

PRODUCT SPECIFICATIONS SHEET

LYCATAB® PGS

Definition

Product Identifier

Product name: LYCATAB® PGS

STARCH, PREGELATINISED (EP) - PREGELATINIZED STARCH (NF) -
PREGELATINIZED STARCH (ChP)

Pregelatinised starch is prepared from Maize starch.

Specifications

A) CHARACTERS

APPEARANCE White or yellowish-white powder. It swells in cold water.

B) IDENTIFICATION

IDENTIFICATION TEST-A(*)	EP	Complies
IDENTIFICATION TEST-B(*)	EP	Complies
IDENTIFICATION TEST(*)	NF	Complies
IDENTIFICATION TEST-1(*)	ChP	Complies
IDENTIFICATION TEST-2(*)	ChP	Complies
IDENTIFICATION TEST-3(*)	ChP	Complies

C) TESTS

pH	EP/NF/ChP	4.5 - 7.0
OXIDISING SUBSTANCES	EP/NF/ChP	Complies
SULFUR DIOXIDE(**)	EP	50 mg/kg max.
SULFUR DIOXIDE(**)	NF	80 mg/kg max.
SULFUR DIOXIDE(**)	ChP	40 mg/kg max.
IRON(**)	EP/NF/ChP	20 mg/kg max.
FOREIGN MATTER(*)	EP	Complies
LOSS ON DRYING	EP	15.0 % max.
LOSS ON DRYING	NF/ChP	14.0 % max.
SULFATED ASH(**)	EP	0.6 % max.
RESIDUE ON IGNITION(**)	NF/ChP	0.5 % max.
HEAVY METALS(**)	ChP	20 mg/kg max.
PARTICLE SIZE :		
- RESIDUE ON 315 microns		20 % max.

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- RESIDUE ON 80 microns	50 % min.
MICROBIOLOGICAL VALUES:	
- TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	100 CFU/g max.
- ESCHERICHIA COLI(**)	Not detected in 1g
- SALMONELLA(**)	Not detected in 10g

Indicatives Values

Water-soluble substances (on DS)	Chp	7.4 %
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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
- "ChP" stands for Chinese Pharmacopoeia
- (*) Compliance data - Tests not performed
- (**) Monitoring plan

Conformity

Conforms to the requirements of the current monograph

- **European Pharmacopoeia (EP)** STARCH, PREGELATINIZED (1267)
- **National Formulary from USP-NF** Pregelatinized Starch
- **Chinese Pharmacopoeia (ChP)** Pregelatinized 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.



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- 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

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.