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Magnesium Hydroxide

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click https://www.uspnf.com/rb-magnesium-hydroxide-20211119.

Change to read:

$Mg(OH)_2$ 58.32

Magnesium hydroxide CAS RN®: 1309-42-8; ▲UNII: NBZ3QY004S.▲ (RB 1-Dec-2022)

Change to read:

DEFINITION

Magnesium Hydroxide contains ▲NLT 95.0% and NMT 100.5%▲ (RB 1-Dec-2022) of magnesium hydroxide [$Mg(OH)_2$], calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Magnesium***

Sample solution: 50 mg/mL ▲of Magnesium Hydroxide▲ (RB 1-Dec-2022) in 3 N hydrochloric acid

Acceptance criteria: Meets the requirements

Delete the following:

▲• **B.** The retention time of the magnesium peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (RB 1-Dec-2022)

ASSAY

Change to read:

• **Procedure**

▲Sample: 75 mg of Magnesium Hydroxide, previously dried

Titrimetric system

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a conical flask. Add 2 mL of 3 N hydrochloric acid, and swirl to dissolve. Add 100 mL of water, adjust the reaction of the solution to a pH of 7 (using pH indicator paper; see *Reagents, Indicators, and Solutions—Indicator and Test Papers*) with 1 N sodium hydroxide, add 5 mL of ammonia–ammonium chloride buffer TS and 0.15 mL of eriochrome black TS, and titrate with the *Titrant* to a blue endpoint. Each milliliter of *Titrant* is equivalent to 2.916 mg of magnesium hydroxide [$Mg(OH)_2$].

Acceptance criteria: 95.0%–100.5% on the dried basis▲ (RB 1-Dec-2022)

IMPURITIES

Change to read:

• **Soluble Salts**

Sample solution: Boil 2.0 g ▲of Magnesium Hydroxide▲ (RB 1-Dec-2022) with 100 mL of water for 5 min in a covered beaker, and filter while hot. Allow to cool, and dilute ▲the filtrate▲ (RB 1-Dec-2022) with water to 100 mL.

Analysis 1: To 50 mL of the *Sample solution* add methyl red TS and titrate with 0.10 N sulfuric acid.

Acceptance criteria 1: NMT 2.0 mL of the acid is consumed.

Analysis 2: Evaporate 25 mL of the *Sample solution* to dryness, and dry at 105° for 3 h.

Acceptance criteria 2: NMT 10 mg (2.0%) of residue remains.

Change to read:

• **Carbonate**

Sample: 0.10 g▲of Magnesium Hydroxide▲ (RB 1-Dec-2022)

Analysis: Boil the *Sample* with 5 mL of water, cool, and add 5 mL of 6 N acetic acid.

Acceptance criteria: NMT a slight effervescence is observed.

Change to read:

• **Limit of Calcium**

▲[Note—A commercially available atomic absorption standard solution for calcium may be used where preparation of a calcium standard stock solution is described below. Concentrations of the *Standard solutions* and the *Sample solution* may be modified to fit the linear or working range of the instrument.]

Dilute hydrochloric acid: Dilute 100 mL of hydrochloric acid with water to 1000 mL.

Lanthanum solution: 50 mg/mL of lanthanum prepared as follows. To 58.65 g of lanthanum oxide add 400 mL of water and add, gradually with stirring, 250 mL of hydrochloric acid. Stir until dissolved, and dilute with water to 1000 mL.

Blank solution: Transfer 4 mL of the *Lanthanum solution* and 10 mL of *Dilute hydrochloric acid* to a 200-mL volumetric flask, and dilute with water to volume.

Standard stock solution: 1.0 mg/mL of calcium prepared as follows. Transfer 249.7 mg of calcium carbonate, previously dried at 300° for 3 h and cooled in a desiccator for 2 h, to a 100-mL volumetric flask. Dissolve in a minimum amount of hydrochloric acid, and dilute with water to volume.

Standard solution 1: 1.0 µg/mL of calcium prepared as follows. Transfer 1.0 mL of *Standard stock solution* to a 1000-mL volumetric flask containing 20 mL of the *Lanthanum solution* and 40 mL of *Dilute hydrochloric acid*, and dilute with water to volume.

Standard solution 2: 5.0 µg/mL of calcium prepared as follows. Transfer 5.0 mL of *Standard stock solution* to a 1000-mL volumetric flask containing 20 mL of the *Lanthanum solution* and 40 mL of *Dilute hydrochloric acid*, and dilute with water to volume.

Standard solution 3: 10.0 µg/mL of calcium prepared as follows. Transfer 10.0 mL of *Standard stock solution* to a 1000-mL volumetric flask containing 20 mL of the *Lanthanum solution* and 40 mL of *Dilute hydrochloric acid*, and dilute with water to volume.

