- **pH** ⟨**791**⟩
  Sample solution: Progressively suspend 3.0 g of Pregelatinized Hydroxypropyl Potato Starch in 100.0 mL of carbon dioxide-free water, stirring continuously. Determine the pH when all the solid is wetted.
  Acceptance criteria: 4.5–8.0
- **Loss on Drying** ⟨**731**⟩**:** Dry about 1 g at 130° for 90 min: it loses NMT 20.0% of its weight.

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Preserve in well-closed containers. Store at room temperature.
- **USP Reference Standards** ⟨**11**⟩
  USP Propylene Glycol RS

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.

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*.
- **Iron** ⟨**241**⟩
  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.