

PRODUCT SPECIFICATIONS SHEET

**LYCAGEL® VS 720**

Definition

Product Identifier

**Product name:** LYCAGEL® VS 720

HYDROXYPROPYL STARCH.

Specifications

**A) CHARACTERS**

<b>APPEARANCE:</b>	White or slightly yellowish powder.
<b>SOLUBILITY:</b>	Practically insoluble in cold water and in ethanol.

**B) IDENTIFICATION**

IDENTIFICATION TEST-A(*)	EP / NF	COMPLIES
IDENTIFICATION TEST-B(*)	EP / NF	COMPLIES
IDENTIFICATION TEST-C(*)	EP / NF	COMPLIES
IDENTIFICATION TEST-D(*)	EP / NF	COMPLIES

**C) TESTS**

HYDROXYPROPYL GROUP	EP	0.5 - 7.0 %
HYDROXYPROPYL GROUP	NF	2.0 - 7.0 %
pH	EP / NF	4.5 - 8.0
OXIDISING SUBSTANCES (H2O2)	EP / NF	20 mg/kg max.
SULFUR DIOXIDE	EP / NF	50 mg/kg max.
IRON(**)	EP / NF	50 mg/kg max.
LOSS ON DRYING	EP / NF	15.0 % max.
SULFATED ASH	EP / NF	0.6 % max.
FOREIGN MATTER(*)	EP / NF	COMPLIES
<b>MICROBIOLOGICAL VALUES:</b>		
- TOTAL AEROBIC MICROBIAL COUNT	EP / NF	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	EP / NF	100 CFU/g max.
- ESCHERICHIA COLI	EP / NF	Not detected in 1g

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- SALMONELLA

EP / NF

Not detected in 10g

## Comments

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

## Conformity

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### Conforms to the requirements of the current monograph

- **European Pharmacopoeia (EP)** STARCH, HYDROXYPROPYL (2165)
- **National Formulary (NF)** HYDROXYPROPYL PEA 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 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.