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Alumina, Magnesia, and Simethicone Oral Suspension

DEFINITION

Alumina, Magnesia, and Simethicone Oral Suspension contains the equivalent of NLT 90.0% and NMT 115.0% of the labeled amounts of aluminum hydroxide [$Al(OH)_3$] and magnesium hydroxide [$Mg(OH)_2$], and an amount of polydimethylsiloxane ([$-(CH_3)_2 SiO-]_n$) that is NLT 85.0% and NMT 115.0% of the labeled amount of simethicone.

IDENTIFICATION

Change to read:

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

  Sample solution: Prepare as directed in the *Assay* for *Polydimethylsiloxane*.

  Analysis: Proceed as directed using a 0.5-mm cell.

  Acceptance criteria: Meets the requirements

- **B. Identification Tests—General, *Magnesium* ⟨191⟩**

  Sample solution: Add 5 g of Oral Suspension to 10 mL of 3 N hydrochloric acid, then add 5 drops of methyl red TS, heat to boiling, add 6 N ammonium hydroxide until the color of the solution just changes to deep yellow, then continue boiling for 2 min, and filter.

  Acceptance criteria: Meets the requirements

- **C. Identification Tests—General, *Aluminum* ⟨191⟩**

  Sample solution: Wash the precipitate from *Identification* test *B* with hot ammonium chloride solution (1 in 50), and dissolve the precipitate in hydrochloric acid. Divide this solution into two portions.

  Analysis 1: Add, dropwise, 6 N ammonium hydroxide to one portion of the *Sample solution*.

  Acceptance criteria 1: A gelatinous white precipitate, which does not dissolve in an excess of 6 N ammonium hydroxide, is obtained.

  Analysis 2: Add, dropwise, 1 N sodium hydroxide to the second portion of the *Sample solution*.

  Acceptance criteria 2: A gelatinous white precipitate, which dissolves in an excess of 1 N sodium hydroxide, leaving some turbidity, is obtained.

ASSAY

- **Aluminum Hydroxide**

  Edetate disodium titrant: Prepare and standardize as directed in *Reagents, Volumetric Solutions*, *Edetate Disodium, Twentieth-Molar (0.05 M)*.

  Sample solution: Transfer a measured amount of Oral Suspension, previously well shaken in its original container, equivalent to 800 mg of aluminum hydroxide, to a suitable beaker. Add 20 mL of water, stir, and slowly add 10 mL of hydrochloric acid. Heat gently, if necessary, to aid solution, cool, and filter into a 200-mL volumetric flask. Wash the filter with water into the flask, and add water to volume.

  Analysis: Pipet 10 mL of the *Sample solution* into a 250-mL beaker, add 20 mL of water, then add, in the order named and with continuous stirring, 25.0 mL of *Edetate disodium titrant* and 20 mL of acetic acid–ammonium acetate buffer TS, and heat the solution near the boiling temperature for 5 min. Cool, add 50 mL of alcohol and 2 mL of dithizone TS. Titrate the excess edetate disodium with 0.05 M zinc sulfate VS until the color changes from green-violet to rose-pink. Perform a blank determination, substituting 10 mL of water for the *Sample solution*, and make any necessary correction. Each mL of *Edetate disodium titrant* consumed is equivalent to 3.900 mg of aluminum hydroxide [$Al(OH)_3$].

  Acceptance criteria: 90.0%–115.0%

- **Magnesium Hydroxide**

  Sample solution: Prepare as directed in the *Assay* for *Aluminum Hydroxide*.

  Analysis: Pipet a volume of the *Sample solution*, equivalent to 40 mg of magnesium hydroxide, into a 400-mL beaker, add 200 mL of water and 20 mL of triethanolamine, and stir. Add 10 mL of ammonia–ammonium chloride buffer TS and 3 drops of an eriochrome black indicator solution (prepared by dissolving 200 mg of eriochrome black T in a mixture of 15 mL of triethanolamine and 5 mL of dehydrated alcohol, and mixing). Cool the solution to between 3° and 4° by immersion of the beaker in an ice bath, then remove, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Perform a blank determination, substituting water for the *Sample solution*, and make any necessary correction. Each mL of 0.05 M edetate disodium consumed is equivalent to 2.916 mg of magnesium hydroxide [$Mg(OH)_2$].

