

MAIZE STARCH 5%

Definition

Product Identifier

Product name: MAIZE STARCH 5%

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

INCI : ZEA MAYS STARCH

Specifications

A) CHARACTERS

APPEARANCE	White or almost white powder.
SOLUBILITY	Insoluble in water or in ethanol.

B) IDENTIFICATION

IDENTIFICATION TEST-1(*)	ChP	Complies
IDENTIFICATION TEST-2(*)	ChP	Complies
IDENTIFICATION TEST-3(*)	ChP	Complies

C) TESTS

ACIDITY (pH)	ChP	5.0 - 8.0
FOREIGN MATTER(*)	ChP	Complies
SULFUR DIOXIDE	ChP	0.004 % max.
OXIDIZING SUBSTANCES	ChP	0.002 % max.
LOSS ON DRYING	ChP	14.0 % max.
LOSS ON DRYING	Internal Spec.	5.0 % max.
ASH	ChP	0.3 % max.
HEAVY METALS(*)	ChP	0.002 % max.
IRON	ChP	0.001 % max.
PARTICLE SIZE (sieve)		
- RESIDUE on 200 microns		0.1 % max.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT	ChP	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS	ChP	100 CFU/g max.
- ESCHERICHIA COLI	ChP	Not detected in 1g
- SALMONELLA		Not detected in 10g

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Comments

Not intended for use in manufacture of parenteral dosage forms.

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

Caption

- "ChP" stands for Chinese Pharmacopoeia
- (*) Compliance data - Tests not performed

Conformity

Conforms to the requirements of the current monograph

- Chinese Pharmacopoeia (ChP) Maize Starch

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

Storage

Expiry date Manufacturing date + 5 years, in its unopened packaging.

- 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 of temperature and humidity.
- Upon opening, use the product as quickly as possible to prevent moisture regain.

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.

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.