

Talc

DEFINITION

Talc is a powdered, selected, natural, hydrated magnesium silicate. Pure talc has the formula $Mg_3Si_4O_{10}(OH)_2$. It may contain variable amounts of associated minerals among which chlorites (hydrated aluminum and magnesium silicates), magnesite (magnesium carbonate), calcite (calcium carbonate), and dolomite (calcium and magnesium carbonate) are predominant.

IDENTIFICATION

- **A. INFRARED ABSORPTION:** The IR spectrum of a potassium bromide dispersion of it exhibits maxima at $3677 \pm 2 \text{ cm}^{-1}$, at $1018 \pm 2 \text{ cm}^{-1}$, and at $669 \pm 2 \text{ cm}^{-1}$.
- **B. PROCEDURE**
Sample: 100 mg
Analysis: Mix about 200 mg of anhydrous sodium carbonate and 2 g of anhydrous potassium carbonate, and melt in a platinum crucible. To the melt add the *Sample*, and continue heating until fusion is complete. Cool, and transfer the fused mixture to a dish or beaker with the aid of about 50 mL of hot water. Add hydrochloric acid to the liquid until effervescence ceases, then add 10 mL more of the acid, and evaporate the mixture on a steam bath to dryness. Cool, add 20 mL of water, boil, and filter the mixture. Save the insoluble residue for use in *Identification* test C.
To 5 mL of the filtrate add 1 mL of 6 N ammonium hydroxide and 1 mL of ammonium chloride TS. Filter, if necessary, and add 1 mL of dibasic sodium phosphate TS to the filtrate.
Acceptance criteria: A white, crystalline precipitate of magnesium ammonium phosphate is formed.
- **C. PROCEDURE**
Sample: 100 mg of the insoluble residue from *Identification* test B
Analysis: In a lead or platinum crucible and using a copper wire, mix the *Sample* with about 10 mg of sodium fluoride and a few drops of sulfuric acid to give a thin slurry. Cover the crucible with a thin transparent plate of plastic under which a drop of water is suspended, and warm gently.
Acceptance criteria: Within a short time, a white ring is rapidly formed around the drop of water.

ASSAY

• CONTENT OF MAGNESIUM

Lanthanum chloride solution: To 5.9 g of lanthanum oxide slowly add 10 mL of hydrochloric acid, and heat to boiling. Allow to cool, and dilute with water to 100 mL.

Magnesium standard stock solution: 10 $\mu\text{g/mL}$ of magnesium, prepared by diluting an 8.365 mg/mL solution of magnesium chloride in diluted hydrochloric acid with water (1 in 100)

Magnesium standard solutions: Into four identical 100-mL volumetric flasks, each containing 10.0 mL of hydrochloric acid and 10 mL of *Lanthanum chloride solution*, transfer respectively 2.5, 3.0, 4.0, and 5.0 mL of *Magnesium standard stock solution*, and dilute with water to volume.

Sample stock solution: [Caution— Perchlorates mixed with heavy metals are known to be explosive. Take proper precautions while performing this analysis.] Weigh 500 mg of Talc in a 100-mL polytetrafluoroethylene dish. Add 5 mL of hydrochloric acid, 5 mL of lead-free nitric acid, and 5 mL of perchloric acid. Stir gently, then add 35 mL of hydrofluoric acid, and evaporate slowly on a hot plate to moist dryness (until about 0.5

mL remains). To the residue, add 5 mL of hydrochloric acid, cover with a watch glass, heat to boiling, and allow to cool. Rinse the watch glass and the dish with water, transfer to a 50-mL volumetric flask, and dilute with water to volume.

Sample solution: Dilute the *Sample stock solution* with water (1 in 200). Transfer 4.0 mL of this solution to a 100-mL volumetric flask, add 10.0 mL of hydrochloric acid and 10 mL of *Lanthanum chloride solution*, and dilute with water to volume.

Instrumental conditions

(See *Spectrophotometry and Light-Scattering* (851).)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: Magnesium emission line at 285.2 nm

Lamp: Magnesium hollow-cathode

Flame: Air-acetylene

Analysis

Samples: *Magnesium standard solutions* and *Sample solution*

Concomitantly determine the absorbance of the solutions.

Acceptance criteria: 17.0%–19.5%

IMPURITIES

• WATER-SOLUBLE SUBSTANCES

Sample: 10.0 g

Analysis: To the *Sample* add 50 mL of carbon dioxide-free water, heat to boiling, and boil under a reflux condenser for 30 min. Allow to cool, filter, and dilute with carbon dioxide-free water to 50.0 mL. Test with litmus paper. Evaporate 25.0 mL of the filtrate to dryness, dry at 105° for 1 h, and weigh the residue.

