

MAIZE STARCH 5%

Definition

Product Identifier

Product name: MAIZE STARCH 5%

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

CAS n° : 9005-25-8

INCI : ZEA MAYS STARCH

Specifications

A) CHARACTERS

APPEARANCE

Matt, white to slightly yellowish, very fine powder that creaks when pressed between the fingers.

SOLUBILITY

Practically insoluble in cold water and in ethanol 96%

B) IDENTIFICATION

IDENTIFICATION TEST-A(*)	EP-USP/NF-JP	Complies
IDENTIFICATION TEST-B(*)	EP-USP/NF-JP	Complies
IDENTIFICATION TEST-C(*)	EP-USP/NF-JP	Complies

C) TESTS

pH	EP-USP/NF-JP	4.0 - 7.0
FOREIGN MATTER(*)	EP-JP	Complies
OXIDIZING SUBSTANCES(as H2O2)	EP-USP/NF-JP	20 ppm max.
SULFUR DIOXIDE	EP-USP/NF-JP	50 ppm max.
IRON	EP-USP/NF-JP	10 ppm max.
LOSS ON DRYING	EP-USP/NF-JP	15.0 % max.
LOSS ON DRYING	Internal Spec.	5.0 % max.
SULFATED ASH	EP-USP/NF-JP	0.6 % max.
PARTICLE SIZE:		
- RESIDUE ON 200 MIC.		0.1 % max.

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MICROBIAL CONTAMINATION:

- TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	100 CFU/g max.
- ESCHERICHIA COLI(**)	Absence in 10g.
- SALMONELLA(**)	Absence in 10g.

Comments

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

Regarding any compliance referred to in the General Chapters of the Pharmacopoeias (elemental impurities, residual solvents, organic volatile impurities, metal catalyst, metal reagent), statements are available on request.

Conformity

Current Pharmacopoeias EP(0344) - USP/NF and JP

Storage

We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations in temperature and humidity.

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

RETEST DATE

ROQUETTE recommends retesting for Loss on Drying after one year.

- * Compliance data - Tests not performed

- ** Monitoring plan

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.