

**PRODUCT SPECIFICATION SHEET  
POTATO STARCH SUPRA NP BACTERIOLOGICAL**

**Definition**

**Product identifier**

**Product name:** POTATO STARCH SUPRA NP BACTERIOLOGICAL

**Specifications**

**Description (characters)**

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

<b>Aspect</b>	Very fine matt powder which creaks when pressed between the fingers.
<b>Colour</b>	White or almost white
<b>Solubility</b>	Practically insoluble in cold water and in ethanol 96%.

**Identification**

<b>Identification test A</b>	EP, USP-NF	Complies
<b>Identification test B</b>	EP, USP-NF	Complies
<b>Identification test C</b>	EP, USP-NF	Complies
<b>Identification test 1</b>	JP, ChP	Complies
<b>Identification test 2</b>	JP, ChP	Complies
<b>Identification test 3</b>	JP, ChP	Complies

**Physical and chemical values (tests)**

<b>Loss on drying</b>	EP, USP-NF, JP, ChP	20,0 %(w/w) max.
<b>pH at 20% (W/W)</b>	EP, USP-NF, JP, ChP	5,0 - 8,0
<b>Residue on ignition</b>	USP-NF, JP, ChP	0,6 %(w/w) max.
<b>Sulphated ash</b>	EP	0,6 %(w/w) max.
<b>Oxidizing substances</b>	EP, USP-NF, JP, ChP	20 mg/kg max.
<b>SO<sub>2</sub></b>	EP, USP-NF, JP, ChP	50 mg/kg max.
<b>Iron</b>	EP, USP-NF, JP, ChP	10 mg/kg max.
<b>Heavy metals</b>	ChP	20 mg/kg max.
<b>Foreign matter</b>	EP, JP, ChP	Complies
<b>Sieve grain size fraction</b>		
- Residue on 200 µm		0,1 % max.

## Microbiological values

<b>Total aerobic microbial count</b>	EP, USP-NF, ChP	1 000 /g max.
<b>Total yeasts and moulds count</b>	EP, USP-NF, ChP	100 /g max.
<b>Escherichia coli</b>	EP, USP-NF, ChP	Not detected in 1g
<b>Salmonella</b>	EP	Not detected in 10g

## Additional data

### Comments

Methods used by ROQUETTE may be the Pharmacopoeia methods or alternative validated methods.

Caption :

- EP stands for European Pharmacopoeia
- USP-NF stands for USP-NF Pharmacopoeia
- JP stands for Japanese Pharmacopoeia
- ChP stands for Chinese Pharmacopoeia

## Conformity

### Legislation / specific regulations

Meets the requirements of the current monograph of:

- European Pharmacopoeia : POTATO STARCH (0355)
- USP-NF Pharmacopoeia : POTATO STARCH
- Japanese Pharmacopoeia : POTATO STARCH
- Chinese Pharmacopoeia : POTATO STARCH

When tested accordingly, this product complies with relevant monograph requirements. The compliance to the general chapters depends on plant manufacturing standards. This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharma cGMPs . Please contact us for further information.

## Storage

<b>Storage conditions</b>	The product durability may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA.
<b>Storage conditions for PACK material</b>	We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations in temperature and humidity. Upon opening, use the product as quickly as possible to prevent moisture regain.
<b>Expiry date of the packed product</b>	Manufacturing date + 5 years, in its unopened packaging.

## ***Disclaimer***

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### **SPECIFIC DISCLAIMER**

Not intended for use in manufacture of parenteral dosage forms, nor preparation for dialysis.

### **GENERAL 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. Analytical criteria are tested either on each batch or monitored or guaranteed, based on the Product Risk Analysis. For each batch, the status of the analysis may be indicated in the Certificate of Analysis. 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. The ultimate use of this Product in any finished product is the responsibility of the purchaser. This Product may have restrictions with respect to its use and/or usage levels, and such may vary on a country-by-country basis. The purchaser is responsible for its use of the Product and for its finished product, and that any claims made regarding its use of the Product and/or the finished product comply with applicable laws and regulations.