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Alumina and Magnesium Carbonate Oral Suspension

» Alumina and Magnesium Carbonate Oral Suspension contains the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of aluminum hydroxide [$Al(OH)_3$] and magnesium carbonate ($MgCO_3$).

Packaging and storage—Preserve in tight containers, and avoid freezing.

Identification—

A: Place about 1 g in a flask equipped with a stopper and glass tubing, the tip of which is immersed in calcium hydroxide TS in a test tube. Add 5 mL of 3 N hydrochloric acid to the flask, and immediately insert the stopper: gas evolves in the flask and a precipitate is formed in the test tube.

B: To a solution of 5 g in 10 mL of 3 N hydrochloric acid add 5 drops of methyl red TS, heat to boiling, add 6 N ammonium hydroxide until the color of the solution changes to deep yellow, then continue boiling for 2 minutes, and filter: the filtrate responds to the tests for *Magnesium* ⟨191⟩.

C: Wash the precipitate obtained in *Identification* test *B* with a hot solution of ammonium chloride (1 in 50), and dissolve the precipitate in hydrochloric acid: the solution responds to the tests for *Aluminum* ⟨191⟩.

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*, *Salmonella* species, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.

Acid-neutralizing capacity ⟨301⟩—Not less than 5 mEq of acid is consumed by the minimum single dose recommended in the labeling, and not less than the number of mEq calculated by the formula:

$$0.55(0.0385A) + 0.8(0.024M)$$

in which 0.0385 and 0.024 are the theoretical acid-neutralizing capacities, in mEq, of $Al(OH)_3$ and $MgCO_3$, respectively; and A and M are the respective quantities, in mg, of $Al(OH)_3$ and $MgCO_3$ in the specimen tested, based on the labeled quantities.

pH ⟨791⟩: between 7.5 and 9.5.

Assay for aluminum hydroxide—

Potassium chloride solution—Prepare a solution containing 4.5 g of potassium chloride in each 100 mL.

Aluminum stock solution—Transfer 1.000 g of aluminum wire to a 1000-mL volumetric flask, and add 50 mL of 6 N hydrochloric acid. Swirl to ensure contact of the aluminum and the acid, and allow the reaction to proceed until all of the aluminum has dissolved. Dilute with water to volume, and mix.

Standard preparations—To separate 100-mL volumetric flasks, each containing 10 mL of *Potassium chloride solution*, transfer 9.0, 10.0, and 11.0 mL, respectively, of *Aluminum stock solution*, dilute with water to volume, and mix. These *Standard preparations* contain 90.0, 100.0, and 110.0 µg of aluminum per mL, respectively.

Assay preparation—Transfer an accurately measured quantity of Oral Suspension, previously shaken in its original container, equivalent to about 75 mg of aluminum hydroxide, to a suitable beaker. Add 25 mL of 6 N hydrochloric acid, and heat on a steam bath for 30 minutes, with occasional swirling. Cool, and transfer with the aid of water to a 250-mL volumetric flask containing 25 mL of *Potassium chloride solution*. Dilute with water to volume, mix, and filter.

Procedure—Concomitantly determine the absorbances of the *Standard preparations* and the *Assay preparation* at the aluminum emission line at 309.3 nm, with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with an aluminum hollow-cathode lamp and a nitrous oxide–acetylene flame, using water as the blank. Calculate the quantity, in mg, of $Al(OH)_3$ in the portion of Oral Suspension taken by the formula:

$$(78.00/26.98)(0.25)(A_U/R_S)$$

in which 78.00 is the molecular weight of aluminum hydroxide; 26.98 is the atomic weight of aluminum; A_U is the absorbance of the *Assay preparation;* and R_S is the average of the ratios of the absorbances of the *Standard preparations* to their respective concentrations, in µg of aluminum per mL.

Assay for magnesium carbonate—

Lanthanum chloride solution—Prepare a solution of lanthanum chloride in water containing 5 mg per mL.

Magnesium stock solution—Transfer 1.000 g of magnesium metal to a 1000-mL volumetric flask containing 50 mL of water, and slowly add 10 mL of hydrochloric acid. Dilute with water to volume, and mix. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, dilute with water to volume, and mix.

Standard preparations—To separate 100-mL volumetric flasks, each containing 10 mL of *Lanthanum chloride solution*, transfer 1.70 mL and 1.80 mL, respectively, of *Magnesium stock solution*, dilute with water to volume, and mix. These *Standard preparations* contain 1.7 µg of magnesium per mL and 1.8 µg of magnesium per mL, respectively.

Assay preparation—Quantitatively dilute an accurately measured volume of the *Assay preparation* prepared as directed in the *Assay for aluminum hydroxide* with water to obtain a solution having a concentration of about 6 µg of magnesium carbonate per mL.

Procedure—Concomitantly determine the absorbances of the *Standard preparations* 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 an air–acetylene flame, using water as the blank. Calculate the quantity, in mg, of magnesium carbonate ($MgCO_3$) in the portion of Oral Suspension taken by the formula:

$$(84.31/24.31)(L/D)(A_U/R_S)$$

in which 84.31 is the molecular weight of magnesium carbonate; 24.31 is the atomic weight of magnesium; L is the labeled quantity, in mg, of magnesium carbonate in the portion of Oral Suspension taken; D is the concentration, in µg of magnesium carbonate per mL, of the *Assay preparation*, based on the labeled amount of magnesium carbonate in the portion of Oral Suspension taken and the extent of dilution; A_U is the absorbance of the *Assay preparation;* and R_S is the average of the ratios of the absorbances of the *Standard preparations* to their respective concentrations, in µg of magnesium per mL.

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

Topic/Question	Contact	Expert Committee
ALUMINA AND MAGNESIUM CARBONATE ORAL SUSPENSION	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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