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## Rice Starch

Portions of this monograph that are national *USP* text, and are not part of the harmonized text, are marked with symbols (†) to specify this fact.

### DEFINITION

Rice Starch is obtained from the caryopsis of *Oryza sativa* L.

### IDENTIFICATION

#### • A. PROCEDURE

**Analysis:** Examine under a microscope, using NLT 20× magnification and using a mixture of glycerin and water (1:1) as a mounting agent.

**Acceptance criteria:** It presents polyhedral, simple grains 1–10 µm, mostly 4–6 µm in size. These simple grains often gather in ellipsoidal, compound grains 50–100 µm in diameter. The granules have a poorly visible central hilum and there are no concentric striations. Between orthogonally orientated polarising plates or prisms, the starch granules show a distinct black cross intersecting at the hilum.

#### • B. PROCEDURE

**Sample solution:** 20 mg/mL in water

**Analysis:** Boil for 1 min, and cool.

**Acceptance criteria:** A thin, cloudy mucilage is formed.

#### • C. PROCEDURE

**Sample solution:** 1 mL of the mucilage obtained in *Identification* test B

**Analysis:** Add 0.05 mL of iodine and potassium iodide TS 2 to the *Sample solution*.

**Acceptance criteria:** An orange-red to dark blue color is produced, which disappears upon heating.

### IMPURITIES

#### Inorganic Impurities

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.6%, determined on a 1.0-g sample

#### *Change to read:*

##### • LIMIT OF IRON

**Standard iron stock solution A:** Equivalent to 10 µg/mL of iron prepared as directed in [▲Iron \(241\), Procedures, Procedure 1▲](#) (CN 1-Jun-2023)

**Standard iron stock solution B:** 1 µg/mL of iron from *Standard iron stock solution A* in water. [NOTE—Prepare immediately before use.]

**Standard iron solution:** Transfer 10 mL of *Standard iron stock solution B* to a test tube, and add 2 mL of citric acid solution (2 in 10) and 0.1 mL of thioglycolic acid. Add 10 N ammonium hydroxide until the solution is distinctly alkaline to litmus, and dilute with water to 20 mL.

**Sample solution:** Shake 1.5 g of Rice Starch with 15 mL of 2 N hydrochloric acid, and filter. Transfer 10 mL of the filtrate to a test tube, and add 2 mL of citric acid solution (2 in 10) and 0.1 mL of thioglycolic acid. Add 10 N ammonium hydroxide until the solution is distinctly alkaline to litmus, and dilute with water to 20 mL.

**Acceptance criteria:** After 5 min, any pink color in the *Sample solution* is not more intense than that in the *Standard iron solution*, corresponding to a limit of 10 ppm of iron.

##### • LIMIT OF SULFUR DIOXIDE

**Carbon dioxide:** Use carbon dioxide, with a flow regulator that will maintain a flow of 100 ± 5 mL/min.

**Hydrogen peroxide solution:** Dilute 30% hydrogen peroxide with water to obtain a 3% solution. Just before use, add 3 drops of bromophenol blue TS, and neutralize to a violet-blue endpoint with 0.1 N sodium hydroxide. Do not exceed the endpoint.

