

- **ARSENIC, Method I (211)**  
**Standard preparation:** Prepare as directed in *Arsenic (211)*, 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)<sub>3</sub>], in 20 mL of 7 N sulfuric acid.  
**Acceptance criteria:** NMT 10 ppm, based on the aluminum hydroxide [Al(OH)<sub>3</sub>] content

**Delete the following:**

- **HEAVY METALS (231)**  
**Test preparation:** Dissolve a portion of Oral Suspension, equivalent to 0.24 g of aluminum hydroxide [Al(OH)<sub>3</sub>], in 10 mL of 3 N hydrochloric acid with the aid of heat, filter, if necessary, and dilute with water to 25 mL.  
**Acceptance criteria:** NMT 83 ppm, based on the aluminum hydroxide [Al(OH)<sub>3</sub>] content. (Official 1-Jan-2013)

**SPECIFIC TESTS**

- **MICROBIAL ENUMERATION TESTS (61) and TESTS FOR SPECIFIED MICROORGANISMS (62):** Its total aerobic microbial count does not exceed 10<sup>2</sup> 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 [Al(OH)<sub>3</sub>], 0.0385 mEq
- $A$  = amount of aluminum hydroxide [Al(OH)<sub>3</sub>] in the specimen tested, based on the labeled quantity (mg)
- $F_M$  = theoretical acid-neutralizing capacity of magnesium hydroxide [Mg(OH)<sub>2</sub>], 0.0343 mEq
- $M$  = amount of magnesium hydroxide [Mg(OH)<sub>2</sub>] 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)<sub>3</sub>].

## Alumina and Magnesia Tablets

**DEFINITION**

Alumina and Magnesia Tablets contain NLT 90.0% and NMT 110.0% of the labeled amounts of aluminum hydroxide [Al(OH)<sub>3</sub>] and magnesium hydroxide [Mg(OH)<sub>2</sub>].

**IDENTIFICATION**

- **A. IDENTIFICATION TESTS—GENERAL, Magnesium (191)**  
**Sample solution:** To a 0.7-g portion of finely powdered Tablets add 10 mL of 3 N hydrochloric acid and 5 drops of methyl red TS, heat to boiling, and add 6 N ammonium hydroxide until the color of the solution changes to deep yellow. 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 hot ammonium chloride solution (1 in 50), 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:** Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 1200 mg of aluminum hydroxide, to a 150-mL beaker. Add 20 mL of water, stir, and slowly add 30 mL of 3 N 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 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* is equivalent to 3.900 mg of aluminum hydroxide [Al(OH)<sub>3</sub>].  
**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 TS 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 [Mg(OH)<sub>2</sub>].  
**Acceptance criteria:** 90.0%–110.0%

**PERFORMANCE TESTS**

- **DISINTEGRATION (701)**  
**Time:** 10 min, simulated gastric fluid TS being substituted for water in the test  
**Acceptance criteria:** Meet the requirements
- **UNIFORMITY OF DOSAGE UNITS (905):** Meet the requirements for *Weight Variation* with respect to alumina and to magnesia

**SPECIFIC TESTS**

- **ACID-NEUTRALIZING CAPACITY (301):** 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)<sub>3</sub>], 0.0385 mEq