PRODUCT SPECIFICATIONS SHEET

KLEPTOSE® LINECAPS 17 - MALTODEXTRIN

Definition

Product Identifier

Product name: KLEPTOSE® LINECAPS 17 - MALTODEXTRIN

Powder maltodextrin with DE nominal value of 17.
Blend of carbohydrates, obtained by controlled enzymatic hydrolysis of pea starch, spray dried.
INCI : MALTODEXTRIN

Specifications

A) CHARACTERS

APPEARANCE		White or almost white slightly hygroscopic powder
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	EP/USP-NF	15 - 20
PROTEIN CONTENT(*)	USP-NF	0.1 % max.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT	EP	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	EP	100 CFU/g max.
- ESCHERICHIA COLI	EP/USP-NF	Not detected 1g.

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- SALMONELLA(**)	EP/USP-NF	Not detected 10g.

Comments

Due to a few rare reported allergic reactions with pea (and their derived products), we strongly suggest to our customers to list the botanical origin of their pea derived products in their ingredient statement.

Caption

- "EP" stands for European Pharmacopoeia
- "USP-NF" stands for USP-NF Pharmacopeia
- (*) Compliance data - Tests not performed
- (**) Monitoring plan

Conformity

Conforms to the requirements of the current monograph

- European Pharmacopoeia MALTODEXTRIN (1542)
- USP-NF Pharmacopeia MALTODEXTRIN

When tested accordingly, this product complies with relevant monograph requirements. The compliance to the general chapters depends on plant manufacturing standards.

Storage

Expiry date of the packaged product manufacturing date + 5 years.

The product durability may very according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA.

We recommend preserving 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.

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Disclaimer

SPECIFIC DISCLAIMER:

Not intended for use in manufacture of parenteral dosage form, nor preparation for dialysis.
This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharma cGMPs.
Please contact us for further information.

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.