Acceptance criteria: The filtrate is neutral to litmus paper, and the weight of the residue is NMT 5 mg (0.1%).

• LIMIT OF IRON

Iron standard stock solution: 250 $\mu\text{g/mL}$ of iron from 4.840 g ferric chloride in a 150 g/L solution of hydrochloric acid in water. Prepare immediately before use.

Iron standard solutions: Into four 100-mL volumetric flasks, each containing 50.0 mL of 0.5 N hydrochloric acid, transfer respectively 2.0, 2.5, 3.0, and 4.0 mL of the *Standard iron stock solution*, and dilute each flask with water to volume.

Sample stock solution: Transfer 10.0 g of Talc to a conical flask fitted with a reflux condenser. Gradually add 50 mL of 0.5 N hydrochloric acid while stirring, and heat on a water bath for 30 min. Allow to cool. Transfer the mixture to a beaker, and allow the undissolved material to settle. Filter the supernatant into a 100-mL volumetric flask, retaining as much as possible of the insoluble material in the beaker. Wash the residue and the beaker with three 10-mL portions of hot water. Wash the filter with 15 mL of hot water, allow the filtrate to cool, and dilute with water to 100.0 mL.

Sample solution: Transfer 2.5 mL of the *Sample stock solution* to a 100-mL volumetric flask, add 50.0 mL of 0.5 N hydrochloric acid, and dilute with water to volume.

Instrumental conditions

(See *Spectrophotometry and Light-Scattering* (851).)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: Iron emission line at 248.3 nm

Lamp: Iron hollow-cathode

Flame: Air-acetylene

Analysis

Samples: *Iron standard solutions* and *Sample solution*
Concomitantly determine the absorbance of the solutions. Make any correction using a deuterium lamp.

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Acceptance criteria: NMT 0.25%

• LIMIT OF LEAD

Sample solution: Use the *Sample stock solution* as directed in the test for *Limit of Iron*.

Diluent: Nitric acid in water (1 in 100)

Lead standard stock solution: 10 µg/mL of lead prepared as follows. Dissolve 160 mg of lead nitrate in 100 mL of *Diluent*, and dilute with water to 1000 mL. Dilute this solution with water (1 in 10).

Lead standard solutions: Into four identical 100-mL volumetric flasks, each containing 50.0 mL of 0.5 N hydrochloric acid, transfer respectively 5.0, 7.5, 10.0, and 12.5 mL of *Lead standard stock solution*, and dilute with water to volume.

Instrumental conditions

(See *Spectrophotometry and Light-Scattering* (851).)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: Lead emission line at 217.0 nm

Lamp: Lead hollow-cathode

Flame: Air-acetylene

Analysis

Samples: *Lead standard solutions* and *Sample solution*
Concomitantly determine the absorbance of the solutions.

Acceptance criteria: NMT 10 ppm

• LIMIT OF CALCIUM

Lanthanum chloride solution: Prepare as directed in the *Assay*.

Calcium standard stock solution: 100 µg/mL of calcium, prepared immediately before use by diluting a 3.67 mg/mL solution of calcium chloride dihydrate in diluted hydrochloric acid with water (1 in 10)

Calcium standard solutions: Into four identical 100-mL volumetric flasks, each containing 10.0 mL of hydrochloric acid and 10 mL of *Lanthanum chloride solution*, transfer respectively 1.0, 2.0, 3.0, and 4.0 mL of *Calcium standard stock solution*, and dilute each solution with water to volume.

Sample stock solution: Prepare as directed in the *Assay*.

Sample solution: Transfer 5.0 mL of the *Sample stock solution* to a 100-mL volumetric flask, add 10.0 mL of hydrochloric acid and 10 mL of *Lanthanum chloride solution*, and dilute with water to volume.

Instrumental conditions

(See *Spectrophotometry and Light-Scattering* (851).)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: Calcium emission line at 422.7 nm

Lamp: Calcium hollow-cathode

Flame: Nitrous oxide-acetylene

Analysis

Samples: *Calcium standard solutions* and *Sample solution*
Concomitantly determine the absorbance of the solutions.

Acceptance criteria: NMT 0.9%

• LIMIT OF ALUMINUM

Cesium chloride solution: 25.3 mg/mL of cesium chloride in water.

Aluminum standard stock solution: 100 µg/mL of aluminum, prepared immediately before use by diluting an 8.947 mg/mL solution of aluminum chloride in water with water (1 in 10)

Aluminum standard solutions: Into four identical 100-mL volumetric flasks, each containing 10.0 mL of hydrochloric acid and 10 mL of *Cesium chloride solution*, transfer respectively 5.0, 10.0, 15.0, and 20.0 mL of *Aluminum standard stock solution*, and dilute with water to volume.

