

## ROQUETTE AMIDO DI MAIS AMYLO N-400

### Definition

#### Product Identifier

**Product name:** ROQUETTE AMIDO DI MAIS AMYLO N-400

ROQUETTE AMIDO DI MAIS AMYLO N-400 is a high amylose maize starch.

CAS n° : 9005-25-8

Characters: Very fine white to off-white powder.

### Specifications

#### A) IDENTIFICATION

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

#### B) TESTS

pH	EP - USP/NF	4.0 - 7.0
FOREIGN MATTER(*)	EP	Complies
LOSS ON DRYING	EP - USP/NF	15.0 % max.
SULPHATED ASH	EP - USP/NF	0.6 % max.
IRON(**)	EP - USP/NF	10 ppm max.
OXIDIZING SUBSTANCES(as H <sub>2</sub> O <sub>2</sub> )	EP - USP/NF	20 ppm max.
SO <sub>2</sub>	EP - USP/NF	50 ppm max.
TOTAL COUNT		1000 CFU/g max.
YEASTS AND MOULDS		100 CFU/g max.
ESCHERICHIA COLI		Abs.in 1 g
SALMONELLA		Abs.in 10 g

### 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** E.P. and USP/NF.

## ROQUETTE AMIDO DI MAIS AMYLO N-400

### Storage

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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.

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

### Disclaimer

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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.