Standard solution 4: 15.0 µg/mL of calcium prepared as follows. Transfer 15.0 mL of *Standard stock solution* to a 1000-mL volumetric flask containing 20 mL of the *Lanthanum solution* and 40 mL of *Dilute hydrochloric acid*, and dilute with water to volume.

Sample solution: 1.25 mg/mL of Magnesium Hydroxide prepared as follows. Transfer 250 mg of previously dried Magnesium Hydroxide to a beaker, add 30 mL of *Dilute hydrochloric acid*, and stir until dissolved, heating if necessary. Transfer the solution to a 200-mL volumetric flask containing 4 mL of *Lanthanum solution*, and dilute with water to volume.

Instrumental conditions

(See *Atomic Absorption Spectroscopy* ⟨852⟩.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 422.7 nm

Lamp: Calcium hollow–cathode

Flame: Nitrous oxide–acetylene

Analysis

Samples: *Blank solution*, *Standard solutions*, and *Sample solution*

Using the *Blank solution* as blank, determine the concentration (C_S), in µg/mL, of calcium in the *Sample solution* using the calibration graph.

Calculate the percentage of calcium in the portion of Magnesium Hydroxide taken:

$$\text{Result} = (C_S \times F/C_U) \times 100$$

C_S = concentration of calcium in the *Sample solution* previously determined (µg/mL)

F = unit conversion factor, 0.001 mg/µg

C_U = concentration of Magnesium Hydroxide in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 1.5%▲ (RB 1-Dec-2022)

• **Limit of Lead**

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

Internal standard solution: 20 µg/L of thallium in water (from commercially available, NIST-traceable standard solution for thallium)

[Note—Use the *Internal standard solution* only if an inductively coupled plasma–mass spectrometry (ICP–MS) instrument is used. The *Internal standard solution* is added inline via a mixing block between the sample probe and the spray chamber.]

Blank solution: 6.0% (v/v) nitric acid in water

Diluent: 2.0% (v/v) nitric acid in water

Standard stock solution: 100 µg/L of lead in *Diluent* (from commercially available, NIST-traceable standard solution for lead)

[Note—Prepare the *Standard stock solution* fresh every 2 months.]

Standard solution A: 10 µg/L of lead in *Blank solution* from *Standard stock solution*

Standard solution B: 1.0 µg/L of lead in *Blank solution* from *Standard solution A*

[Note—Prepare *Standard solution A* and *Standard solution B* fresh weekly.]

Sample solution: Accurately weigh about 0.25 g of Magnesium Hydroxide. Cautiously add 3.0 mL of nitric acid, and mix until the sample is dissolved. Accurately transfer this solution to a 50-mL volumetric flask, and dilute with water to volume.

[Note—The concentrations specified in *Standard solution A*, *Standard solution B*, and the *Sample solution* are recommended if an ICP–MS instrument is used. If an inductively coupled plasma–optical emission spectroscopy (ICP–OES) instrument is used, the concentrations may

be modified to adapt to the working range of the instrument.]

Instrumental conditions

(See *Plasma Spectrochemistry ⟨730⟩*.)

Mode: Quadrupole ICP–MS or ICP–OES

ICP–MS analytical isotopes: 206, 207, and 208 amu for lead; 205 amu for thallium internal standard. [NOTE—The instrument should read all isotopes for lead (206, 207, and 208 amu) and the thallium internal standard (205 amu), and should report the total lead content using the sum of all three isotopes.]

ICP–OES analytical wavelength: 220.353 nm. [NOTE—To minimize matrix interference when using ICP-OES, it is recommended that the method of standard additions be used.]

System suitability

[NOTE—Instrument performance must be verified to conform to the manufacturer's specifications for resolution and sensitivity. Before analyzing samples, the instrument must pass a suitable performance check (see *Plasma Spectrochemistry ⟨730⟩, Qualification of Plasma Spectrophotometers, Performance Qualification*).]

Samples: *Blank solution*, *Standard solution A*, and *Standard solution B*

Suitability requirements

Linearity: Construct a linear calibration curve using the responses from the *Blank solution*, *Standard solution A*, and *Standard solution B*. The correlation coefficient is NLT 0.999.

Analysis: Aspirate the *Sample solution*, at least in duplicate, and calculate the amount of lead using the calibration curve obtained from the *System suitability*. Report the average reading as the lead content of the sample. Calculate the content of lead in the portion of Magnesium Hydroxide taken.

Acceptance criteria: NMT 0.00015% (1.5 ppm)

SPECIFIC TESTS

• **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⟩**

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 2.0%

• **LOSS ON IGNITION ⟨733⟩**

Analysis: Ignite at 800°, increasing the heat gradually, to constant weight.

Acceptance criteria: 30.0%–33.0%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.

Delete the following:

▲• **USP REFERENCE STANDARDS ⟨11⟩**

USP Calcium Carbonate RS

USP Magnesium Hydroxide RS▲ (RB 1-Dec-2022)

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

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

Chromatographic Database Information: Chromatographic Database

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