Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2023
Document Type: NF Monographs
DocId: GUID-DC063C56-9DA1-47A6-BB7D-D8371C1871CF_5_en-US
DOI: https://doi.org/10.31003/USPNF_M75250_05_01
DOI Ref: bhbny

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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 ± 25° 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 µg/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 µg/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

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• **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:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-DC063C56-9DA1-47A6-BB7D-D8371C1871CF_5_en-US
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