

LYCATAB CT

Definition

Product Identifier

Product name: LYCATAB CT

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

Pregelatinised starch prepared from maize starch.

CAS No. 9005-25-8

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

14.0 % 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.

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.

- RESIDUE ON 270 MESH

75.0 % max.

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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 pharmacopeia methods or alternative validated methods which have been compared to the pharmacopeia methods.

Conformity

Complies with USP-NF and Ph. Eur.monograph requirements.

Please contact us for any statement regarding compliance to the general chapter (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.

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.