**Apparatus:** See [Figure 1](#).

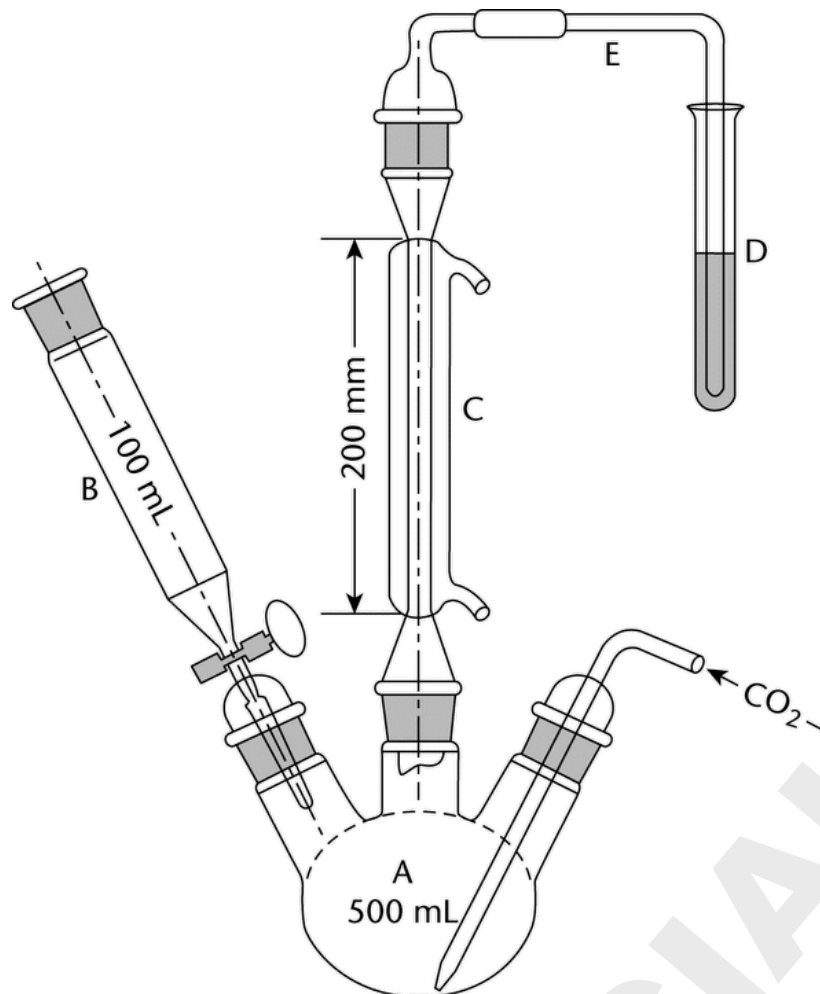


Figure 1

In this test, the sulfur dioxide is released from the sample in a boiling acid medium and is removed by a stream of carbon dioxide. The separated gas is collected in a dilute hydrogen peroxide solution where the sulfur dioxide is oxidized to sulfuric acid and titrated with standard alkali. The apparatus consists essentially of a 500-mL three-neck, round-bottom boiling flask, A; a separatory funnel, B, with a capacity of 100 mL or greater; a gas inlet tube of sufficient length to permit introduction of the carbon dioxide within 2.5 cm of the bottom of the boiling flask; a reflux condenser, C, with a jacket length of 200 mm; and a delivery tube, E, connecting the upper end of the reflux condenser to the bottom of a receiving test tube, D. Apply a thin film of stopcock grease to the sealing surfaces of all of the joints except the joint between the separatory funnel and the boiling flask, and clamp the joints to ensure tightness.

**Sample:** 25.0 g of Rice Starch

**Analysis:** Add 150 mL of water to the boiling flask. Close the stopcock of the separatory funnel, and begin the flow of carbon dioxide at a rate of  $100 \pm 5$  mL/min through the *Apparatus*. Start the condenser coolant flow. Add 10 mL of *Hydrogen peroxide solution* to a receiving test tube. After 15 min, without interrupting the flow of carbon dioxide, remove the separatory funnel from the boiling flask, and transfer the *Sample* into the boiling flask with the aid of 100 mL of water. Apply stopcock grease to the outer joint of the separatory funnel, and replace the separatory funnel in the boiling flask. Close the stopcock of the separatory funnel, and add 80 mL of 2 N hydrochloric acid to the separatory funnel. Open the stopcock of the separatory funnel to permit the hydrochloric acid solution to flow into the boiling flask, guarding against the escape of sulfur dioxide into the separatory funnel by closing the stopcock before the last few mL of hydrochloric acid drain out. Boil the mixture for 1 h. Remove the receiving test tube, and transfer its contents to a 200-mL wide-necked, conical flask. Rinse the receiving test tube with a small portion of water, add the rinsing to the 200-mL conical flask, and mix. Heat on a water bath for 15 min, and allow to cool.

Add 0.1 mL of bromophenol blue TS, and titrate the contents with 0.1 N sodium hydroxide VS until the color changes from yellow to violet-blue. Perform a blank determination, and make any necessary correction (see [Titrimetry \(541\)](#)).

Calculate the content, in ppm, of sulfur dioxide in the *Sample* taken:

$$\text{Result} = (V \times N \times F) / W \times 1000$$

$V$  = volume of titrant consumed (mL)

$N$  = normality of the titrant

$F$  = milliequivalent weight of sulfur dioxide, 32.03

$W$  = weight of the *Sample* (g)

**Acceptance criteria:** NMT 50 ppm

• **LIMIT OF OXIDIZING SUBSTANCES**

**Sample solution:** Transfer 4.0 g 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.

**Analysis:** Titrate with 0.002 N sodium thiosulfate VS 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 1.4 mL of 0.002 N sodium thiosulfate is required [20 ppm, calculated as hydrogen peroxide ( $H_2O_2$ )]

**SPECIFIC TESTS**

• **MICROBIAL ENUMERATION TESTS (61)**, and **TESTS FOR SPECIFIED MICROORGANISMS (62)**: The total aerobic microbial count does not exceed  $10^3$  cfu/g; the total combined molds and yeasts count does not exceed  $10^2$  cfu/g; and it meets the requirements of the test for the absence of *Escherichia coli*.

• **LOSS ON DRYING (731)**

**Sample:** 1 g

**Analysis:** Dry the *Sample* at 130° for 90 min.

**Acceptance criteria:** NMT 15.0%

• **pH (791)**

**Sample solution:** Prepare a slurry by weighing 5.0 g of Rice Starch, transferring to a suitable nonmetallic container, and adding 25.0 mL of freshly boiled and cooled water.

**Analysis:** Agitate continuously at a moderate rate for 1 min. Stop the agitation, and allow to stand for 15 min. Determine the pH to the nearest 0.1 unit.

**Acceptance criteria:** 5.0–8.0

**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
RICE STARCH	<a href="#">Documentary Standards Support</a>	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	CE2020 Complex Excipients

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