water to volume. This stock solution contains about 500 µg/mL of calcium carbonate.

Standard solutions: To three separate 100-mL volumetric flasks add 2.0, 3.0, and 4.0 mL of the *Standard stock solution*, and dilute each with *Lanthanum chloride solution* to volume. These *Standard solutions* contain 10, 15, and 20 µg/mL of calcium carbonate, respectively.

Sample stock solution: Transfer the equivalent to 3000 mg of calcium carbonate, from powdered Lozenges, to a 1000-mL volumetric flask. Add 100 mL of 1 N hydrochloric acid and 300 mL of water, and sonicate to dissolve the powder. Dilute with water to volume.

Sample solution: Transfer 5.0 mL of *Sample stock solution* to a 1000-mL volumetric flask, and dilute with *Lanthanum chloride solution* to volume.

Instrumental conditions

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

Mode: Atomic absorption spectrophotometry

Lamp: Calcium hollow-cathode

Flame: Nitrous oxide–acetylene

Analytical wavelength: Calcium emission line at 422.7 nm

Blank: *Lanthanum chloride solution*

Analysis

Samples: *Standard solutions*, *Sample solution*, and *Blank*

Plot the absorbances of the *Standard solutions* versus their concentrations of calcium carbonate, in µg/mL, by drawing a straight line best fitting the three plotted points. From the graph determine the concentration, *C*, in µg/mL, of calcium carbonate in the *Sample solution*.

Calculate the percentage of label claim of calcium carbonate ($CaCO_3$) in the portion of Lozenges taken:

$$\text{Result} = (C/C_U) \times 100$$

C = measured concentration of calcium carbonate in the *Sample solution* (µg/mL), as calculated above

C_U = nominal concentration of calcium carbonate in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

• **Sodium Content** ⟨if so labeled⟩

[Note—The *Standard solutions* and the *Sample solution* may be modified, if necessary, to obtain solutions of suitable concentrations adaptable to the linear or working range of the instrument.]

Standard stock solution: Transfer 2.542 g of sodium chloride, previously dried at 105° for 2 h, to a 1000-mL volumetric flask. Dissolve in and dilute with water to volume. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, and dilute with water to volume.

Standard solutions: To three separate 100-mL volumetric flasks, add 1.0, 3.0, and 5.0 mL of the *Standard stock solution*, and dilute each with water to volume. These *Standard solutions* contain 1.0, 3.0, and 5.0 µg/mL of sodium, respectively.

Sample stock solution: Prepare as directed in the *Assay*. Pass a portion of it, if necessary, through a filter of 0.5-µm or finer pore size, and use the clear solution.

Sample solution: Transfer 10.0 mL of the *Sample stock solution* to a 25-mL volumetric flask, and dilute with water to volume.

Instrumental conditions

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

Mode: Atomic absorption spectrophotometry

Lamp: Sodium hollow-cathode

Flame: Air–acetylene

Analytical wavelength: Sodium emission line at 589.6 nm

Blank: Water

Analysis

Samples: *Standard solutions*, *Sample solution*, and *Blank*

Plot the absorbances of the *Standard solutions* versus their contents of sodium, in µg/mL, by drawing a straight line best fitting the three plotted points. From the graph determine the quantity, *C*, in µg, of sodium in each mL of the *Sample solution*.

Calculate the percentage of label claim of sodium in the portion of Lozenges taken:

$$\text{Result} = (C/C_U) \times 100$$

C = measured concentration of sodium in the *Sample solution* (µg/mL), as calculated above

C_U = nominal concentration of sodium in the *Sample solution* (µg/mL)

Acceptance criteria: NMT 115.0% of the labeled amount

PERFORMANCE TESTS

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

SPECIFIC TESTS

• **Acid-Neutralizing Capacity** ⟨301⟩

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

$$\text{Result} = (F_C \times C) \times 0.9$$

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 LOZENGES	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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