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Magaldrate

Aluminum magnesium hydroxide sulfate ($Al_5Mg_{10}(OH)_{31}(SO_4)_2 \cdot xH_2O$).

Aluminum magnesium hydroxide sulfate, hydrate CAS RN®: 74978-16-8; UNII: 6V88E24N5T.

Anhydrous 1097.38

» Magaldrate is a chemical combination of aluminum and magnesium hydroxides and sulfate, corresponding approximately to the formula:

$$Al_5Mg_{10}(OH)_{31}(SO_4)_2 \cdot xH_2O.$$

It contains the equivalent of not less than 90.0 percent and not more than 105.0 percent of $Al_5Mg_{10}(OH)_{31}(SO_4)_2$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Magaldrate RS

Identification—

A: Dissolve about 600 mg in 20 mL of 3 N hydrochloric acid, add 3 drops of methyl red TS and about 30 mL of water, and heat to boiling. Add 6 N ammonium hydroxide until the color just changes to yellow, continue boiling for 2 minutes, and filter: the filtrate responds to the tests for *Magnesium* ⟨191⟩.

B: Wash the precipitate obtained in *Identification* test *A* with 50 mL of hot ammonium chloride solution (1 in 50), then dissolve the precipitate in 15 mL of 3 N hydrochloric acid: the solution responds to the tests for *Aluminum* ⟨191⟩.

C: Its X-ray diffraction pattern (see *X-Ray Powder Diffraction* ⟨941⟩) in the d-spacings region below 0.257 nm (2.57 angstrom units) conforms to that of USP Magaldrate RS.

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩—It meets the requirements of the test for absence of *Escherichia coli*.

Loss on drying ⟨731⟩—Dry it at 200° for 4 hours: it loses between 10.0% and 20.0% of its weight.

Soluble chloride—Boil 1 g of it, accurately weighed, with 50.0 mL of water for 5 minutes, cool, add water to restore the original volume, mix, and filter. To 25.0 mL of the filtrate add 0.1 mL of potassium chromate TS, and titrate with 0.10 N silver nitrate until a persistent pink color is obtained: not more than 5.0 mL of 0.10 N silver nitrate is required (3.5%).

Soluble sulfate ⟨221⟩—A 2.5-mL portion of the filtrate obtained in the test for *Soluble chloride* shows no more sulfate than corresponds to 1.0 mL of 0.020 N sulfuric acid (1.9%).

Sodium—Transfer 2 g of it, accurately weighed, to a 100-mL volumetric flask, place in an ice bath, add 5 mL of nitric acid, and swirl to dissolve. Allow to warm to room temperature, dilute with water to volume, and mix. Filter, if necessary, to obtain a clear solution. Dilute 10.0 mL of the filtrate with water to 100.0 mL: the emission intensity of this solution, determined with a suitable flame photometer at 589 nm and corrected for background transmission at 580 nm, is not greater than that produced by a standard containing 2.2 µg of Na per mL, similarly measured (0.11%).

Arsenic ⟨211⟩, *Procedures, Procedure 1*: 8 ppm.

Magnesium hydroxide content—Dissolve about 100 mg, accurately weighed, in 3 mL of dilute hydrochloric acid (1 in 10), and dilute with water to about 200 mL. Add, with stirring, 1 g of ammonium chloride, 20 mL of triethanolamine, 10 mL of ammonia–ammonium chloride buffer TS, and 0.1 mL of eriochrome black TS, and titrate with 0.05 M edetate disodium VS to a blue color. Perform a blank determination, and make any necessary correction. Each mL of 0.05 M edetate disodium is equivalent to 2.916 mg of $Mg(OH)_2$: between 49.2% and 66.6% of $Mg(OH)_2$ is found, calculated on the dried basis.

Aluminum hydroxide content—

Edetate disodium titrant—Prepare and standardize as directed in the *Assay* under *Ammonium Alum*.

Procedure—Dissolve about 100 mg of Magaldrate, accurately weighed, in 3 mL of dilute hydrochloric acid (1 in 10), and dilute with water to about 30 mL. Add, with stirring, 25.0 mL of *Edetate disodium titrant*, mix, and allow to stand for 5 minutes. Then add 20 mL of acetic acid-ammonium acetate buffer TS, 60 mL of alcohol, and 2 mL of dithizone TS, and titrate with 0.05 M zinc sulfate 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 3.900 mg of $Al(OH)_3$: between 32.1% and 45.9% of $Al(OH)_3$ is found, calculated on the dried basis.

Sulfate content—

Chromatographic column—Transfer 15 mL of strongly acidic 50- to 100-mesh styrene-divinylbenzene cation-exchange resin to a 1-cm inside diameter glass column. Wash the resin with 30 mL of water.

Indicator solution—Prepare a solution in water containing 2 mg of sodium alizarinsulfonate per mL.

Magnesium acetate solution—Dissolve 26.8 g of magnesium acetate in 500 mL of water.

0.05 M Barium chloride—Dissolve 12.2 g of barium chloride in about 900 mL of water, adjust with 1 N hydrochloric acid to a pH of 3.0, dilute with water to 1000 mL, and mix. Standardize this solution as follows: Transfer 10.0 mL of 0.1 N sulfuric acid VS to a 125-mL conical flask. Adjust by adding *Magnesium acetate solution* to a pH of 3.0. Add 25 mL of methanol and 3 or 4 drops of *Indicator solution*. Add from a buret an accurately measured volume of 8 to 9 mL of 0.05 M barium chloride. Add an additional 4 drops of *Indicator solution*, and titrate slowly until the yellow color disappears and a pink tinge is visible. Calculate the molarity of the barium chloride titrant taken by the formula:

$$5(N/V)$$

in which N is the normality of the sulfuric acid; and V is the volume, in mL, of titrant consumed.

Test preparation—Transfer about 875 mg of Magaldrate, accurately weighed, to a 25-mL volumetric flask. Dissolve in 10 mL of water and 5 mL of glacial acetic acid, dilute with water to volume, and mix. Transfer 5.0 mL of this solution to the chromatographic column and wash the column with 15 mL of water, collecting the eluate in a 125-mL conical flask (*Test preparation*).

Procedure—Add to the *Test preparation* 5 mL of *Magnesium acetate solution*, 32 mL of methanol, and 3 or 4 drops of *Indicator solution*. Add from a buret an accurately measured volume of 5.0 to 5.5 mL of 0.05 M barium chloride. Add an additional 3 drops of *Indicator solution*, and titrate slowly until the yellow color disappears and a pink tinge is visible. Each mL of 0.05 M barium chloride is equivalent to 4.803 mg of sulfate (SO_4): between 16.0% and 21.0% of SO_4 is found, calculated on the dried basis.

Change to read:

Assay—Transfer about 3 g of Magaldrate, accurately weighed, to a 250-mL beaker, add 100.0 mL of 1 N hydrochloric acid VS, and stir until the solution becomes clear. Titrate the excess acid with 1 N sodium hydroxide VS to a pH of 3.0, determined potentiometrically. Perform a blank determination (see ▲*Titrimetry (541)*▲ (CN 1-Aug-2024)). Each mL of 1 N hydrochloric acid is equivalent to 35.40 mg of $Al_5Mg_{10}(OH)_{31}(SO_4)_2$.

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

Topic/Question	Contact	Expert Committee
MAGALDRATE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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