

**PRODUCT SPECIFICATION SHEET
MAIZE STARCH EXTRA WHITE**

Definition

Product identifier

Product name: MAIZE STARCH EXTRA WHITE

Specifications

Description (characters)

Maize starch is obtained from the caryopsis of Zea mays L.

Aspect	Very fine powder
Colour	White
Solubility	Practically insoluble in cold water and in ethanol 96%.

Identification

Identification test A	EP, NF	Complies
Identification test B	EP, NF	Complies
Identification test C	EP, NF	Complies
Identification test 1	JP, ChP	Complies
Identification test 2	JP, ChP	Complies
Identification test 3	JP, ChP	Complies

Physical and chemical values (tests)

Loss on drying	EP, NF, JP	15,0 %(w/w) max.
Loss on drying	ChP	14,0 %(w/w) max.
pH	EP, NF, JP	4,0 - 7,0
pH	ChP	4,5 - 7,0
Sulphated ash	EP, NF, JP, ChP	0,6 %(w/w) max.
Oxidizing substances	EP, NF, JP, ChP	20 mg/kg max.
SO₂	EP, NF, JP	50 mg/kg max.
SO₂	ChP	40 mg/kg max.
Iron	EP, NF, JP, ChP	10 mg/kg max.
Heavy metals	ChP	20 mg/kg max.
Foreign matter	EP, JP, ChP	Complies
Sieve grain size fraction		
- Residue on 200 µm		0,1 % max.

Microbiological values

Total aerobic microbial count	EP / NF / ChP	1 000 /g max.
Total yeasts and moulds count	EP / NF / ChP	100 /g max.
Escherichia coli	EP / NF / ChP	Not detected in 1g
Salmonella	EP	Not detected in 10g

Additional data

Comments

Methods used by ROQUETTE may be the Pharmacopoeia methods or alternative validated methods.

Caption :

- EP stands for European Pharmacopoeia
- NF stands for National Formulary from USP - NF
- JP stands for Japanese Pharmacopoeia
- ChP stands for Chinese Pharmacopoeia

Not intended for use in manufacture of parenteral dosage forms.

Conformity

Legislation / specific regulations

Meets the requirements of the current monograph of:

- European Pharmacopoeia : MAIZE STARCH (0344)
- National Formulary from USP - NF : CORN STARCH
- Japanese Pharmacopoeia : CORN STARCH
- Chinese Pharmacopoeia : MAIZE STARCH

Please contact us for any question regarding compliance to the General Chapters (elemental impurities, residual solvents organic volatile impurities, metal catalyst, metal reagent).

Storage

Storage conditions	The product durability may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA.
Storage conditions for PACK material	We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations in temperature and humidity. Upon opening, use the product as quickly as possible to prevent moisture regain.
Expiry date of the packed product	Manufacturing date + 5 years, in its unopened packaging.

Disclaimer

The information provided in this Product Specification Sheet relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. Analytical criteria are tested either on each batch or monitored or guaranteed, based on the Product Risk Analysis. For each batch, the status of the analysis may be indicated in the Certificate of Analysis. All information and instructions provided in this Product Specification Sheet are based on the current state of our knowledge at the latest revision date indicated. It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession ,handling and use.