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Silicon Dioxide

$SiO_2 \cdot xH_2O$
Anhydrous
60.08

DEFINITION

Silicon Dioxide is obtained by insolubilizing the dissolved silica in sodium silicate solution. Where obtained by the addition of sodium silicate to a mineral acid, the product is termed silica gel. Where obtained by the destabilization of a solution of sodium silicate in such manner as to yield very fine particles, the product is termed precipitated silica. After ignition at 1000° for NLT 1 h, it contains NLT 99.0% of SiO_2.

IDENTIFICATION

• **Procedure**

Sample: 5 mg

Analysis: Transfer the *Sample* to a platinum crucible, mix with 200 mg of anhydrous potassium carbonate, ignite at a red heat over a burner for 10 min, and cool. Dissolve the melt in 2 mL of recently distilled water, warming if necessary, and slowly add 2 mL of ammonium molybdate TS.

Acceptance criteria: A deep yellow color is produced.

ASSAY

• **Procedure**

Sample: 1 g

Analysis: Ignite the *Sample* in a tared platinum dish 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 10 mL of hydrofluoric acid and 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.

Acceptance criteria: NLT 99.0% on the previously ignited basis

IMPURITIES

Inorganic Impurities

• **Loss on Ignition** ⟨733⟩

Sample: 1 g

Analysis: Ignite the *Sample*, previously dried and weighed, at 1000° for NLT 1 h.

Acceptance criteria: It loses NMT 8.5% of its weight.

• **Chloride and Sulfate,** *Chloride* ⟨221⟩**:** Boil 5 g in 50 mL of water under a reflux condenser for 2 h, cool, and filter. A 7-mL portion of the filtrate shows no more chloride than corresponds to 1.0 mL of 0.020 N hydrochloric acid (0.1%).

• **Chloride and Sulfate,** *Sulfate* ⟨221⟩**:** A 10-mL portion of the filtrate from the test for *Chloride* shows no more sulfate than corresponds to 5.0 mL of 0.020 N sulfuric acid (0.5%).

Change to read:

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

Sample solution: Transfer 4.0 g 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 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 the *Sample solution*.

Acceptance criteria: Meets the requirements of the test (NMT 3 ppm)

SPECIFIC TESTS

- **pH** ⟨791⟩**:** 4–8 in a slurry (1 in 20)
- **Loss on Drying** ⟨731⟩**:** Dry a sample at 145° for 4 h; it loses NMT 5.0% of its weight.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, protected from moisture.
- **Labeling:** Label it to state whether it is silica gel or precipitated silica.

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

Topic/Question	Contact	Expert Committee
SILICON DIOXIDE	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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