

**Roquette India Pvt.Ltd. Gokak**

**MAIZE STARCH IP**

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Starch consists of polysaccharide granules obtained from the caryopsis of maize or corn, *Zea mays* Linn. (family Poaceae).

**Reference:-**IP 2018 page No.3867 & 3868

**Category:** - Pharmaceutical aid.

**Description**

A very fine, white or slightly yellowish powder or irregular white masses which are readily reducible to powder, creaks when pressed between the fingers; odourless and tasteless. The presence of granules showing cracks or edge irregularities.

**Solubility**

Practically insoluble in cold water and in ethanol (95%)

**Identification**

- A. Corn or maize starch-Polyhedral granules, 2 to 23  $\mu\text{m}$  in size, or rounded granules, 25 to 32  $\mu\text{m}$  in diameter. The central hilum consists of a distinct cavity or two to five-rayed cleft; no concentric striations. Viewed between crossed nicol prisms, a distinct black cross is seen intersecting at the helium.
- B. Heat to boiling for 1 minute a suspension of 1 g in 50 ml of water and cool; a thin and cloudy mucilage is produced.
- C. To 10 ml of the mucilage obtained in test B add 0.05 ml of 0.01 M iodine, a dark blue colour is produced, which disappears on heating and reappears on cooling.

## **SPECIFICATIONS**

### TESTS

Acidity	Add 10 g to 100 ml of ethanol (70 %) previously neutralized to phenolphthalein solution, shake for 1 hr, filter and titrate 50 ml of the filtrate with 0.1 M sodium hydroxide. Not more than 2.0 ml is required to change the colour of the solution.
Iron	Dissolve the residue obtained in the test for sulphated ash in 4 ml of hydrochloric acid with the aid of gentle heat, dilute with water to 50 ml and mix; 25ml of the resulting solution complies with the limit test for iron (40ppm)
Fluorescence	No fluorescence should be visible under screened ultra-violet light.
Oxidizing substance	To 5.0g and 10ml of water and 1 ml of acidic and stir until a homogeneous suspension is obtained. Add 0.5ml of a freshly prepared saturated solution of potassium iodide, mix and allow to stand for 5 minutes; no distinct brown or blue colour is observed.
Microbial Contamination	1.0 g is free from Escherichia Coli and 10.0g is free from Salmonella and Shigella.
Sulphated Ash	Not more than 0.6 %, determined on 2.0g
Loss on Drying	Not more than 15.0 %, determined on 0.2 g by drying in an oven at 105°C.
Storage	Store protected from light and moisture.
Labeling	The label states the type of starch

## **CONFORMITY**

Indian Pharmacopoeia 2018, Page no: 3867 & 3868

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**PACKING**

Valve mouth or open mouth PP/Paper bag with 25 kg capacity

**Net Weight: - 25.0 kg**

**Gross Weight:-**

Shelf life of packed product: 2 years from date of manufacture.

**Method of analysis:** - as per Indian Pharmacopoeia 2018

<b>Revision History:</b>		
Revision No.	Date of revision	Reason for revision
0	First issue(07.11.2016)	NA
1	03.04.2018	Addition of Solubility test as per customer requirement
2	19.04.19	Specification revised as per IP 2018 monograph. Document No.revised as per Roquette document control procedure & coded .Prepared & approved revised.



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