Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Jun-2023
Document Type: NF Monographs
DocId: GUID-2789236E-A3C5-4EDA-9AF2-52C8DADE9C62_2_en-US
DOI: https://doi.org/10.31003/USPNF_M78122_02_01
DOI Ref: 5c80x

Modified Starch

DEFINITION

Modified Starch is Starch modified by chemical means. Food Starch may be acid-modified, bleached, oxidized, esterified, etherified, or treated enzymatically to change its functional properties (21 CFR 172.892).

IDENTIFICATION

• **A.**

Corn starch: Polygonal, rounded, or spheroidal granules up to 35 µm in diameter and usually having a circular or several-rayed central cleft

Tapioca starch: Spherical granules with one truncated side, typically 5–35 µm in diameter and usually having a circular or several-rayed central cleft

Potato starch: Irregularly shaped, ovoid, or pear-shaped granules, usually 30–100 µm in size but occasionally exceeding 100 µm; or rounded, 10–35 µm in size. There are occasional compound granules having two to four components. The ovoid and pear-shaped granules have an eccentric hilum, and the rounded granules have an accentric or slightly eccentric hilum. All granules show clearly visible concentric striations.

Wheat starch: Large and small granules, usually 10–60 µm in diameter. The central hilum and striations are visible or barely visible.

• **B.**

Sodium hydroxide solution: 2% (w/w)

Sample: 0.6 g

Analysis: Transfer the *Sample* to a 25-mL glass vial with a plastic cap. Add 9.4 g of water, cap, and shake vigorously to evenly disperse the starch. Add 10 g of the *Sodium hydroxide solution*, cap, and shake vigorously for 1 min to create a smooth mixture. Evaluate within 1 min.

Acceptance criteria: The final solution is translucent to opaque with a fluid consistency. A yellow tint of the final solution is acceptable.

• **C.** A water slurry of the Modified Starch is colored orange-red to deep blue by iodine TS.

IMPURITIES

• **Residue on Ignition ⟨281⟩**

Sample: 2.0 ± 0.1 g

Analysis: Proceed as directed in the chapter.

Acceptance criteria: NMT 1.5%

Change to read:

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

Test preparation: Dissolve the residue obtained in the test for *Residue on Ignition* in 8 mL of hydrochloric acid with the aid of gentle heating. Dilute with water to 100 mL in a volumetric flask, and mix. Dilute 25 mL of this solution with water to 47 ± 1 mL.

Analysis: Proceed as directed in the chapter.

Acceptance criteria: NMT 20 ppm

• **Limit of Sulfur Dioxide**

Sample: 20.0 ± 0.1 g

Analysis: Mix the *Sample* with 200 mL of 5% alcohol until a smooth suspension is obtained, and vacuum-filter through paper (Whatman No.1 or equivalent). To 100 mL of the filtrate add 3 mL of starch TS, and titrate with 0.01 N iodine VS to the first permanent blue color.

Acceptance criteria: NMT 1.7 mL of 0.01 N iodine VS is consumed, which corresponds to NMT 50 ppm of sulfur dioxide being found.

• **Oxidizing Substances**

Sample: 4.0 g

Titrimetric system

Mode: Direct titration

Titrant: 0.002 N sodium thiosulfate VS

Blank: 30.0 mL of water, accurately measured

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a glass-stoppered, 125-mL conical flask, and add 50.0 mL of water. Insert the stopper, and swirl for 5 min. Transfer to a glass-stoppered, 50-mL centrifuge tube, and centrifuge to clarify. Transfer 30.0 mL of the 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 *Titrant* to the disappearance of the starch–iodine color. Perform a blank determination, and make any necessary correction. 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 is required (180 ppm, calculated as H_2O_2), which corresponds to NMT 0.018% of oxidizing substances

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed 10^3 cfu/g, and the total combined molds and yeasts count does not exceed 10^2 cfu/g. It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

• **pH ⟨791⟩**

Sample: 20.0 ± 0.1 g

Analysis: Transfer the *Sample* to a suitable nonmetallic container, and add 100 mL of water to obtain a slurry. Stir using a magnetic stirrer at a moderate rate for 5 min, and determine the pH to the nearest 0.1 unit.

Acceptance criteria: 3.0–9.0

• **Loss on Drying ⟨731⟩**

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

Acceptance criteria

Corn starch and **Wheat starch:** NMT 15.0%

Tapioca starch: NMT 18.0%

Potato starch: NMT 21.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. No storage requirements specified.

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

Topic/Question	Contact	Expert Committee
MODIFIED STARCH	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 30(4)

Current DocID: GUID-2789236E-A3C5-4EDA-9AF2-52C8DADE9C62_2_en-US

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