Sample stock solution: Proceed as directed in the *Assay*. Transfer 5 mL of the *Cesium chloride solution* to the 50-mL flask prior to transfer of the residue, and dilute with water to volume.

Sample solution: Transfer 5.0 mL of the *Sample stock solution* to a 100-mL volumetric flask, add 10 mL of the *Cesium chloride solution* and 10.0 mL of hydrochloric acid, and dilute with water to volume.

Instrumental conditions

(See *Spectrophotometry and Light-Scattering* (851).)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: Aluminum emission line at 309.3 nm

Lamp: Aluminum hollow-cathode

Flame: Nitrous oxide-acetylene

Analysis

Samples: *Aluminum standard solutions* and *Sample solution*
Concomitantly determine the absorbance of the solutions.

Acceptance criteria: NMT 2.0%

• ABSENCE OF ASBESTOS

[NOTE—Suppliers of Talc may use one of the following methods to determine the absence of asbestos.]
Proceed as directed for *Procedure 1* or *Procedure 2*. If either test is positive, perform *Procedure 3*.

Procedure 1: Infrared Absorption

The IR absorption spectrum of a potassium bromide dispersion of Talc at the absorption band at $758 \pm 1 \text{ cm}^{-1}$, using scale expansion, may indicate the presence of tremolite or chlorite. If the absorption band remains after ignition of the substance at 850° for at least 30 min, it indicates the presence of tremolite. In the range 600 cm^{-1} to 650 cm^{-1} using scale expansion, any absorption band or shoulder may indicate the presence of serpentines.

Procedure 2: Use the following conditions (see *X-Ray Diffraction* (941)):

Cu K α monochromatic 40 kV radiation, 24–30 mA; the incident slit is set at 1° ; the detection slit is set at 0.2° ; the goniometer speed is $1/10^\circ 2\theta/\text{min}$; the scanning range is $10^\circ\text{--}13^\circ 2\theta$ and $24^\circ\text{--}26^\circ 2\theta$; the sample is not oriented. Prepare a random sample, and place on the sample holder. Pack and smooth its surface with a polished glass microscope slide. Record the diffractograms: the presence of amphiboles is detected by a diffraction peak at $10.5 \pm 0.1^\circ 2\theta$, and the presence of serpentines is detected by diffraction peaks at $24.3 \pm 0.1^\circ 2\theta$ to $12.1 \pm 0.1^\circ 2\theta$.

Procedure 3: The presence of asbestos (see *Optical Microscopy* (776)) is shown if there is a range of length to width ratios of 20:1 to 100:1, or higher for fibers longer than 5 µm; if there is a capability of splitting into very thin fibrils; and if there are two or more of the following four criteria: (1) parallel fibers occurring in bundles, (2) fiber bundles displaying frayed ends, (3) fibers in the form of thin needles, and (4) matted masses of individual fibers and/or fibers showing curvature.

SPECIFIC TESTS

• MICROBIAL ENUMERATION TESTS (61) and TESTS FOR SPECIFIED MICROORGANISMS (62)

Intended for topical administration

Total aerobic microbial count: NMT 100 cfu/g

Total combined molds and yeasts count: NMT 50 cfu/g

Intended for oral administration

Total aerobic microbial count: NMT 1000 cfu/g

Total combined molds and yeasts count: NMT 100 cfu/g

• **ACIDITY AND ALKALINITY:** Boil 2.5 g of Talc with 50 mL of carbon dioxide-free water under reflux. Filter under vac-

uum. To 10 mL of the filtrate, add 0.1 mL of bromothymol blue TS. Add 0.01 N hydrochloric acid until the indicator changes color. To a second 10 mL of the filtrate, add 0.1 mL of phenolphthalein TS. Add 0.01 N sodium hydroxide until the indicator turns pink.

Acceptance criteria: NMT 0.4 mL of 0.01 N hydrochloric acid is required to change the color of the bromothymol blue indicator. NMT 0.3 mL of 0.01 N sodium hydroxide is required to change the color of the phenolphthalein indicator to pink.

• **Loss on Ignition** (733)

Sample: 1 g

Analysis: Ignite at $1075 \pm 25^\circ$ to constant weight.

Acceptance criteria: It loses NMT 7.0% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. No storage requirements specified.
- **LABELING:** The label states, where applicable, that the substance is suitable for oral or topical administration.

The certificate of analysis states the absence of asbestos. It also indicates which method specified in the test for *Absence of Asbestos* was used for analysis.

Change to read:

• **LABELING:** The label states, where applicable, that the substance is suitable for oral or topical administration. The certificate of analysis states the absence of asbestos. It also indicates that Talc is not derived from deposits that are known to contain associated asbestos, and which method specified in the test for *Absence of Asbestos* was used for analysis.

• (Postponed indefinitely) (RB 1-Aug-2011)