Pregelatinized Starch

DEFINITION

Pregelatinized Starch is Starch that has been chemically and/or mechanically processed to rupture all or part of the granules in the presence of water and subsequently dried. Some types of Pregelatinized Starch may be modified to render them compressible and flowable in character.

IDENTIFICATION

- A water slurry of it is colored orange-red to deep blue by iodine TS.

IMPURITIES

Inorganic Impurities

- **Residue on Ignition** ⟨281⟩**:** NMT 0.5%, determined on a 2.0-g test specimen
- **Iron** ⟨241⟩**:** NMT 20 ppm

Analysis: Dissolve the residue obtained in the test for *Residue on Ignition* in 8 mL of hydrochloric acid with the aid of gentle heating, and dilute with water to 100 mL. Dilute 25 mL of this solution with water to 47 mL.

- **Limit of Sulfur Dioxide**

Sample solution: Mix 20 g with 200 mL of a 1-in-5 solution of anhydrous sodium sulfate, 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 is consumed (80 ppm).

SPECIFIC TESTS

- **Microbial Enumeration Tests** ⟨61⟩ and **Tests for Specified Microorganisms** ⟨62⟩**:** It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*. The total aerobic microbial count does not exceed 1000 cfu/g; and the total combined molds and yeasts count does not exceed 100 cfu/g.
- **pH** ⟨791⟩**:** 4.5–7.0

Prepare a slurry by weighing 10.0 ± 0.1 g in 10 mL of alcohol and by diluting with water to 100 mL. Agitate continuously at a moderate rate for 5 min, then cease agitation and immediately potentiometrically determine the pH to the nearest 0.1 unit.

- **Loss on Drying** ⟨731⟩**:** Dry a sample at 120° for 4 h: it loses NMT 14.0% of its weight.
- **Oxidizing Substances**

Sample: 5 g

Analysis: To the *Sample* add 20 mL of a mixture of equal volumes of methanol and water, then 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.
- **Labeling:** Label it to indicate the botanical source from which it was derived.