Potato Starch

Published on: 18.05.2026 **Last date for comments: 03.07.2026**

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to arnd-ipc@gov.in , with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

Description	Details
Document version	1.0
Monograph proposed for inclusion	Addendum to IP 2026
Tentative effective date of monograph	April, 2028
First draft published on IPC website for public comments	
Draft revision published on IPC website for public comments	
Further follow-up action as required.	

Potato Starch

This Monograph has been harmonized with corresponding texts of the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopoeia. Portion of the IP text that are not part of the PDG harmonized text, are marked with symbols (♦ ♦).

Potato Starch is obtained from the tuber of potato, *Solanum tuberosum* Linn (Fam. Solanaceae).

♦**Category**. Pharmaceutical aid.

Description. A very fine, white or almost white powder which creaks when pressed between the fingers or irregular angular white masses (Which may be bleached). Odourless and tasteless. ♦

Potato starch does not contain starch granules of any other origin. It may contain a minute quantity, if any, of tissue fragments of the original plant.

Identification

A. On microscopic examination (2.5.8), using a mixture of equal volume of *glycerin* and *water* as a mounting agent. It presents granules, either irregularly shaped, ovoid or pear-shaped, usually 30 µm to 100 µm in size but occasionally exceeding 100 µm, or rounded, 10 µm to 35 µm in size. There are occasional compound granules having two to four components. The ovoid and pear-shaped granules have an eccentric hilum and the rounded granules acentric or slightly eccentric hilum. All granules show clearly visible concentric striations. Between orthogonally oriented polarizing plates or prisms, the granules show a distinct black cross intersecting at the hilum.

B. Suspend 1 g in 50 ml of *water* and boil for 1 minute and cool; a thin and cloudy mucilage is formed.

C. To 1 ml of the mucilage obtained in identification test B, add 0.05 ml of *iodine and potassium iodide solution*; an orange red to dark blue colour is produced, which disappears on heating.

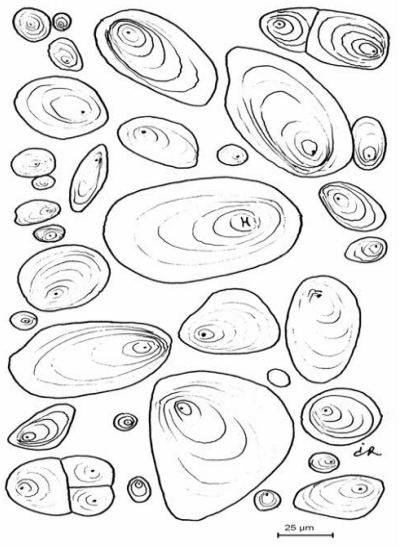

Fig.- Illustration for identification test A of potato starch

Tests

pH (2.4.24). 5.0 to 8.0, determined in a slurry prepared by shaking 5.0 g of substance under examination with 25.0 ml of *carbon dioxide-free water* for 1 minute and allow to stand for 15 minutes.

Iron (2.3.14). Shake 1.5 g of the substance under examination with 15 ml of *2 M hydrochloric acid*, and filter. 10 ml of the filtrate complies with the limit test for iron (10 ppm), using 1.0 ml of iron standard solution (10 ppm).

Sulphur dioxide (2.3.40). Not more than 50 ppm.

Oxidising substances. 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 minutes. Transfer to a glass-stoppered, 50-ml centrifuge tube, and centrifuge to clarify. Transfer 30.0 ml of the clear supernatant liquid to a glass-stoppered, 125-ml conical flask. Add 1 ml of *glacial acetic acid* and 0.5 g to 1.0 g of *potassium iodide*. Insert the stopper, swirl, and allow to stand for 25 minutes to 30 minutes in the dark. Add 1 ml of *starch solution* prepared by mixing 1 g of *soluble starch* with 10 mg of *red mercuric iodide* and add sufficient cold *water* to make a thin a paste. Add 200 ml of boiling *water* and boil for 1 minute with continuous stirring. Cool and use only the clear solution. Titrate with *0.002 M sodium thiosulphate* to the disappearance of the starch-iodine colour. Carry out a blank titration.

Each ml of *0.002 M sodium thiosulphate* is equivalent to 34 µg of oxidant, calculated as *hydrogen peroxide*.

Not more than 1.4 ml of *0.002 M sodium thiosulphate* is required (20 ppm, calculated as H_2O_2).

Microbial contamination (2.2.9). The total aerobic viable count is not more than 10^3 CFU per g; the total combined molds and yeasts count is not more than 10^2 CFU per g. 1 g is free from *Escherichia coli* and 10 g is free from *Salmonella species.*

Sulphated ash (2.3.18). Not more than 0.6 per cent.

Loss on drying (2.4.19). Not more than 20.0 per cent, determined on 1.0 g by drying in an oven at 130º for 90 minutes.

♦**Storage**. Store protected from moisture.

Labelling. Where Potato Starch is intended for use in preparing absorbable dusting powder, it is so labelled, and the label states that it must be subjected to further processing during the preparation of absorbable dusting powder. ♦

Solubility. Practically insoluble in cold *water* and in *ethanol (96 per cent).*