

PRODUCT SPECIFICATIONS SHEET

LYCATAB® CT

Definition

Product Identifier

Product name: LYCATAB® CT

STARCH, PREGELATINISED (EP) - PREGELATINIZED STARCH (NF)
 PREGELATINIZED STARCH (ChP) - PREGELATINIZED STARCH (JPE)
 Pregelatinised starch prepared from maize starch.

Specifications

A) CHARACTERS

APPEARANCE Moderately coarse to fine, white to off-white, powder.
ODOUR Odourless.

B) IDENTIFICATION

IDENTIFICATION TESTS Complies

C) TESTS

LOSS ON DRYING	13.0 % max.
pH	4.5 - 7.0
RESIDUE ON IGNITION	0.5 % max.
IRON	10 mg/kg max.
OXIDISING SUBSTANCES	Complies
SULFUR DIOXIDE	10 mg/kg max.
SULPHUROUS ACID	0.003 % max.
HEAVY METALS	20 mg/kg max.
ARSENIC	3 mg/kg max.
FOREIGN MATTER	Complies
BULK DENSITY	0.55 - 0.75 g/mL
TAP DENSITY	0.70 - 1.05 g/mL
COLD WATER SOLUBLES	10 - 20 %
PROTEIN CONTENT	0.5 % max
PARTICLE SIZE :	
- RESIDUE ON 8 MESH	0 % max.
- RESIDUE ON 40 MESH	0.5 % max.
- RESIDUE ON 100 MESH	10.0 % max.

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- RESIDUE ON 270 MESH	75.0 % max.
MICROBIOLOGICAL VALUES:	
- TOTAL AEROBIC MICROBIAL COUNT	500 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	100 CFU/g max.
- ESCHERICHIA COLI	Not detected in 1g
- PSEUDOMONAS AERUGINOSA	Not detected in 1g
- SALMONELLA	Not detected in 10g
- STAPHYLOCOCCUS AUREUS	Not detected in 1g

Comments

Methods used by Roquette may be the Pharmacopoeia methods or alternative validated methods which have been compared to the Pharmacopoeia methods.

Conformity

Conforms to the requirements of the current monograph

- **European Pharmacopoeia** STARCH, PREGELATINISED (1267)
- **USP-NF Pharmacopoeia** Pregelatinized Starch
- **Chinese Pharmacopoeia (ChP)** Pregelatinized Starch
- **JPE** PREGELATINIZED STARCH

Please contact us for any statement regarding compliance to the General Chapters (elemental impurities, residual solvent, organic volatile impurities, metal catalyst, metal reagent).

Storage

Store in dry area in original well-closed containers.

Retest date manufacturing date + 60 months.



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Disclaimer

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.