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Magaldrate and Simethicone Chewable Tablets

Former title: Magaldrate and Simethicone Tablets

» Magaldrate and Simethicone Chewable Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of magaldrate [$Al_5Mg_{10}(OH)_{31}(SO_4)_2$], 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 the Chewable Tablets to indicate that they are to be chewed before being swallowed.

USP Reference standards ⟨11⟩—
USP Magaldrate RS
USP Polydimethylsiloxane RS

Identification—

A: Transfer a quantity of powdered Chewable Tablets, equivalent to about 2 g of magaldrate, to a 100-mL centrifuge tube. Add about 60 mL of water, cap, and shake for 3 minutes. Centrifuge the suspension, and discard the supernatant. Repeat the washing with three more 60-mL portions of water. Transfer the residue to a 250-mL beaker, and heat on a steam bath to dryness: the residue so obtained meets the requirements of the *Identification* tests under *Magaldrate*.

B: The IR absorption spectrum, in the 7- to 11-µm region, determined in a 0.5-mm cell, of the *Assay preparation* prepared as directed in the *Assay for polydimethylsiloxane,* exhibits maxima only at the same wavelengths as that of the *Standard preparation* containing about 2 mg of USP Polydimethylsiloxane RS per mL prepared as directed in the *Assay for polydimethylsiloxane*.

Microbial enumeration tests ⟨61⟩ and Tests for specified microorganisms ⟨62⟩—Chewable Tablets meet the requirements of the test for absence of *Escherichia coli*.

Uniformity of dosage units ⟨905⟩: meet the requirements for *Weight Variation* with respect to magaldrate.

Acid-neutralizing capacity—Proceed as directed under *Acid-neutralizing Capacity ⟨301⟩*. The acid consumed by the minimum single dose recommended in the labeling is not less than 5 mEq, and not less than the number of mEq calculated by the formula:

$$0.8(0.0282M)$$

in which 0.0282 is the theoretical acid-neutralizing capacity, in mEq per mg, of magaldrate, and M is the quantity, in mg, of the labeled amount of magaldrate.

Magnesium hydroxide content—

Test preparation—Weigh and finely powder not fewer than 20 Chewable Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 1 g of magaldrate, to a 100-mL volumetric flask, add 30 mL of dilute hydrochloric acid (1 in 10), shake for 15 minutes, dilute with water to volume, and mix.

Procedure—Transfer 10.0 mL of the *Test preparation* to a 400-mL beaker, and proceed as directed in the test for *Magnesium hydroxide content* under *Magaldrate,* beginning with "and dilute with water to about 200 mL." Not less than 492 mg and not more than 666 mg of magnesium hydroxide [$Mg(OH)_2$] per g of the labeled amount of magaldrate is found.

Aluminum hydroxide content—

Edetate disodium titrant—Prepare and standardize as directed in the *Assay* under *Ammonium Alum*.

Test preparation—Prepare as directed in the test for *Magnesium hydroxide content*.

Procedure—Transfer 10.0 mL of *Test preparation* and 20 mL of water to a 250-mL beaker, and proceed as directed for *Procedure* in the test for *Aluminum hydroxide content* under *Magaldrate*, beginning with "Add, with stirring, 25.0 mL of *Edetate disodium*." Not less than 321 mg and not more than 459 mg of aluminum hydroxide [$Al(OH)_3$] per g of the labeled amount of magaldrate is found.

Change to read:

Assay for magaldrate—Weigh and finely powder not fewer than 20 Chewable Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 6 g of magaldrate, to a 200-mL volumetric flask. Add 100.0 mL of 2 N hydrochloric acid VS, and swirl by mechanical means for 30 minutes. Dilute with water to volume, mix, and filter. Transfer 100.0 mL of the filtrate to a beaker. Titrate the excess acid with 1 N sodium hydroxide VS to a pH of 3.0, determined potentiometrically. Perform a blank determination (see ▲*Titrimetry ⟨541⟩*▲ (CN 1-Aug-2024)). Each mL of 2 N hydrochloric acid is equivalent to 70.80 mg of $Al_5Mg_{10}(OH)_{31}(SO_4)_2$.

Assay for polydimethylsiloxane—Weigh and finely powder not fewer than 20 Chewable Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 20 mg of simethicone, to a 60-mL separator. Add 10.0 mL of hexanes and 25 mL of 6 N hydrochloric acid, cap the separator, and shake by mechanical means for not less than 2 hours. Allow to stand for about 10 minutes, and drain off as much of the lower,

aqueous layer as possible without removing any of the unseparated interphase. Add 25 mL of 4 N sodium hydroxide to the separator, cap it, and shake by mechanical means for 1 hour. Transfer the mixture from the separator to a 50-mL centrifuge tube, cap, and centrifuge to obtain clear layers. Transfer not less than 5 mL of the clear upper hexanes layer to a test tube containing about 0.5 g of anhydrous sodium sulfate. Cap the tube, shake vigorously, and allow to stand to obtain a clear supernatant (*Assay preparation*). Prepare three *Standard preparations* in hexanes having known concentrations of about 1.6, 2.0, and 2.4 mg of USP Polydimethylsiloxane RS per mL, respectively. Concomitantly determine the absorbances of the *Assay preparation* and the *Standard preparations* in a 0.5-mm cell at the wavelength of maximum absorbance at about 1260 cm^{-1} with an IR spectrophotometer, using hexanes as the blank. [NOTE—Between each measurement, rinse the cell with heptane, empty, and dry it.] Plot the absorbances for the *Standard preparations* versus concentration, in mg per mL, of USP Polydimethylsiloxane RS, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, *C,* in mg per mL, of polydimethylsiloxane in the *Assay preparation.* Calculate the quantity, in mg, of $[-(CH_3)_2SiO-]_n$ in the portion of Chewable Tablets taken by multiplying *C* by 10.

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

Topic/Question	Contact	Expert Committee
MAGALDRATE AND SIMETHICONE CHEWABLE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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