

GLUCIDEX® 9

Definition

Product Identifier

Product name: GLUCIDEX® 9

MALTODEXTRIN (EP) - MALTODEXTRIN (NF)

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

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 / NF	4.0 - 7.0
SULFUR DIOXIDE	EP	20 mg/kg max.
SULFUR DIOXIDE	NF	40 mg/kg max.
LOSS ON DRYING	EP / NF	6.0 % max.
SULFATED ASH(*)	EP	0.5 % max.
RESIDUE ON IGNITION(*)	NF	0.5 % max.
DEXTROSE EQUIVALENT(DE)	EP / NF	8 - 10
PROTEIN CONTENT(*)	NF	0.1 % max.
		PARTICLE SIZE (Sieve)
- RESIDUE ON 250 Microns		10 % max.
- RESIDUE ON 40 Microns		50 % min.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT		1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT		100 CFU/g max.

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- ESCHERICHIA COLI(**)	Not detected in 1g
- SALMONELLA(**)	Not detected in 10g

Indicatives Values

Poured bulk density	450 g/l approx.
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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
- (*) Compliance data - Tests not performed
- (**) Monitoring plan

Conformity

Conforms to the current edition of

- **European Pharmacopoeia** MALTODEXTRIN (1542)
- **National Formulary from USP-NF** MALTODEXTRIN

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.
- 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.



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PRODUCT SPECIFICATIONS SHEET

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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.