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Magaldrate and Simethicone Oral Suspension

» Magaldrate and Simethicone Oral Suspension contains 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 tight containers, and keep from freezing.

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

Identification—

A: Dissolve an amount of Oral Suspension, equivalent to about 800 mg of magaldrate, in 20 mL of 3 N hydrochloric acid, dilute with water to about 50 mL, add 3 drops of methyl red TS, and proceed as directed in *Identification* test *A* under *Magaldrate*, beginning with "and heat to boiling."

B: Wash the precipitate obtained in *Identification* test *A* with hot ammonium chloride solution (1 in 50), and dissolve the precipitate in hydrochloric acid. Divide this solution into two portions: the dropwise addition of 6 N ammonium hydroxide to one portion yields a gelatinous white precipitate, which does not dissolve in an excess of 6 N ammonium hydroxide. The dropwise addition of 1 N sodium hydroxide to the other portion yields a gelatinous white precipitate, which dissolves in an excess of 1 N sodium hydroxide, leaving some turbidity.

C: Transfer an amount of Oral Suspension, equivalent to about 1 g of magaldrate, to a 100-mL centrifuge tube. Add about 60 mL of water, insert the cap, and shake for 3 minutes. Centrifuge the suspension, and discard the supernatant. Repeat the washing of the residue with three 60-mL portions of water. Transfer the residue to a 250-mL beaker, and heat on a steam bath to dryness: the X-ray diffraction pattern (see *X-Ray Powder Diffraction ⟨941⟩*), in the d-spacings region below 2.57 angstrom units, of the residue so obtained conforms to that of USP Magaldrate RS.

D: The IR absorption spectrum, in the 7- to 15-µm region, determined in a 0.1-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* prepared as directed in the *Assay for polydimethylsiloxane*.

Microbial enumeration tests ⟨61⟩ and Tests for specified microorganisms ⟨62⟩—Its total aerobic microbial count does not exceed 100 cfu per mL, and it meets the requirements of the test for absence of *Escherichia coli*.

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—Transfer an accurately measured quantity of Oral Suspension, equivalent to about 1 g of magaldrate, to a 100-mL volumetric flask, add 30 mL of dilute hydrochloric acid (1 in 10), shake to dissolve, dilute with water to volume, and mix.

Procedure—Transfer 10.0 mL of *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 titrant*." 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.

Other requirements—Evaporate a volume of Oral Suspension, equivalent to about 5 g of magaldrate, on a steam bath to dryness: the residue so obtained meets the requirements of the tests for *Arsenic* under *Magaldrate*.

Change to read:

Assay for magaldrate—Transfer an accurately measured quantity of Oral Suspension, equivalent to about 3 g of magaldrate, to a beaker. Add 100.0 mL of 1 N hydrochloric acid VS, and mix, using a magnetic stirrer to achieve dissolution. 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 1 N hydrochloric acid is equivalent to 35.40 mg of magaldrate [$Al_5Mg_{10}(OH)_{31}(SO_4)_2$].

Assay for polydimethylsiloxane—Transfer an accurately measured quantity of Oral Suspension, equivalent to about 250 mg of simethicone, to a 200-mL centrifuge bottle. Add an equal volume of hydrochloric acid, swirl to dissolve the Oral Suspension, add 25.0 mL of hexanes, and immediately close the bottle securely with a cap having an inert liner. Shake the bottle for 30 minutes, and centrifuge the mixture until a clear supernatant layer is obtained (*Assay preparation*). Prepare a *Standard preparation* of USP Polydimethylsiloxane RS in hexanes having a known concentration of about 10 mg per mL. Concomitantly determine the absorbances of the *Assay preparation* and the *Standard preparation* in 0.1-mm cells at the wavelength of maximum absorbance at about 7.9 µm and at the wavelengths of minimum absorbance at about 7.5 µm and 8.3 µm, with a suitable IR spectrophotometer, using hexanes as the blank. Draw a linear baseline between the two minima, and determine the absorbances for the *Standard preparation* and the *Assay preparation* with respect to the baseline, making any necessary correction for the blank. Calculate the quantity, in mg, of $[-(CH_3)_2SiO-]_n$ in the portion of Oral Suspension taken by the formula:

$$25C(A_U/A_S)$$

in which C is the concentration, in mg per mL, of USP Polydimethylsiloxane RS in the *Standard preparation;* 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
MAGALDRATE AND SIMETHICONE ORAL SUSPENSION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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