



Edition: BP 2025 (Ph. Eur. 11.6 update)

## Rice Starch<sup>1</sup>



### [General Notices](#)

(Ph. Eur. monograph 0349)

### Action and use

Excipient.

When Starch is specified and the type is not indicated, Maize Starch, Potato Starch, Rice Starch, Wheat Starch or, in tropical countries where these are not available, Tapioca Starch may be supplied or used.

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## DEFINITION

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

## ◆ CHARACTERS

### Appearance

Very fine, white or almost white powder, which creaks when pressed between the fingers.

### Solubility

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

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 ([2.8.23](#)) using a 50 per cent V/V solution of [glycerol R](#). It presents polyhedral, simple grains 1-10 µm (mostly 4-6 µm) in size (Figure 0349.-1). These simple grains often gather in ellipsoidal, compound grains 50-100 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.

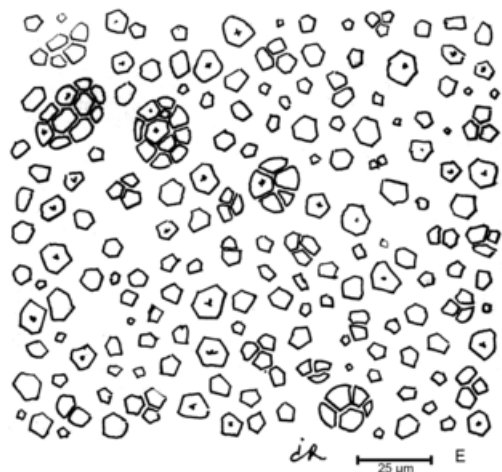


Figure 0349.-1. – Illustration for identification test A of rice starch

B. Suspend 1 g in 50 mL of [water R](#), boil for 1 min and cool. A thin, cloudy mucilage is formed.

C. To 1 mL of the mucilage obtained in identification test B add 0.05 mL of [iodine solution R1](#). An orange-red to dark blue colour is produced, which disappears on heating.

## TESTS

### [pH \(2.2.3\)](#)

5.0 to 8.0.

Shake 5.0 g with 25.0 mL of [carbon dioxide-free water R](#) for 60 s. Allow to stand for 15 min.

### ◆ Foreign matter

Examined under a microscope using a 50 per cent V/V solution of [glycerol R](#), not more than traces of matter other than starch granules are present. No starch granules of any other origin are present.◆

### [Oxidising substances \(2.5.30\)](#)

Maximum 20 ppm, calculated as H<sub>2</sub>O<sub>2</sub>.

### [Sulfur dioxide \(2.5.29\)](#)

Maximum 50 ppm.

### [Iron \(2.4.9\)](#)

Maximum 10 ppm.

Shake 1.5 g with 15 mL of [dilute hydrochloric acid R](#). Filter. The filtrate complies with the test.

### [Loss on drying \(2.2.32\)](#)

Maximum 15.0 per cent, determined on 1.00 g by drying in an oven at 130 °C for 90 min.

### [Sulfated ash \(2.4.14\)](#)

Maximum 0.6 per cent, determined on 1.0 g.

**Microbial contamination**

TAMC: acceptance criterion  $10^3$  CFU/g ([2.6.12](#)).

TYMC: acceptance criterion  $10^2$  CFU/g ([2.6.12](#)).

Absence of *Escherichia coli* ([2.6.13](#)).

◇ Absence of *Salmonella* ([2.6.13](#)).◇

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<sup>1</sup> This monograph has undergone pharmacopoeial harmonisation. See chapter [5.8 Pharmacopoeial harmonisation](#).