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Pregelatinized Modified Starch

DEFINITION

Pregelatinized Modified Starch is Modified Starch that has been chemically or mechanically processed, or both, to rupture all or part of the granules to produce a product that swells in cold water.

IDENTIFICATION

- **A.**

  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 2% (w/w) NaOH 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.

- **B.** An aqueous dispersion of Pregelatinized Modified Starch is colored orange-red to deep blue by iodine TS.

IMPURITIES

- **Residue on Ignition ⟨281⟩**

  Sample: 2.0 ± 0.1 g

  Acceptance criteria: NMT 1.5%

- **Limit of Sulfur Dioxide**

  Sample solution: Mix 20.0 ± 0.1 g of Pregelatinized Modified Starch with 100 mL of 95% alcohol, and stir for several min to completely wet the starch.

  Analysis: Slowly add 100 mL of water to the *Sample solution*, and stir until a smooth suspension is obtained. Allow the starch mixture to set undisturbed until most of the starch has settled, and filter the aqueous portion through paper (Whatman No. 1 or equivalent). To 100 mL of the clear filtrate add 100 mL of water. Add 3 mL of starch TS, and titrate with 0.01 N iodine VS to the first permanent blue or purple color.

  Acceptance criteria: NMT 1.7 mL of 0.010 N iodine is consumed (NMT 0.005%).

SPECIFIC TESTS

- **pH ⟨791⟩**

  Sample: 10.0 ± 0.1 g

  Analysis: Wet the *Sample* with 10 mL of alcohol, then dilute with water to 300 mL to obtain an aqueous dispersion. Stir continuously 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 at 120° for 4 h.

  Acceptance criteria: NMT 15%

- **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed 1×10^3 cfu/g, and the total combined molds and yeasts count does not exceed 1×10^2 cfu/g. It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

Change to read:

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

  Sample: The residue obtained in the test for *Residue on Ignition* ⟨281⟩

  Analysis: Dissolve the *Sample* in 8 mL of hydrochloric acid with the aid of gentle heating. Dilute with water to 100 mL in a volumetric flask. Dilute 25 mL of this solution with water to 47 ± 1 mL.

  Acceptance criteria: NMT 20 µg/g

• **Oxidizing Substances**

Sample solution: To 5 g of Pregelatinized Modified Starch add 20 mL of a mixture of methanol and water (1:1).

Analysis: To the *Sample solution* add 1 mL of 6 N acetic acid, and stir until a homogeneous suspension is obtained. Add 0.5 mL of a freshly prepared saturated solution of potassium iodide, and allow to stand for 5 min.

Acceptance criteria: No distinct blue, brown, or purple color is observed.

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

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