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# Tapioca Starch

## DEFINITION

Tapioca Starch consists of starch granules separated from the tubers of tapioca (cassava) [*Manihot utilissima* Pohl (Fam. Euphorbiaceae)].

## IDENTIFICATION

### • A.

**Analysis:** Examine Tapioca Starch under a microscope, using not less than 20× magnification and using glycerin as the mounting agent.

**Acceptance criteria:** It appears as spherical granules, each having one truncated side, typically having a 5- to 35-μm diameter, and having circular or several-rayed central clefts.

### • B.

**Sample suspension:** 1 g of Tapioca Starch in 50 mL of water

**Analysis:** Boil the *Sample suspension* for 1 min, and cool.

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

### • C.

**Sample:** The mucilage obtained in *Identification test B*

**Analysis:** To 1 mL of the *Sample* add 0.05 mL of iodine and potassium iodide TS 2.

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

## IMPURITIES

### • [RESIDUE ON IGNITION \(281\)](#).

**Sample:** 1.0 g

**Acceptance criteria:** NMT 0.6%

### Change to read:

### • [▲ \[IRON \\(241\\), Procedures, Procedure 1\]\(#\)](#) ▲ (CN 1-JUN-2023)

**Test preparation:** Shake 0.75 g of Tapioca Starch with 15 mL of 0.1 N hydrochloric acid, filter, and use 10 mL.

**Acceptance criteria:** NMT 20 μg/g

### • LIMIT OF OXIDIZING SUBSTANCES

**Sample:** 4.0 g

**Blank:** 50 mL of water

#### Titrimetric system

(See [Titrimetry \(541\)](#).)

**Mode:** Direct titration

**Titrant:** 0.002 N sodium thiosulfate VS

**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.

Decant into 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 VS is equivalent to 34 μg of oxidant, calculated as hydrogen peroxide.

**Acceptance criteria:** NMT 1.4 mL of 0.002 N sodium thiosulfate VS is required (0.002%).

### • LIMIT OF SULFUR DIOXIDE

**Sample solution:** Mix 20 g of Tapioca Starch with 200 mL of water until a smooth suspension is obtained, and filter.

**Analysis:** To 100 mL of the clear filtrate from the *Sample solution* add 3 mL of starch TS, and titrate with 0.01 N iodine solution VS to the first permanent blue color.

**Acceptance criteria:** NMT 1.7 mL of 0.01 N iodine solution VS is required (0.005%).

#### 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 yeasts and molds count does not exceed  $10^2$  cfu/g. Tapioca Starch meets the requirements of the test for absence of *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. Agitate continuously at a moderate rate for 5 min, then stop agitation, and immediately determine the pH.

**Acceptance criteria:** 4.5–7.0

• [LOSS ON DRYING \(731\)](#).

**Analysis:** Dry at 130° for 90 min.

**Acceptance criteria:** NMT 16.0%

#### 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
TAPIOCA 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

**Chromatographic Database Information:** [Chromatographic Database](#)

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