

LYCASIN® 80/55-MALTITOL SYRUP

Definition

Product Identifier

Product name: LYCASIN® 80/55-MALTITOL SYRUP

Aqueous solution of a hydrogenated, partly hydrolysed starch, composed of a mixture of mainly D-maltitol with D-sorbitol and hydrogenated oligo - and polysaccharides.

INCI: HYDROGENATED STARCH HYDROLYSATE

Specifications

A) CHARACTERS

APPEARANCE	Clear, colourless, syrupy liquid
SOLUBILITY	Miscible with water and with glycerol

B) IDENTIFICATION

IDENTIFICATION TEST-A	EP	COMPLIES
IDENTIFICATION TEST-A(*)	NF	COMPLIES
IDENTIFICATION TEST-B	NF	COMPLIES
IDENTIFICATION TEST-C(**)	NF	COMPLIES

C) TESTS

D-MALTITOL on DS	EP / NF	50.0 % min.
D-SORBITOL on DS	EP / NF	8.0 % max.
APPEARANCE OF SOLUTION	EP	COMPLIES
CONDUCTIVITY	EP	10 microS/cm max.
REDUCING SUGARS as is	EP	0.2 % max.
REDUCING SUGARS on DS	NF	0.3 % max.
NICKEL(**)	NF	1 mg/kg max.
DRY SUBSTANCE	EP	68.0 - 85.0 %
WATER CONTENT	EP	15.0 - 32.0 %
WATER CONTENT	NF	31.5 % max.
RESIDUE ON IGNITION(*)	NF	0.1 % max.
pH	NF	5.0 - 7.5

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MICROBIOLOGICAL VALUES:

- TOTAL AEROBIC MICROBIAL COUNT(**)	NF	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT(**)	NF	100 CFU/g max.
- ESCHERICHIA COLI(**)		Not detected in 10g
- SALMONELLA(**)		Not detected in 10g

Indicatives Values

- Content D-Maltitol on DS: 50 - 55 %
- The Certificate of Analysis states the content of D-maltitol (=nominal value).

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 requirements of the current monograph

- **European Pharmacopoeia** MALTITOL, LIQUID (1236)
- **National Formulary from USP-NF** MALTITOL SOLUTION

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

Storage

- **For packed delivery**

Expiry date Manufacturing date + 3 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.

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

- For bulk delivery

Expiry date depends on the customer's storage conditions.

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.