  Acceptance criteria: 90.0%–115.0%

- **Polydimethylsiloxane**

  Standard solution: Prepare similarly to the *Sample solution* below, except dissolve 50 mg of USP Polydimethylsiloxane RS in 25.0 mL of toluene, add 40 mL of 0.1 N sodium hydroxide, and add a volume of water equal to that of the specimen of Oral Suspension taken for the *Sample solution*.

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Sample solution: Transfer an amount of Oral Suspension, equivalent to 50 mg of simethicone, to a suitable round, narrow-mouth, screw-capped, 120-mL bottle, add 40 mL of 0.1 N sodium hydroxide, and swirl to disperse. Add 25.0 mL of toluene, close the bottle securely with a cap having an inert liner, and shake for 15 min on a reciprocating shaker (e.g., about 200 oscillations/min and a stroke of 38 ± 2 mm). Transfer the mixture to a 125-mL separator. Remove about 5 mL of the upper, organic layer to a screw-capped, 15-mL test tube containing 0.5 g of anhydrous sodium sulfate. Close the tube with a screw-cap having an inert liner, agitate vigorously, and centrifuge the mixture until a clear supernatant is obtained.

Blank: Mix 10 mL of toluene with 0.5 g of anhydrous sodium sulfate, and centrifuge to obtain a clear supernatant.

Analysis: Concomitantly determine the absorbances of the *Standard solution* and the *Sample solution* in 0.5-mm cells at the wavelength of maximum absorbance at about 7.9 µm, with a suitable IR spectrophotometer, using the *Blank* to set the instrument.

Calculate the percentage of polydimethylsiloxane ($[-(CH_3)_2\ SiO-]_n$) in the portion of Oral Suspension taken:

$$\text{Result} = (A_U/A_S) \times (W_S/W_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

W_S = weight of USP Polydimethylsiloxane RS taken to prepare the *Standard solution* (mg)

W_U = nominal amount of simethicone in the portion of the Oral Suspension taken to prepare the *Sample solution* (mg)

Acceptance criteria: 85.0%–115.0%

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count is NMT 10^2 cfu/mL, and it meets the requirements of the test for the absence of *Escherichia coli*.

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

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

$$\text{Result} = 0.55 \times (F_A \times A) + 0.8 \times (F_M \times M)$$

F_A = theoretical acid-neutralizing capacity of aluminum hydroxide [$Al(OH)_3$], 0.0385 mEq

A = amount of aluminum hydroxide [$Al(OH)_3$] in the specimen tested, based on the labeled quantity (mg)

F_M = theoretical acid-neutralizing capacity of magnesium hydroxide [$Mg(OH)_2$], 0.0343 mEq

M = amount of magnesium hydroxide [$Mg(OH)_2$] in the specimen tested, based on the labeled quantity (mg)

• **pH ⟨791⟩:** 7.0–8.6

• **Sodium Content**

Potassium chloride solution: 38 mg/mL of potassium chloride

Sodium chloride stock solution: 25.42 µg/mL of sodium chloride (previously dried at 105° for 2 h) in water. The solution contains 10 µg/mL of sodium.

Standard solutions: On the day of use, transfer 4.0 mL of 1 N hydrochloric acid and 10.0 mL of *Potassium chloride solution* to each of two 100-mL volumetric flasks. To the respective flasks add 5.0 and 10.0 mL of *Sodium chloride stock solution*. Dilute with water to volume. The resulting *Standard solutions* contain 0.5 and 1.0 µg/mL of sodium (Na), respectively.

Sample solution: Transfer 5.0 mL of Oral Suspension, previously well shaken in its original container, to a 100-mL volumetric flask. Add 50 mL of 1 N hydrochloric acid, boil for 15 min, cool to room temperature, and dilute with water to volume. Filter, discarding the first few mL of the filtrate. Transfer 5.0 mL of the filtrate to a 100-mL volumetric flask containing 10.0 mL of *Potassium chloride solution*, and dilute with water to volume.

Blank solution: Combine 4.0 mL of 1 N hydrochloric acid and 10.0 mL of *Potassium chloride solution* in a 100-mL volumetric flask, and dilute with water to volume.

Analysis

Samples: *Standard solution* and *Sample solution*

Concomitantly determine the absorbances of the *Standard solutions* and the *Sample 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. Plot the absorbances of the *Standard solutions* versus concentration, in µg/mL, of sodium, and draw a straight line between the plotted points. From the graph so obtained, determine the concentration, C, in µg/mL, of sodium in the *Sample solution*.

Calculate the quantity, in mg, of sodium (Na) in each mL of Oral Suspension taken:

$$\text{Result} = (1/N) \times C \times D \times F$$

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