

PRODUCT SPECIFICATION SHEET

LYCASIN®80/55 – MALTITOL SYRUP

Definition

Product identifier

Product name: LYCASIN®80/55 – MALTITOL SYRUP
INCI: HYDROGENATED STARCH HYDROLYSATE

Specifications

Description (characters)

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

Aspect	Syrupy liquid
Colour	Clear and colourless
Solubility	Miscible with water and with glycerol

Identification

Identification test A	EP , NF	Complies
Identification test B	NF	Complies
Identification test C	NF	Complies

Physical and chemical values (tests)

Appearance of solution	EP	Complies
Dry substance	EP	68,0 – 85,0%
D–Sorbitol (on DS)	EP / NF	8,0 % max.
D–Maltitol (on DS)	EP / NF	50,0 % min.
Water content	EP	15,0 – 32,0 %
Water content	NF	31,5 % max.
Reducing sugars (as is)	EP	0,2 % max.
Reducing sugars (on DS)	NF	0,3 % max.
pH	NF	5,0 – 7,5
Residue on Ignition	NF	0,1 % max.
Conductivity	EP	10 µS/cm max.
Nickel	NF	1 mg/kg max.

Microbiological values

Total aerobic microbial count	NF	1 000 CFU/g max.
Total yeasts and moulds count	NF	100 CFU/g max.
Escherichia coli		Not detected in 1g
Salmonellae		Not detected in 10g

Additional data

Typical 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.

Caption:

- "EP" stands for European Pharmacopoeia
- "NF" stands for National Formulary from USP-NF

Conformity

Legislation / specific regulations

Meets the requirements of the current monograph of:

- 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

The product durability may vary according to packaging type and manufacturing plant.

Proper information is shown on labelling and CoA.

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

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. 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.

This Product Specification Sheet has been edited from a non-productive environment. Minor modifications could occur when edited from the final productive environment.