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Calcium Carbonate, Magnesia, and Simethicone Chewable Tablets

Former title: Calcium Carbonate, Magnesia, and Simethicone Tablets

» Calcium Carbonate, Magnesia, and Simethicone Chewable Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of calcium carbonate ($CaCO_3$) and magnesium hydroxide [$Mg(OH)_2$], and an amount of polydimethylsiloxane [$-(CH_3)_2SiO-]_n$ that is not less than 85.0 percent and not more than 115.0 percent of the labeled amount of simethicone.

Packaging and storage—Preserve in well-closed containers.

Labeling—Label it to indicate that the Chewable Tablets are to be chewed before swallowing. Label the Chewable Tablets to state the sodium content, in mg per Chewable Tablet, if it is greater than 5 mg per Chewable Tablet.

USP Reference standards ⟨11⟩—
USP Polydimethylsiloxane RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests ⟨197⟩, Infrared Spectroscopy:197S*▲ (CN 1-May-2020) —

Solution—Using Chewable Tablets, proceed to obtain IR absorption spectra as directed in the *Assay for polydimethylsiloxane* under *Alumina, Magnesia, and Simethicone Chewable Tablets.*

B: The addition of 1 N hydrochloric acid to a Chewable Tablet produces effervescence, and the resulting solution, after having been filtered, meets the requirements of the tests for *Calcium* ⟨191⟩.

C: Heat 2 Chewable Tablets in 20 mL of 1 N sulfuric acid. Cool, add 20 mL of alcohol, mix, and allow to stand for 30 minutes. Filter this solution, and to the filtrate add 2 mL of 1 N hydrochloric acid: this solution meets the requirements of the tests for *Magnesium* ⟨191⟩.

Uniformity of dosage units ⟨905⟩**:** meet the requirements for *Weight Variation* with respect to calcium carbonate and to magnesium hydroxide.

Acid-neutralizing capacity ⟨301⟩—Not less than 5 mEq of acid is consumed by the minimum single dose recommended in the labeling.

Content of sodium (if so labeled)—

Lanthanum chloride solution—Prepare as directed in the *Assay for calcium carbonate and magnesium hydroxide.*

Dilute hydrochloric acid—Prepare as directed in the *Assay for polydimethylsiloxane.*

Standard solution—Transfer 2.542 g of sodium chloride, previously dried at 105° for 2 hours, to a 1000-mL volumetric flask, dissolve in and dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 4.0 mL of this solution to a second 100-mL volumetric flask containing 6.0 mL of *Dilute hydrochloric acid* and 2.0 mL of *Lanthanum chloride solution,* dilute with water to volume, and mix. This solution contains 2.0 µg of sodium (Na) per mL.

Test solution—Transfer 3.0 mL of the aqueous layer retained from the preparation of the *Assay preparation* in the *Assay for polydimethylsiloxane* to a 50-mL volumetric flask containing 1.0 mL of *Lanthanum chloride solution,* dilute with water to volume, and mix.

Blank solution—Transfer 15.0 mL of *Dilute hydrochloric acid* and 5.0 mL of *Lanthanum chloride solution* to a 250-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard solution* and the *Test solution* at the sodium emission line at 589.0 nm with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with a sodium hollow-cathode lamp and an air–acetylene flame, using the *Blank solution* as the blank. Calculate the mg of sodium (Na) in each Chewable Tablet taken by the formula:

$$(5C/6)(A/W)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of sodium in the *Standard solution; A* is the average weight, in mg, of each Chewable Tablet; W is the weight, in mg, of the portion of Chewable Tablets from the preparation of the *Assay preparation* in the *Assay for polydimethylsiloxane* used to prepare the *Test solution;* and A_U and A_S are the absorbances of the *Test solution* and the *Standard solution,* respectively. Each Chewable Tablet contains not more than the number of mg of sodium stated on the label.

Assay for polydimethylsiloxane—

Saccharin solution—Prepare a solution of saccharin in 4-methyl-2-pentanone containing 12.5 mg per mL.

Dilute hydrochloric acid—Mix 200 mL of hydrochloric acid with sufficient water to make 1000 mL.

Standard preparation—Dissolve a suitable quantity of USP Polydimethylsiloxane RS in 4-methyl-2-pentanone to obtain a stock solution having a known concentration of about 1 mg per mL. On the day of use, transfer 20.0 mL of this solution and 5.0 mL of *Saccharin solution* to a 250-mL volumetric flask, dilute with 4-methyl-2-pentanone to volume, and mix. This solution contains about 0.08 mg of USP Polydimethylsiloxane RS per mL.

Assay preparation—Weigh and finely powder not fewer than 20 Chewable Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 20 mg of polydimethylsiloxane, to a 125-mL separator. Cautiously add 50.0 mL of *Dilute hydrochloric acid,* and swirl until the reaction subsides. Insert the stopper, and mix. Carefully release the pressure, add 50.0 mL of 4-methyl-2-pentanone, and mix for 10 minutes. Allow the layers to separate, and drain the aqueous layer into a suitable stoppered container. [NOTE—Retain this aqueous layer for use in preparing the *Assay preparation* in the *Assay for calcium carbonate and magnesium hydroxide* and for the preparation of the *Test solution* in the test for *Content of sodium.*] Filter the organic layer through a filter containing 50 g of anhydrous sodium sulfate. Transfer 10.0 mL of the filtrate to a 50-mL volumetric flask, add 1.0 mL of *Saccharin solution,* dilute with methyl isobutyl ketone to volume, and mix.
Blank solution—Transfer 1.0 mL of *Saccharin solution* to a 50-mL volumetric flask, dilute with 4-methyl-2-pentanone to volume, and mix.
Procedure—Concomitantly determine the absorbances of the *Standard preparation* and the *Assay preparation* at the silicon emission line at 251.6 nm, with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with a silicon hollow-cathode lamp and a nitrous oxide–acetylene flame, using the *Blank solution* as the blank. Calculate the quantity, in mg, of polydimethylsiloxane in each Chewable Tablet taken by the formula:

