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Purified Siliceous Earth

DEFINITION

Purified Siliceous Earth is a form of silica (SiO_2) consisting of the frustules and fragments of diatoms, purified by calcining.

IMPURITIES

- [Loss on Ignition \(733\)](#)

Sample: 1 g, previously dried

Analysis: Ignite the *Sample* at $980 \pm 25^\circ$ for 1 h in a tared platinum or porcelain crucible.

Acceptance criteria: NMT 2.0%

Change to read:

- [LEACHABLE ARSENIC](#)

Sample solution: To 10.0 g in a 250-mL beaker add 50 mL of 0.5 N hydrochloric acid, cover with a watch glass, and heat at 70° for 15 min.

Cool, and decant through a Whatman No. 3 filter paper into a 100-mL volumetric flask. Wash the slurry with three 10-mL portions of water, preheated to 70° , and dilute with water to volume.

Analysis: A 3.0-mL portion of the *Sample solution* meets the requirements in [Arsenic \(211\), Procedures, Procedure 1](#). ▲ (ERR 1-Aug-2023)

Acceptance criteria: NMT 10 $\mu\text{g}/\text{g}$

- [LEACHABLE LEAD](#)

Sample: A 10.0-mL portion of the *Sample solution* prepared in the test for *Leachable Arsenic*

Control: 10 mL of *Diluted Standard Lead Solution* in [Lead \(251\), Procedures, Procedure 1](#)

Analysis: The *Sample* meets the requirements in [Lead \(251\), Procedures, Procedure 1](#).

Acceptance criteria: NMT 10 $\mu\text{g}/\text{g}$

- [LIMIT OF NONSILICEOUS SUBSTANCES](#)

Sample: 200 mg

Analysis: Transfer the *Sample* to a tared platinum crucible, add 5 mL of hydrofluoric acid and 2 drops of dilute sulfuric acid (1 in 2), and evaporate gently to dryness. Cool, add 5 mL of hydrofluoric acid, evaporate again to dryness, and ignite to constant weight.

Acceptance criteria: The weight of the residue is NMT 50 mg.

SPECIFIC TESTS

- [Loss on Drying \(731\)](#)

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

Acceptance criteria: NMT 0.5%

- [ACID-SOLUBLE SUBSTANCES](#)

Sample: 10.0 g

Analysis: Digest the *Sample* with 50 mL of 0.5 N hydrochloric acid at 70° for 15 min, and filter. Wash the residue, adding the washings to the filtrate to obtain a total volume of 100 mL. Evaporate at 110° in a tared porcelain dish to dryness.

Acceptance criteria: NMT 2.0% (weight of the dried residue is NMT 200 mg)

- [WATER-SOLUBLE SUBSTANCES](#)

Sample: 12.5 g

Analysis: Place the *Sample* in a 500-mL conical flask, add 250 mL of water, and shake for 2 h at room temperature. Filter with the aid of vacuum, and again filter if necessary to obtain a clear filtrate. Evaporate in a tared platinum or porcelain dish, and dry at 110° .

Acceptance criteria: NMT 0.2% (weight of the residue is NMT 25 mg)

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
PURIFIED SILICEOUS EARTH	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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