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Alumina and Magnesium Trisilicate Tablets

DEFINITION

Alumina and Magnesium Trisilicate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amounts of aluminum hydroxide $[\text{Al}(\text{OH})_3]$ and magnesium trisilicate ($\text{Mg}_2\text{Si}_3\text{O}_8$).

IDENTIFICATION

Delete the following:

▲ A. [IDENTIFICATION TESTS—GENERAL \(191\), Chemical Identification Tests, Magnesium](#) ▲ (USP 1-MAY-2024)

Add the following:

▲ A. Characteristic emission lines for magnesium at 279 and 285 nm from the *Sample solution* correspond to those of *Standard solution 1*, *Standard solution 2*, or *Standard solution 3*, as obtained in the Assay. ▲ (USP 1-May-2024)

Delete the following:

▲ B. [IDENTIFICATION TESTS—GENERAL \(191\), Chemical Identification Tests, Aluminum](#) ▲ (USP 1-MAY-2024)

Add the following:

▲ B. Characteristic emission lines for aluminum at 308 and 394 nm from the *Sample solution* correspond to those of *Standard solution 1*, *Standard solution 2*, or *Standard solution 3*, as obtained in the Assay. ▲ (USP 1-May-2024)

Change to read:

• C. SILICON DIOXIDE

Sample: One Tablet

Analysis: Powder the *Sample*. Mix the powder with 10 mL of 3 N [hydrochloric acid](#). To this mixture 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. Wash the solids on the filter with 20 mg/mL of hot [ammonium chloride](#) solution, add 10 mL of 3 N [hydrochloric acid](#), and filter. Transfer the filter paper and its contents to a small platinum dish and ignite to constant weight (W_i). Cool in a desiccator after each ignition. Moisten the residue with [water](#), and add 6 mL of [hydrofluoric acid](#). Evaporate to dryness, ignite for 5 min, cool in a desiccator, and weigh (W_f).

[NOTE—The loss in weight represents the weight of silicon dioxide (SiO_2).]

▲ Calculate the percentage of silicon dioxide (SiO_2) that is lost between the initial ignition and the final ignition:

$$\text{Result} = [(W_i - W_f)/W_i] \times 100$$

W_i = weight of the residue from the initial ignition

W_f = weight of the residue from the final ignition ▲ (USP 1-May-2024)

Acceptance criteria: NLT 10%

ASSAY

Delete the following:

▲ **PROCEDURE 1: ALUMINUM HYDROXIDE** ▲ (USP 1-MAY-2024)

Delete the following:

▲ **PROCEDURE 2: MAGNESIUM TRISILICATE** ▲ (USP 1-MAY-2024)

Add the following:

▲ PROCEDURE

Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.

Diluent: 2% (w/v) [nitric acid](#)

Standard stock solution: 500 mg/L of aluminum and 250 mg/L of magnesium in *Diluent* prepared as follows. Transfer appropriate amounts of [USP Aluminum Sulfate RS](#) and [USP Magnesium Carbonate RS](#) to a suitable volumetric flask. Dissolve and dilute with *Diluent* to volume.

Internal standard solution: 100 mg/L of yttrium¹ in *Diluent*

Blank solution: 2 mg/L of yttrium from the *Internal standard solution* in *Diluent*

Standard solution 1: 10 mg/L of aluminum, 5 mg/L of magnesium, and 2 mg/L of yttrium from the *Standard stock solution* and the *Internal standard solution* in *Diluent*

Standard solution 2: 50 mg/L of aluminum, 25 mg/L of magnesium, and 2 mg/L of yttrium from the *Standard stock solution* and the *Internal standard solution* in *Diluent*

Standard solution 3: 75 mg/L of aluminum, 37.5 mg/L of magnesium, and 2 mg/L of yttrium from the *Standard stock solution* and the *Internal standard solution* in *Diluent*

Sample stock solution: Nominally 360 mg/L of aluminum hydroxide from Tablets prepared as follows. Finely powder Tablets (NLT 30).

Transfer a portion of the powder, equivalent to 18 mg of aluminum hydroxide, to a microwave digestion vessel. Add 5 mL each of [water](#) and [nitric acid](#), in the order named. Perform the closed-vessel microwave-assisted digestion according to parameters specified in [Table 1](#). Cool down to room temperature, transfer to a 50-mL volumetric flask, wash the vessel with [water](#), adding the washings to the flask, and dilute with *Diluent* to volume. [NOTE—A cool down time of 15 min may be suitable after digestion.]

Table 1

Stage	Ramp Time (min)	Temperature (°)	Hold Time (min)
1	20	170	15

Sample solution: Nominally 144 mg/L of aluminum hydroxide and 2 mg/L of yttrium prepared from the *Internal standard solution* and the *Sample stock solution*

[NOTE—Concentrations of aluminum and magnesium in the *Sample solution* may be modified to fit the linear or working range.]

Instrumental conditions

(See [Plasma Spectrochemistry \(730\)](#).)

Mode: ICP–OES

Analytical wavelengths: Characteristic emission lines for aluminum at 308 nm, magnesium at 279 nm, and yttrium at 371 nm. For *Identification A*, detect additional magnesium emission line at 285 nm. For *Identification B*, detect additional aluminum emission line at 394 nm.

System suitability

Samples: *Blank solution*, *Standard solution 1*, *Standard solution 2*, and *Standard solution 3*

Suitability requirements

Correlation coefficient: NLT 0.999 for aluminum and magnesium, from the linear regression in the *Analysis*

Drift: NMT 5.0% for aluminum and magnesium, compare concentrations determined from *Standard solution 2* before and after the analysis of the *Sample solution*

Relative standard deviation: NMT 2.0% for aluminum and magnesium from five replicate analyses of *Standard solution 2*

Analysis

Samples: *Blank solution*, *Standard solution 1*, *Standard solution 2*, *Standard solution 3*, and *Sample solution*

Use internal standardization technique to construct linear calibration curves by plotting the intensity of the emission (corrected for any changes in yttrium emission intensity) from *Blank solution*, *Standard solution 1*, *Standard solution 2*, and *Standard solution 3* versus their corresponding concentrations, in mg/L, for aluminum and magnesium, respectively. Determine the concentration (C_s), in mg/L, for aluminum and magnesium in the *Sample solution* using the corresponding linear calibration curve.

Calculate the percentage of the labeled amount of aluminum hydroxide $[\text{Al}(\text{OH})_3]$ in the portion of Tablets taken:

$$\text{Result} = (C_s/C_U) \times (M_r/A_r) \times 100$$

C_s = concentration of aluminum in the *Sample solution* determined (mg/L)

C_U = nominal concentration of aluminum hydroxide in the *Sample solution* (mg/L)

M_r = molecular weight of aluminum hydroxide, 78.00

A_r = atomic weight of aluminum, 26.98

Calculate the percentage of the labeled amount of magnesium trisilicate $(\text{Mg}_2\text{Si}_3\text{O}_8)$ in the portion of Tablets taken:

$$\text{Result} = (C_s/C_U) \times (M_r/A_r) \times (1/F) \times 100$$

C_s = concentration of magnesium in the *Sample solution* determined (mg/L)

C_U = nominal concentration of magnesium trisilicate in the *Sample solution* (mg/L)

M_r = molecular weight of magnesium trisilicate, 260.86

A_r = atomic weight of magnesium, 24.31