

Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Rice Starch

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This draft proposal contains general chapter text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to revisions before publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

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.	

Rice 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 (◆◆).

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

◆◆**Category.** Pharmaceutical aid.

Description. A very fine, white or almost white powder, which creaks when pressed between the fingers.

Rice starch does not contain starch granules of any other origin. It may contain traces of, if any, fragments of the endosperm tissue of the fruit. ◆

Identification

A. Microscopic examination (2.5.8), using a mixture of equal volume of *glycerin* and *water* as a mounting agent. It presents polyhedral, simple grains 1 µm to 10 µm (mostly 4 µm to 6 µm) in size. These simple grains often gather in ellipsoidal, compound grains 50 µm to 100 µm in diameter. The grains 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.

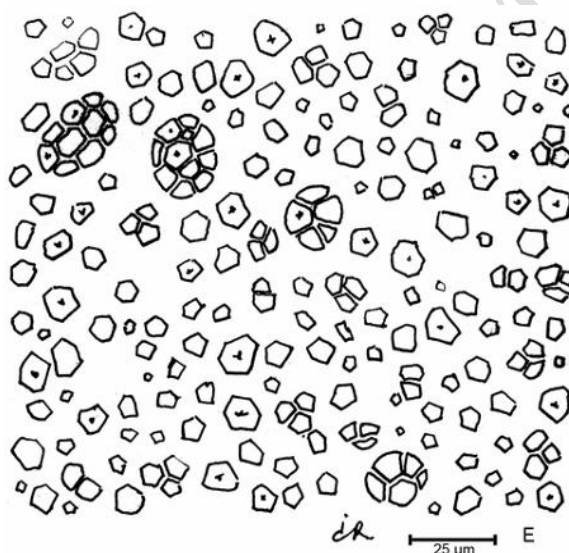


Fig. – Illustration for identification test A of rice starch.

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.

Tests

pH (2.4.24). 5.0 to 8.0, determined in 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. Transfer 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 H₂O₂).

Microbial contamination (2.2.9). The total aerobic viable count is not more than 10³ CFU per g; the total combined molds and yeasts count is not more than 10² 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 15.0 per cent, determined on 1.0 g by drying in an oven at 130° for 90 minutes.

◆**Storage**. Store protected from moisture. ◆

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

DRAFT FOR COMMENTS