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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 \times 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- μ m 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 μ g/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 μ g 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	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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