

## LYCASIN® 75/75-MALTITOL SYRUP

### Definition

#### Product Identifier

**Product name:** LYCASIN® 75/75-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(*)	USP-NF	COMPLIES
IDENTIFICATION TEST-B	USP-NF	COMPLIES
IDENTIFICATION TEST-C(**)	USP-NF	COMPLIES

#### C) TESTS :

D-MALTITOL on DS	EP/USP-NF	50.0 % min.
D-SORBITOL on DS	EP/USP-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	USP-NF	0.3 % max.
NICKEL(**)	USP-NF	1 mg/kg max.
DRY SUBSTANCE	EP	68.0 - 85.0 %
WATER CONTENT	EP	15.0 - 32.0 %
WATER CONTENT	USP-NF	31.5 % max.
RESIDUE ON IGNITION	USP-NF	0.1 % max.
pH	USP-NF	5.0 - 7.5

## LYCASIN® 75/75-MALTITOL SYRUP

### MICROBIOLOGICAL VALUES:

- TOTAL AEROBIC MICROBIAL COUNT(**) USP-NF	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT(**) USP-NF	100 CFU/g max.
- ESCHERICHIA COLI(**)	Not detected in 1g
- SALMONELLA(**)	Not detected in 10g

### Indicative Values

---

- Content D-Maltitol on DS: 72 - 76 %
- The Certificate of Analysis states the content of D-maltitol (=nominal value).

### Comments

---

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

### Conformity

---

#### Conforms to the requirements of the current monograph

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

### 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. 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 storage conditions



## PRODUCT SPECIFICATIONS SHEET

# LYCASIN® 75/75-MALTITOL SYRUP

### 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.