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Alumina and Magnesia Oral Suspension

DEFINITION

Alumina and Magnesia Oral Suspension is a mixture containing aluminum hydroxide $[\text{Al}(\text{OH})_3]$ and Magnesium Hydroxide $[\text{Mg}(\text{OH})_2]$. It contains the equivalent of NLT 90.0% and NMT 110.0% of the labeled amounts of aluminum hydroxide $[\text{Al}(\text{OH})_3]$ and magnesium hydroxide $[\text{Mg}(\text{OH})_2]$. It may contain a flavoring agent, and may contain suitable antimicrobial agents.

IDENTIFICATION

A. [IDENTIFICATION TESTS—GENERAL, Magnesium\(191\)](#)

Sample solution: 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 min, and filter.

Acceptance criteria: The filtrate meets the requirements.

B. [IDENTIFICATION TESTS—GENERAL, Aluminum\(191\)](#)

Sample solution: Wash the precipitate obtained in *Identification* test A with a hot solution containing 20 mg/mL of ammonium chloride, and dissolve the precipitate in hydrochloric acid.

Acceptance criteria: The solution meets the requirements.

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 volume of Oral Suspension, previously well shaken in its original container, equivalent to 1200 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 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 near the boiling point for 5 min. Cool, add 50 mL of alcohol and 2 mL of dithizone TS, and mix. 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 $[\text{Al}(\text{OH})_3]$.

Acceptance criteria: 90.0%–110.0%

• 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 mix. 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 10 mL of 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 $[\text{Mg}(\text{OH})_2]$.

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• [CHLORIDE AND SULFATE, Chloride\(221\)](#)

Sample solution: Dissolve 5.0 g in the minimum volume of nitric acid required to achieve complete solution, add 1 mL of acid in excess, then add water to make 100 mL, and filter.

Acceptance criteria: NMT 0.14%; a 10-mL portion of the *Sample solution* shows no more chloride than corresponds to 1.0 mL of 0.020 N hydrochloric acid.

• [CHLORIDE AND SULFATE, Sulfate\(221\)](#)

Sample solution: Dissolve 5.0 g in 5 mL of 3 N hydrochloric acid, with gentle heating. Cool, add water to make 250 mL, and filter.

Acceptance criteria: NMT 0.1%; a 20-mL portion of the *Sample solution* shows no more sulfate than corresponds to 0.40 mL of 0.020 N sulfuric acid.

Change to read:

- [ARSENIC \(211\), Procedures, Procedure 1](#) ▲ (CN 1-Jun-2023)

Standard preparation: Prepare as directed in ▲ [Arsenic \(211\), Procedures, Procedure 1](#) ▲ (CN 1-Jun-2023) , except prepare it to contain 5 µg of arsenic instead of 3 µg.

Test preparation: Dissolve a portion of Oral Suspension, equivalent to 0.5 g of aluminum hydroxide $[\text{Al}(\text{OH})_3]$, in 20 mL of 7 N sulfuric acid.

Acceptance criteria: NMT 10 ppm, based on the aluminum hydroxide $[\text{Al}(\text{OH})_3]$ content

SPECIFIC TESTS

• [MICROBIAL ENUMERATION TESTS \(61\)](#) and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): Its total aerobic microbial count does not exceed 10^2 cfu/mL, and it meets the requirements for the absence of *Escherichia coli*.

• [pH \(791\)](#): 7.3–8.5

• [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 $[\text{Al}(\text{OH})_3]$, 0.0385 mEq

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

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

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

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers, and avoid freezing.

• **LABELING:** Oral Suspension may be labeled to state the aluminum hydroxide content in terms of the equivalent amount of dried aluminum hydroxide gel, on the basis that each mg of dried gel is equivalent to 0.765 mg of aluminum hydroxide $[\text{Al}(\text{OH})_3]$.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ALUMINA AND MAGNESIA 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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