$$250C(A/W)(A_U/A_S)$$

in which C is the concentration, in mg per mL, of USP Polydimethylsiloxane RS in the *Standard preparation; A* is the average weight, in mg, of each Chewable Tablet; W is the weight, in mg, of the portion of Chewable Tablets taken to prepare the *Assay preparation;* and A_U and A_S are the absorbances of the *Assay preparation* and the *Standard preparation,* respectively.

Assay for calcium carbonate and magnesium hydroxide—

Lanthanum chloride solution—Transfer 26.8 g of lanthanum chloride to a 200-mL volumetric flask, add 100 mL of water, and carefully add 50 mL of hydrochloric acid. Mix, and allow to cool. Dilute with water to volume, and mix.
Dilute hydrochloric acid—Prepare as directed in the *Assay for polydimethylsiloxane.*
Calcium stock standard solution—Transfer 499.5 mg of primary standard calcium carbonate to a 200-mL volumetric flask, and add 10 mL of water. Carefully add 5 mL of *Dilute hydrochloric acid,* and swirl to dissolve the calcium carbonate. Dilute with water to volume, and mix. This solution contains 1000 µg of calcium (Ca) per mL.
Magnesium stock standard solution—Transfer 1.000 g of magnesium metal to a 1000-mL volumetric flask containing 10 mL of water, slowly add 10 mL of hydrochloric acid, and swirl to dissolve the metal. Dilute with water to volume, and mix. This solution contains 1000 µg of magnesium (Mg) per mL.
Calcium and magnesium standard preparation—To a 250-mL volumetric flask add 10.0 mL of *Calcium stock standard solution* and 5.0 mL of *Magnesium stock standard solution,* dilute with water to volume, and mix. This solution contains 40 µg of calcium (Ca) and 20 µg of magnesium (Mg) per mL. On the day of use, transfer 4.0 mL of this solution to a 100-mL volumetric flask containing 2.0 mL of *Lanthanum chloride solution,* dilute with water to volume, and mix. This solution contains 1.6 µg of calcium (Ca) and 0.8 µg of magnesium (Mg) per mL.
Assay preparation—Transfer an accurately measured volume of the aqueous layer retained from the preparation of the *Assay preparation* in the *Assay for polydimethylsiloxane,* equivalent to about 28 mg of calcium carbonate, to a 200-mL volumetric flask, dilute with water to volume, and mix. Transfer 3.0 mL of this solution to a 100-mL volumetric flask containing 2.0 mL of *Lanthanum chloride solution*, dilute with water to volume, and mix.
Blank solution—Transfer 5.0 mL of *Lanthanum chloride solution* to a 250-mL volumetric flask, dilute with water to volume, and mix.
Procedure for calcium carbonate—Concomitantly determine the absorbances of the *Standard preparation* and the *Assay preparation* at the calcium emission line at 422.7 nm, with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with a calcium hollow-cathode lamp and a nitrous oxide–acetylene flame, using the *Blank solution* as the blank. Calculate the quantity, in mg, of calcium carbonate ($CaCO_3$) in each Chewable Tablet taken by the formula:

$$(100.09/40.08)(1000C/3V)(A/W)(A_U/A_S)$$

in which 100.09 is the molecular weight of calcium carbonate; 40.08 is the atomic weight of calcium; C is the concentration, in µg per mL, of calcium in the *Standard preparation; V* is the volume, in mL, of the aqueous layer retained from the preparation of the *Assay preparation* in the *Assay for polydimethylsiloxane* used to prepare the *Assay preparation; A* is the average weight, in mg, of each Chewable Tablet; W is the weight, in mg, of the portion of Chewable Tablets taken to prepare the *Assay preparation* in the *Assay for polydimethylsiloxane;* and A_U and A_S are the absorbances of the *Assay preparation* and the *Standard preparation,* respectively.
Procedure for magnesium hydroxide—Concomitantly determine the absorbances of the *Standard preparation* and the *Assay preparation* at the magnesium emission line at 285.2 nm, with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with a magnesium hollow-cathode lamp and a nitrous oxide–acetylene flame, using the *Blank solution* as the blank. Calculate the quantity, in mg, of magnesium hydroxide [$Mg(OH)_2$] in each Chewable Tablet taken by the formula:

$$(58.34/24.305)(1000C/3V)(A/W)(A_U/A_S)$$

in which 58.34 is the molecular weight of magnesium hydroxide; 24.305 is the atomic weight of magnesium; C is the concentration, in µg per mL, of magnesium in the *Standard preparation; V* is the volume, in mL, of the aqueous layer retained from the preparation of the *Assay preparation* in the *Assay for polydimethylsiloxane* used to prepare the *Assay preparation; A* is the average weight, in mg, of each Chewable Tablet taken; W is the weight, in mg, of the portion of Chewable Tablets taken to prepare the *Assay preparation* in the *Assay for polydimethylsiloxane;* and A_U and A_S are the absorbances of the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
CALCIUM CARBONATE, MAGNESIA, AND SIMETHICONE CHEWABLE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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