

LYCATAB® DSH

Definition

Product Identifier

Product name: LYCATAB® DSH

MALTODEXTRIN (EP) - MALTODEXTRIN (NF)

Mixture of glucose, disaccharides and polysaccharides, obtained by the partial hydrolysis of starch.

CAS n° : 9050-36-6

INCI : MALTODEXTRIN

Specifications

A) CHARACTERS

| | |
|------------|--|
| APPEARANCE | White or almost white, slightly hygroscopic powder or granules |
| SOLUBILITY | Freely soluble in water |

B) IDENTIFICATION

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

C) TESTS

| | | |
|--------------------------|-------------|---------------|
| pH | EP / USP-NF | 4.0 - 7.0 |
| SULFUR DIOXIDE | EP | 20 mg/kg max. |
| SULFUR DIOXIDE | USP-NF | 40 mg/kg max. |
| LOSS ON DRYING | EP / USP-NF | 6.0 % max. |
| SULFATED ASH(*) | EP | 0.5 % max. |
| RESIDUE ON IGNITION(*) | USP-NF | 0.5 % max. |
| DEXTROSE EQUIVALENT(DE) | EP / USP-NF | 11 - 14 |
| PROTEIN CONTENT(*) | USP-NF | 0.1 % max. |
| PARTICLE SIZE(sieve) | | |
| - RESIDUE ON 200 microns | | 15 % max. |

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| | |
|---------------------------------|---------------------|
| - RESIDUE ON 45 microns | 80 % 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 10g |
| - SALMONELLA(**) | Not detected in 10g |

Indicatives Values

Poured bulk density : 500 g/l approx.

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 current edition of

- European Pharmacopoeia (EP)
- National Formulary (NF)

Regarding any compliance referred to in the General Chapters of the Pharmacopoeias (elemental impurities, residual solvents, organic volatile impurities, metal catalyst, metal reagent), statements are available on request.

Storage

We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations in temperature and humidity.

Expiry date Manufacturing date + 5 years, in its unopened packaging.

- * Compliance data - Tests not performed
- ** Monitoring plan

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.