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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 [$Al(OH)_3$] and magnesium trisilicate ($Mg_2Si_3O_8$).

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 yttrium[1] 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 [$Al(OH)_3$] 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 ($Mg_2Si_3O_8$) 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

F = number of magnesium in one mole of magnesium trisilicate, 2

Acceptance criteria: 90.0%–110.0%▲ (USP 1-May-2024)

PERFORMANCE TESTS

• **Disintegration ⟨701⟩**

Medium: Simulated gastric fluid TS

Time: 10 min

Acceptance criteria: Meet the requirements

[Note—Tablets that must be chewed before swallowing are exempt from this requirement.]

• **Uniformity of Dosage Units ⟨905⟩, *Weight Variation*:** Meet the requirements with respect to aluminum hydroxide [$Al(OH)_3$] and to magnesium trisilicate ($Mg_2Si_3O_8$).

SPECIFIC TESTS

• **Acid-Neutralizing Capacity ⟨301⟩**

Acceptance criteria: NLT 5 mEq of acid is consumed by the minimum single dose recommended in the labeling.

[Note—Tablets labeled for the temporary relief of heartburn (acid indigestion) due to acid reflux are exempt from this requirement.]

• **Foam** [where Tablets are labeled for the temporary relief of heartburn (acid indigestion) due to acid reflux]

Sample solution: Finely powder a number of Tablets, equivalent to the minimum single dose recommended in the labeling, and transfer the powder to a 100-mL beaker having an inside diameter of 45 mm. Add 5 mL of alcohol and sufficient water to make 40 mL.

Analysis: Mix the *Sample solution* at 300 rpm for 60 s, using a magnetic stirrer and a 9.5-mm × 38-mm polytef-coated stirring bar. Stop the stirrer, and carefully add 10 mL of 0.5 N hydrochloric acid down the side of the beaker. Stir for 30 s at 300 rpm. Allow to stand for 10 min, and measure the thickness of the foam layer above the liquid in the beaker.

Acceptance criteria: NLT 10 mm

• **pH ⟨791⟩** (where Tablets are labeled for the temporary relief of heartburn (acid indigestion) due to acid reflux)

Sample: The foam layer obtained in the *Foam* test

[Note—Take care that the electrodes do not touch the liquid beneath the foam.]

Acceptance criteria: NLT 4.5

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in well-closed containers. ▲Store at up to 25° in a dry place.▲ (USP 1-May-2024)

• **Labeling:** Tablets prepared with the use of *Dried Aluminum Hydroxide Gel* 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 milligram of dried gel is equivalent to 0.765 mg of aluminum hydroxide [$Al(OH)_3$]. Tablets intended for the temporary relief of heartburn (acid indigestion) due to acid reflux are so labeled. Tablets that must be chewed before swallowing are so labeled.

Change to read:

• ▲**USP Reference Standards ⟨11⟩**

USP Aluminum Sulfate RS

USP Magnesium Carbonate RS▲ (USP 1-May-2024)

[1] From commercially available National Institute of Standards and Technology (NIST)-traceable standard solution for yttrium.

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

Topic/Question	Contact	Expert Committee
ALUMINA AND MAGNESIUM TRISILICATE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

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