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Aluminum Oxide

Al_2O_3 101.96 CAS RN®: 1344-28-1.

DEFINITION

Aluminum Oxide contains NLT 47.0% and NMT 60.0% of Al_2O_3.

IDENTIFICATION

• **Identification Tests—General,** *Aluminum* ⟨191⟩

Sample: 2.5 g

Analysis: Dissolve the *Sample* in 15 mL of hydrochloric acid on a heated water bath. Dilute with water to 100 mL.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Sample: 800 mg

Analysis: Add the *Sample* to 10 mL of 2 M hydrochloric acid on a heated water bath. Cool, and dilute with water to 50.0 mL. To 10.0 mL of the solution, add dilute ammonia solution (460 mL of strong ammonia solution/L) until a precipitate begins to appear. Add the smallest quantity of 0.6 M hydrochloric acid needed to dissolve the precipitate, and dilute with water to 20 mL. Transfer 20 mL of the *Sample* to a 500-mL conical flask, add 25.0 mL of 0.1 M edetate disodium and 10 mL of a mixture of equal volumes of a 155 g/L solution of ammonium acetate and 2 N acetic acid. Boil for 2 min, then cool. Add 50 mL of ethanol and 3 mL of a freshly prepared 250 mg/L solution of dithizone in alcohol. Titrate (see *Titrimetry* ⟨541⟩) the excess of edetate sodium with 0.1 M zinc sulfate until the color changes from greenish-blue to reddish-violet. Each mL of 0.1 M edetate sodium is equivalent to 5.098 mg of Al_2O_3.

Acceptance criteria: 47.0%–60.0% of Al_2O_3

IMPURITIES

Change to read:

Inorganic Impurities

• ▲**Arsenic** ⟨211⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023)

Sample solution: Dissolve 2.5 g of Aluminum Oxide in 15 mL of hydrochloric acid on a heated water bath. Dilute with water to 100 mL. Use 30 mL of this solution for the test.

Acceptance criteria: NMT 4 ppm

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

Chloride solution: 0.824 mg/mL of sodium chloride

Standard solution: On the day of use, dilute 1.0 mL of *Chloride solution* with water to 100 mL. Mix 10 mL of this solution (5 ppm Cl) with 5 mL of water.

Sample solution: Dissolve 0.1 g of Aluminum Oxide with heating in 10 mL of dilute nitric acid and dilute with water to 100 mL. Dilute 5 mL of the solution with water to 15 mL.

Analysis: Proceed as directed.

Acceptance criteria: The *Sample solution* shows no more chloride than the *Standard solution* (NMT 10,000 ppm).

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

Sulfate stock solution: 1.8 mg/mL of potassium sulfate

Sulfate solution: On the day of use, dilute 1.0 mL of *Sulfate stock solution* with water to 100 mL (10 ppm SO_4).

Standard solution: Add 3 mL of a 250 mg/mL solution of barium chloride to 4.5 mL of *Sulfate solution*. Shake and allow to stand for 1 min.

Sample solution: Dissolve 2.5 g of Aluminum Oxide in 15 mL of hydrochloric acid on a heated water bath. Dilute with water to 100 mL. Dilute 4 mL of this solution with water to 100 mL.

Analysis: To two separate glass cylinders, add 2.5 mL of *Standard solution*. Then to cylinder 1, add 15 mL of the *Sample solution* and 0.5 mL of acetic acid. To cylinder 2 add 15 mL of the *Sulfate solution* and 0.5 mL of acetic acid.

Acceptance criteria: After 5 min, any opalescence in cylinder 1 containing the *Sample solution* is not more intense than that of cylinder 2 containing the *Sulfate solution* (NMT 10,000 ppm).

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic bacterial count is NMT 1000 cfu/g and the total combined molds and yeasts count is NMT 100 cfu/g. It also meets the requirements of the tests for absence of *Escherichia coli* and bile-tolerant Gram-negative bacteria.

• **Appearance of Solution**

Dilute hydrochloric acid: 10 mg/mL

Control solution: [Note—Prepare immediately before use.] Mix 9.6 mL of ferric chloride CS, 0.2 mL of cobaltous chloride CS, and 0.2 mL of cupric sulfate CS with *Dilute hydrochloric acid* to make 10 mL, and dilute 1.5 mL of this solution with the *Dilute hydrochloric acid* to 100 mL.

Sample solution: 2.5 g of Aluminum Oxide in 15 mL of hydrochloric acid on a heated water bath. Dilute with water to 100 mL.

Analysis: Make the comparison by viewing 2.0 mL of *Sample solution* and 2.0 mL of *Control solution* downward in matched color-comparison tubes against a white surface (see *Color and Achromicity ⟨631⟩*.

Acceptance criteria: The *Sample solution* is not more intensely colored than the *Control solution*.

Change to read:

• **Clarity of Solution**

Hydrazine sulfate solution: 10 mg/mL of hydrazine sulfate. Allow to stand for 4–6 h before use. [**Caution—**Hydrazine sulfate is highly toxic. Avoid skin contact.]

Methenamine solution: 2.5 g of methenamine to a 100-mL glass-stoppered flask, add 25.0 mL of water, insert the glass stopper, and mix to dissolve.

Primary opalescent mixture: To the flask containing *Methenamine solution*, add 25.0 mL of *Hydrazine sulfate solution*, mix, and allow to stand for 24 h. [Note—This suspension is stable for 2 months. Mix before use, and do not use if it adheres to the container.]

Opalescent standard: Dilute 15.0 mL of the *Primary opalescent mixture* with water to 1000.0 mL. [Note—Use this suspension within 24 h after preparation.]

Reference suspension: Transfer 30.0 mL of *Opalescence standard* to a 100-mL volumetric flask, and dilute with water to volume.

Sample solution: Use the *Sample solution* from the test for *Appearance of Solution*.

Analysis: Transfer a sufficient portion of the *Sample solution* to a test tube of colorless, transparent, neutral glass with a flat base and an internal diameter of 15–25 mm to obtain a depth of 40 mm. Similarly transfer a portion of the *Reference suspension* to a separate matching test tube. Compare the *Sample solution* and the *Reference suspension* in diffused daylight, viewing vertically against a black background (see *Visual Comparison ⟨630⟩*). [Note—The *Sample solution* is to be compared to the *Reference suspension* 5 min after preparation of the *Reference suspension*.]

Acceptance criteria: The *Sample solution* is not more opalescent than the *Reference suspension*.

• **Alkaline Impurities**

Sample: 1.0 g

Analysis: Shake the *Sample* with 20 mL of carbon dioxide-free water for 1 min and filter. To 10 mL of the filtrate add 0.1 mL of phenolphthalein TS.

Acceptance criteria: Any pink color disappears with the addition of 0.3 mL of 0.1 M hydrochloric acid.

• **Neutralizing Capacity:** Carry out the test at 37°. Disperse 0.5 g of aluminum oxide in 100 mL of water, heat, add 100.0 mL of 0.1 M hydrochloric acid, previously heated, and stir continuously: the pH of the solution after 10, 15, and 20 min is NLT 1.8, 2.3, and 3.0 respectively and is at no time greater than 4.5. Add 10.0 mL of 0.5 M hydrochloric acid, previously heated, stir continuously for 1 h, and titrate with 0.1 M sodium hydroxide to pH 3.5: NMT 35.0 mL of 0.1 M sodium hydroxide is required.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in a tight container at a temperature not exceeding 30°.

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

Topic/Question	Contact	Expert Committee
ALUMINUM OXIDE	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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