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Topical Starch

DEFINITION
Topical Starch consists of the granules separated from the mature grain of corn [*Zea mays* L. (Fam. Gramineae)].

IDENTIFICATION

• **A.**

Sample: 1 g

Analysis: Prepare a smooth mixture of the *Sample* with 2 mL of cold water, stir it into 15 mL of boiling water, boil gently for 2 min, and cool.

Acceptance criteria: A translucent, whitish jelly is produced.

• **B.** A water slurry of it is colored reddish violet to deep blue by iodine TS.

IMPURITIES

• **Residue on Ignition ⟨281⟩**

Sample: 2.0 g

Analysis: Ignite the *Sample* at a temperature of 575 ± 25°.

Acceptance criteria: NMT 0.5%

Change to read:

• ▲**Iron ⟨241⟩**, *Procedures, Procedure 1*▲ (CN 1-Jun-2023)

Sample: The residue obtained in the test for *Residue on Ignition*

Analysis: Dissolve the *Sample* in 4 mL of hydrochloric acid with the aid of gentle heating, dilute with water to 50 mL, and mix. Dilute 25 mL of the resulting solution with water to 47 mL.

Acceptance criteria: NMT 10 µg/g

• **Sulfur Dioxide**

Sample suspension: Mix 20 g with 200 mL water to obtain a smooth suspension, and filter.

Analysis: To 100 mL of the clear filtrate add 3 mL of starch TS, and titrate with 0.01 N iodine VS to the first permanent blue color.

Acceptance criteria: NMT 2.7 mL of 0.01 N iodine VS is consumed (0.008%).

• **Oxidizing Substances**

Sample: 4.0 g

Analysis: Add 50.0 mL of water to the *Sample* in a glass-stoppered, 125-mL conical flask. Insert the stopper, and swirl for 5 min. Decant into a glass-stoppered, 50-mL centrifuge tube, and spin to clarify. Transfer 30.0 mL of clear supernatant to a glass-stoppered, 125-mL conical flask. Add 1 mL of glacial acetic acid and 0.5–1.0 g of potassium iodide. Insert the stopper, swirl, and allow to stand for 25–30 min in the dark. Add 1 mL of starch TS, and titrate with 0.002 N sodium thiosulfate VS to the disappearance of the starch–iodine color. [Note—Each mL of 0.002 N sodium thiosulfate is equivalent to 34 µg of oxidant, calculated as hydrogen peroxide.]

Acceptance criteria: NMT 12.6 mL of 0.002 N sodium thiosulfate VS is required (0.018%).

SPECIFIC TESTS

• **Botanic Characteristics:** Polygonal, rounded, or spheroidal granules up to about 35 µm in diameter, and usually having a circular or several-rayed central cleft.

• **Loss on Drying ⟨731⟩**

Analysis: Dry a sample at 120° for 4 h.

Acceptance criteria: NMT 14.0%

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed 5×10^2 cfu/g, and the total combined molds and yeasts count does not exceed 5×10^1 cfu/g.

• **pH ⟨791⟩**

Sample: 20.0 g ± 100 mg

Analysis: Prepare a slurry of the *Sample* in 100 mL of water in a suitable nonmetallic container. Agitate continuously at a moderate rate for 5 min, then stop agitation, and immediately determine the pH potentiometrically to the nearest 0.1 unit.

Acceptance criteria: 4.5–7.0

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
TOPICAL STARCH	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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