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Dental-Type Silica

DEFINITION

Dental-Type Silica is obtained from sodium silicate solution by destabilizing with acid in such a way as to yield very fine particles. The sum of the *Assay* values for Silicon Dioxide and Sodium Sulfate is NLT 98.0%.

ASSAY

- **Silicon Dioxide**

  Sample: 1 g

  Analysis: Ignite the *Sample* at 1000° for 1 h, cool in a desiccator, and weigh. Carefully wet with water, and add 10 mL of hydrofluoric acid, in small increments. Evaporate on a steam bath to dryness, and cool. Add about 10 mL of hydrofluoric acid and about 0.5 mL of sulfuric acid, and evaporate to dryness. Slowly increase the temperature until all of the acids have been volatilized, and ignite at 1000°. Cool in a desiccator, and weigh. The difference between the final weight and the weight of the initially ignited portion represents the weight of SiO_2.

- **Sodium Sulfate**

  Sample: 1 g

  Analysis 1: In a platinum dish, wet the *Sample* with a few drops of water, add 15 mL of perchloric acid, and place the dish on a hot plate. Add 10 mL of hydrofluoric acid. Heat until copious fumes are evolved. Add 5 mL of hydrofluoric acid, and again heat to copious fumes. Add 5 mL of boric acid solution (1 in 25), and heat to fumes. Cool, and transfer the residue to a 400-mL beaker with the aid of 10 mL of hydrochloric acid. Adjust the volume with water to about 300 mL, and bring to boiling on a hot plate. Add 20 mL of hot barium chloride TS. Keep the beaker on the hot plate for 2 h, maintaining the volume above 200 mL. After cooling, transfer the precipitate and solution to a dried, tared crucible with a filter of 0.8-µm pore size. Wash the filter and precipitate 8 times with hot water, dry the crucible at 105° for 1 h, and weigh. The weight, multiplied by 0.6085, is the sodium sulfate content of the amount of specimen taken.

  Acceptance criteria 1: NMT 4.0%

  Analysis 2: Calculate the sum of the *Assay* values for the silicon dioxide and the sodium sulfate, and calculate the percentage in the Dental-Type Silica taken.

  Acceptance criteria 2: NLT 98.0%

SPECIFIC TESTS

- **pH** ⟨791⟩

  Sample solution: 50 mg/mL of slurry

  Acceptance criteria: 4.0–8.5

- **Loss on Drying** ⟨731⟩

  Analysis: Dry a sample at 105° for 2 h.

  Acceptance criteria: It loses NMT the maximum percentage of its weight as indicated in the labeling.

- **Loss on Ignition** ⟨733⟩

  Sample: 1 g, previously dried

  Analysis: Ignite the *Sample* at 1000° for NLT 1 h.

  Acceptance criteria: NMT 8.5%

- **Chloride and Sulfate,** *Chloride*⟨221⟩

  Sample solution: Boil 5 g in 50 mL of water under a reflux condenser for 2 h, cool, and filter.

  Control: 1.0 mL of 0.020 N hydrochloric acid

  Analysis: Use a 7-mL portion of *Sample solution*.

  Acceptance criteria: 0.1%; the *Sample solution* shows no more chloride than the *Control*.

Change to read:

• ▲**Arsenic** ⟨211⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023)

Sample solution: Transfer 4.0 g of Dental-Type Silica to a platinum dish, add 5 mL of nitric acid and 35 mL of hydrofluoric acid, and evaporate on a steam bath. Cool, add 5 mL of perchloric acid, 10 mL of hydrofluoric acid, and 10 mL of sulfuric acid, and evaporate on a hot plate to the production of heavy fumes. Cool, cautiously transfer to a 100-mL beaker with the aid of a few mL of hydrochloric acid, and evaporate to dryness. Cool, add 5 mL of hydrochloric acid, dilute with water to about 40 mL, and heat to dissolve any residue. Cool, transfer to a 100-mL volumetric flask, and dilute with water to volume.

Analysis: Use a 25.0-mL portion of *Sample solution*.

Acceptance criteria: NMT 3 ppm

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** Label it to indicate the maximum percentage of loss on drying.

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

Topic/Question	Contact	Expert Committee
DENTAL-TYPE SILICA	Documentary Standards Support	SE2020 Simple Excipients
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