

PRODUCT SPECIFICATIONS SHEET

POTATO STARCH SUPRA NP BACTERIOLOGICAL

Definition

Product Identifier

Product name: POTATO STARCH SUPRA NP BACTERIOLOGICAL

Potato starch is obtained from the tuber of " SOLANUM TUBEROSUM L.".

Specifications

A)CHARACTERS:

APPEARANCE	Very fine, white or almost white powder which creaks when pressed between the fingers.
SOLUBILITY	Practically insoluble in cold water and in ethanol 96%.

B)IDENTIFICATION:

IDENTIFICATION TEST-A(*)	EP/NF	COMPLIES
IDENTIFICATION TEST-B(*)	EP/NF	COMPLIES
IDENTIFICATION TEST-C(*)	EP/NF	COMPLIES
IDENTIFICATION TEST-1(*)	JP/ChP	COMPLIES
IDENTIFICATION TEST-2(*)	JP/ChP	COMPLIES
IDENTIFICATION TEST-3(*)	JP/ChP	COMPLIES

C)TESTS:

FOREIGN MATTER(*)	EP/JP/ChP	COMPLIES
ACIDITY and ALCALINITY (pH)	ChP	5.0 - 8.0
pH	EP/NF/JP	5.0 - 8.0
SULFUR DIOXIDE	EP/NF/JP/ChP	50 mg/kg max.
OXIDISING SUBSTANCES-H2O2	EP/NF/JP/ChP	20 mg/kg max.
LOSS ON DRYING	EP/NF/JP/ChP	20.0 % max.
SULFATED ASH	EP/NF/JP	0.6 % max.
RESIDUE ON IGNITION	ChP	0.6 % max.
IRON	EP/NF/JP/ChP	10 mg/kg max.
HEAVY METALS(*)	ChP	20 mg/kg max.
PARTICLE SIZE (Sieve)		
- RESIDUE ON 200 microns		0.1 % max.

MICROBIOLOGICAL VALUES:

- TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.
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- TOTAL YEASTS & MOLDS COUNT	100 CFU/g max.
- ESCHERICHIA COLI	Not detected in 1g
- SALMONELLA	Not detected in 10g

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

- "EP" stands for European Pharmacopoeia
- "NF" stands for National Formulary from USP-NF
- "JP" stands for Japanese Pharmacopoeia
- "ChP" stands for Chinese Pharmacopoeia
- (*) Compliance data - Tests not performed

Conformity

Conforms to the requirements of the current monograph

- **European Pharmacopoeia (EP)** POTATO STARCH (0355)
- **National Formulary from USP-NF** POTATO STARCH
- **Japanese Pharmacopoeia (JP)** POTATO STARCH
- **Chinese Pharmacopoeia (ChP)** POTATO 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

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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.