Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Jun-2023
Document Type: USP Monographs
DocId: GUID-CB6E5B87-76ED-4889-85CE-28209394AABA_4_en-US
DOI: https://doi.org/10.31003/USPNF_M1710_04_01
DOI Ref: kzv4s

© 2025 USPC
Do not distribute

Alumina, Magnesia, and Calcium Carbonate Oral Suspension

DEFINITION

Alumina, Magnesia, and Calcium Carbonate Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amounts of aluminum hydroxide [$Al(OH)_3$], magnesium hydroxide [$Mg(OH)_2$], and calcium carbonate ($CaCO_3$).

IDENTIFICATION

- **A. Identification Tests—General, *Calcium*⟨191⟩**

  Sample solution: To 5 g of Oral Suspension add 25 mL of 2 N sulfuric acid, stir, and allow to stand for 5 min. Add 25 mL of alcohol, stir, and place in an ice bath for 30 min. Filter while cold, retaining the filtrate for *Identification* test *B*. Wash the precipitate with 50 mL of 0.75 N sulfuric acid, and discard the washings. Dissolve the precipitate in 3 N hydrochloric acid, filter, and use the filtrate.

  Acceptance criteria: Meets the requirements

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

  Sample solution: To the filtrate obtained in *Identification* test *A*, add 5 drops of methyl red TS, and heat to boiling. Add 6 N ammonium hydroxide until the color of the solution changes to deep yellow, continue boiling for 2 min, and filter through hardened filter paper. (Retain the filtrate for *Identification* test *C*.) Wash the precipitate with 350 mL of a hot solution containing 20 mg/mL of ammonium chloride, discarding the washings. Dissolve the precipitate so obtained in 3 N hydrochloric acid.

  Acceptance criteria: Meets the requirements

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

  Sample solution: The filtrate obtained in *Identification* test *B*.

  Acceptance criteria: 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 an amount of Oral Suspension, previously shaken in its original container, equivalent to 600 mg of aluminum hydroxide, to a tared beaker, and weigh. Add 20 mL of water, stir, and slowly add 40 mL of 3 N hydrochloric acid. Heat gently, if necessary, to aid solution, cool, and transfer to a 200-mL volumetric flask. Wash the beaker with water, adding the washings to 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, and 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 [$Al(OH)_3$].

  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 trolamine, and mix. Add 50 mL of ammonia–ammonium chloride buffer TS and 2 drops of an eriochrome black indicator solution (prepared by dissolving 200 mg of eriochrome black T in a mixture of 15 mL of trolamine and 5 mL of dehydrated alcohol, and mixing). Cool the solution to between 3° and 4° by immersing the beaker in an ice bath, and titrate with 0.05 M edetate disodium VS until the color changes to pure blue. Perform a blank determination, substituting 10 mL of water for the *Sample solution*, and make any necessary correction. From the volume of 0.05 M edetate disodium consumed, subtract the volume of 0.05 M edetate disodium consumed in the *Assay* for *Calcium Carbonate*. Each mL of 0.05 M edetate disodium is equivalent to 2.916 mg of magnesium hydroxide [$Mg(OH)_2$].

  Acceptance criteria: 90.0%–110.0%

- **Calcium Carbonate**

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

  Analysis: Pipet a volume of the *Sample solution*, equivalent to 50 mg of calcium carbonate, into a 400-mL beaker, and add 200 mL of water, 5 mL of sodium hydroxide solution (1 in 2), and 250 mg of hydroxy naphthol blue. Stir with a magnetic stirrer, and titrate immediately with 0.05 M edetate disodium VS until the solution is distinctly blue. Each mL of 0.05 M edetate disodium is equivalent to 5.004 mg of calcium carbonate ($CaCO_3$).

OFFICIAL
AVA Documents Document Sharing Hub
Full document details: Alumina, Magnesia, and Calcium Carbonate Oral Suspension

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Chloride and Sulfate,** *Chloride*⟨221⟩

Sample solution: Dissolve 5.0 g in 3 mL of nitric acid, add water to make 100 mL, and filter.

Acceptance criteria: NMT 0.14%; a 10.0-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 7 mL of 3 N hydrochloric acid, and gently heat. Cool, add water to make 250 mL, and filter.

Acceptance criteria: NMT 0.1%; a 20.0-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 [$Al(OH)_3$], in 20 mL of 7 N sulfuric acid.

Acceptance criteria: NMT 10 ppm, based on the aluminum hydroxide [$Al(OH)_3$] 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 of the test for the absence of *Escherichia coli*.

• **pH** ⟨791⟩**:** 7.5–8.5

• **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:

$$\text{Result} = 0.55 \times (F_A \times A) + 0.8 \times (F_M \times M) + 0.9 \times (F_C \times C)$$

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)

F_C = theoretical acid-neutralizing capacity of calcium carbonate ($CaCO_3$), 0.02 mEq

C = amount of calcium carbonate ($CaCO_3$) 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 [$Al(OH)_3$].

OFFICIAL

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

Topic/Question	Contact	Expert Committee
ALUMINA, MAGNESIA, AND CALCIUM CARBONATE ORAL SUSPENSION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 27(6)

Current DocID: GUID-CB6E5B87-76ED-4889-85CE-28209394AABA_4_en-US

DOI: https://doi.org/10.31003/USPNF_M1710_04_01

DOI ref: kzv4s

Documents
Document Sharing Hub

Full document details: Alumina, Magnesia, and Calcium Carbonate Oral Suspension