

PRODUCT SPECIFICATIONS SHEET

MAIZE STARCH B

Definition

Product Identifier

Product name: MAIZE STARCH B

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

Specifications

A) CHARACTERS

APPEARANCE	Very fine matt powder that creaks when pressed between the fingers
COLOUR	White to slightly yellowish
SOLUBILITY	Practically insoluble in cold water and in ethanol 96%

B) 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

C) TESTS

LOSS ON DRYING	EP-USP/NF-JP	15.0 % max.
FOREIGN MATTER(*)	EP - JP	Complies.
OXIDIZING SUBSTANCES(as H2O2)	EP-USP/NF-JP	20 mg/Kg max.
S02	EP-USP/NF-JP	50 mg/Kg max.
IRON	EP-USP/NF-JP	10 mg/Kg max.
pH	EP-USP/NF-JP	4.0 - 7.0
SULFATED ASH	EP-USP/NF-JP	0.6 % max.
PARTICLE SIZE:		
- RESIDUE ON 200 MICRONS		0.1 % max.

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MICROBIOLOGICAL VALUES :

TOTAL AEROBIC MICROBIAL COUNT	EP-USP/NF	1000 CFU/g max.
TOTAL YEASTS AND MOULDS COUNT	EP-USP/NF	100 CFU/g max.
ESCHERICHIA COLI	EP-USP/NF	Not detected in 10g
SALMONELLA	EP	Not detected in 10g

- * Compliance data - Tests not performed
- ** Monitoring plan

Comments

Methods used by ROQUETTE may be the Pharmacopoeia methods or alternative validated methods which have been compared to the Pharmacopoeia methods.

Caption

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

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

Conformity

Meets the requirements of the current monograph of

- **European Pharmacopoeia** MAIZE STARCH (0344)
- **USP - NF Pharmacopoeai** 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

The product durability may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA. 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 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



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when such product is used in combination with other materials or in any process.

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.

Notes : All the dates are formatted like YYYY/MM/DD.