

PRODUCT SPECIFICATIONS SHEET

**WHEAT STARCH TB**

Definition

Product Identifier

**Product name:** WHEAT STARCH TB

WHEAT STARCH is obtained from the caryopsis of Triticum aestivum L.  
INCI: TRITICUM VULGARE STARCH

Specifications

**A) CHARACTERS**

<b>APPEARANCE</b>	Very fine, white or almost white powder that creaks when pressed between the fingers.
<b>SOLUBILITY</b>	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	COMPLIES
IDENTIFICATION TEST-2(*)	JP	COMPLIES
IDENTIFICATION TEST-3(*)	JP	COMPLIES

**C) TESTS**

pH	EP / NF / JP	4.5 - 7.0
FOREIGN MATTER(*)	EP / JP	COMPLIES
TOTAL PROTEIN	EP / NF / JP	0.3 % max.
OXIDISING SUBSTANCES(as H2O2)	EP / NF / JP	20 mg/kg max.
SULFUR DIOXIDE	EP / NF / JP	50 mg/kg max.
IRON	EP / NF / JP	10 mg/kg max.
LOSS ON DRYING	EP / NF / JP	15.0 % max.
SULPHATED ASH	EP / NF / JP	0.6 % max
PARTICLE SIZE (sieve)		
- RESIDUE on 200 MICRONS		0.1 % max.
<b>MICROBIOLOGICAL VALUES:</b>		
- TOTAL AEROBIC MICROBIAL COUNT	EP	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	EP	100 CFU/g max.

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- <b>ESCHERICHIA COLI</b>	EP	Not detected in 1g
- <b>SALMONELLA</b>	EP	Not detected in 10g

Comments

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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 JP Pharmacopoeia
- (\*) Compliance data - Tests not performed

Conformity

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Conforms to the requirements of the current monograph

- **European Pharmacopoeia (EP)** WHEAT STARCH (0359)
- **National Formulary (NF) from USP-NF** Wheat Starch
- **Japanese Pharmacopoeia (JP)** Wheat 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

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**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



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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.