

**PRODUCT SPECIFICATION SHEET
MAIZE STARCH B**

Definition

Product identifier

Product name: MAIZE STARCH B

Specifications

Description (characters)

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

Aspect	Very fine powder which creaks when pressed between the fingers.
Colour	White to slightly yellowish
Solubility	Practically insoluble in cold water and in ethanol 96%.

Identification

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

Physical and chemical values

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

Microbiological values

Total aerobic microbial count	EP, USP-NF	1 000 /g max.
Total yeasts and moulds count	EP, USP-NF	100 /g max.
Escherichia coli	EP, USP-NF	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
- USP-NF stands for USP-NF Pharmacopoeia
- JP stands for Japanese Pharmacopoeia

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

When tested accordingly, this product complies with relevant monograph requirements. The compliance to the general chapters depends on plant manufacturing standards. This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharma cGMPs . Please contact us for further information.

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

SPECIFIC DISCLAIMER

Not intended for use in manufacture of parenteral dosage forms, nor preparation for dialysis.

GENERAL 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.

Typical values are made available to the purchaser on an informational basis. No warranty, whether expressed or implied, or guarantee of those values is intended or implied.

The ultimate use of this Product in any finished product is the responsibility of the purchaser. This Product may have restrictions with respect to its use and/or usage levels, and such may vary on a country-by-country basis. The purchaser is responsible for its use of the Product and for its finished product, and that any claims made regarding its use of the Product and/or the finished product comply with applicable laws and regulations.