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Colloidal Silicon Dioxide

SiO_2 60.08

Silica CAS RN®: 7631-86-9.

DEFINITION

Colloidal Silicon Dioxide is a submicroscopic fumed silica prepared by the vapor-phase hydrolysis of a silicon compound. When ignited at 1000° for 2 h, it contains NLT 99.0% and NMT 100.5% of SiO_2.

IDENTIFICATION

• **A. Procedure**

Analysis: Transfer 5 mg to a platinum crucible, and mix with 200 mg of anhydrous potassium carbonate. Heat the crucible to a red color with the aid of a Bunsen burner for 10 min, and cool. Dissolve the melt in 2 mL of freshly distilled water, warming if necessary, and slowly add 2 mL of ammonium molybdate TS to the solution.

Acceptance criteria: A deep yellow color is produced.

• **B. Procedure**

[Note—Avoid contact with *o*-tolidine when performing this test, and conduct the test in a well-ventilated hood.]

Analysis: Place 1 drop of the yellow silicomolybdate solution from *Identification* test *A* on a filter paper, and evaporate the solvent. Add 1 drop of a saturated solution of *o*-tolidine in glacial acetic acid to reduce the silicomolybdate to molybdenum blue, and place the paper over ammonium hydroxide.

Acceptance criteria: A greenish blue spot is produced.

ASSAY

• **Procedure**

Sample: 500 mg

Analysis: Ignite the *Sample* in a tared platinum crucible at 1000 ± 25° for 2 h, cool in a desiccator, and weigh. Add 3 drops of sulfuric acid, and add enough alcohol to just moisten the sample completely. Add 15 mL of hydrofluoric acid, and in a well-ventilated hood evaporate on a hot plate to dryness, using medium heat (95°–105°) and taking care that the sample does not spatter as dryness is approached. Heat the crucible to a red color with the aid of a Bunsen burner. Ignite the residue at 1000 ± 25° for 30 min, cool in a desiccator, and weigh. If a residue remains, repeat the *Analysis*, beginning with "Add 15 mL of hydrofluoric acid". The weight lost by the assay specimen, previously ignited at 1000 ± 25°, represents the weight of SiO_2 in the portion taken.

Acceptance criteria: 99.0%–100.5% on the previously ignited basis

IMPURITIES

Inorganic Impurities

• **Loss on Ignition ⟨733⟩:** Ignite the portion of Colloidal Silicon Dioxide, retained from the test for *Loss on Drying*, at 1000 ± 25° to constant weight: the previously dried Colloidal Silicon Dioxide loses NMT 2.0% of its weight.

Change to read:

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

Sample solution: To 2.5 g add 50 mL of 3 N hydrochloric acid, and reflux for 30 min using a water condenser. Cool, filter with the aid of suction, and transfer the filtrate to a 100-mL volumetric flask. Wash the filter and flask with several portions of hot water, and add the washings to the flask. Cool, and dilute with water to volume.

Analysis: A 15.0-mL portion of *Sample solution*, to which 3 mL of hydrochloric acid has been added, meets the requirements of the test, the addition of the 7 N sulfuric acid being omitted.

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Acceptance criteria: NMT 8 ppm

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.5–5.5, in a (1 in 25) dispersion

• **Loss on Drying** ⟨731⟩**:** Dry in a tared platinum crucible at 105° for 2 h: it loses NMT 2.5% of its weight. Retain the dried specimen in the crucible for the test for *Loss on Ignition*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

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

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

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