Volumetric Solutions, Edetate Disodium, Twentieth-Molar (0.05 M).
Sample: 800 mg
Analysis: Transfer the *Sample* to a 400-mL beaker, moisten with 1 mL of glacial acetic acid, and add 50 mL of water, 50.0 mL of *Edetate disodium titrant*, and 20 mL of acetic acid–ammonium acetate buffer TS. Warm on a steam bath until solution is complete, and boil gently for 5 min. Cool, add 50 mL of alcohol and 2 mL of dithizone TS, and titrate 0.05 M zinc sulfate VS to a bright rose-pink color. Perform a blank determination, and make any necessary correction. Each mL of 0.05 M *Edetate disodium titrant* is equivalent to 12.91 mg of potassium alum [$AlK(SO_4)_2$].
Acceptance criteria: 99.0%–100.5% on the dried basis

IMPURITIES

Delete the following:

•• **Heavy Metals,** *Method I* ⟨231⟩
Sample solution: Dissolve 1 g in water to make 20 mL, and add 5 mL of 0.1 N hydrochloric acid. Evaporate the solution in a porcelain evaporating dish to dryness. Treat the residue with 20 mL of water, and add 50 mg of hydroxylamine hydrochloride. Heat the solution on a steam bath for 10 min, cool, and dilute with water to 25 mL.
Analysis: Proceed as directed, except add 50 mg of hydroxylamine hydrochloride to the *Standard Preparation*.
Acceptance criteria: 20 ppm • (Official 1-Jan-2018)

• **Iron**
Sample solution: Potassium alum in water (1 in 150)
Analysis: Add 5 drops of potassium ferrocyanide TS to 20 mL of the *Sample solution*.
Acceptance criteria: No blue color is produced immediately.

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩
Sample: 2.0 g
Analysis: Transfer the *Sample* in a tared porcelain crucible to a muffle furnace at 200°. Increase the temperature to 400°, and dry at 400° to constant weight. Cool in a desiccator, and weigh.
Acceptance criteria: 43.0%–46.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store at room temperature.

Alumina and Magnesia Oral Suspension

DEFINITION

Alumina and Magnesia Oral Suspension is a mixture containing *aluminum hydroxide* [$Al(OH)_3$] and Magnesium Hydroxide [$Mg(OH)_2$]. It contains the equivalent of NLT 90.0% and NMT 110.0% of the labeled amounts of aluminum hydroxide [$Al(OH)_3$] and magnesium hydroxide [$Mg(OH)_2$]. 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 [$Al(OH)_3$].
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 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 [$Mg(OH)_2$].
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.