

NEOSORB 70/70 SB

Definition

Product Identifier

Product name: NEOSORB 70/70 SB

Sorbitol, liquid (non crystallising)

Aqueous solution of a hydrogenated, partly hydrolysed starch.

CAS n° : 68425-17-2, 1259528-21-6

INCI : SORBITOL / HYDROGENATED STARCH HYDROLYSATE

Specifications

A) CHARACTERS

APPEARANCE	Syrupy liquid
COLOUR	Clear, colourless
SOLUBILITY	Miscible with water

B) IDENTIFICATION

IDENTIFICATION TEST A	EP	Complies
IDENTIFICATION TEST B	EP	Complies
IDENTIFICATION TEST C	EP	Complies
IDENTIFICATION TEST A(*)	NF	Complies
IDENTIFICATION TEST B	NF	Complies
IDENTIFICATION TEST C	NF	Complies

C) TESTS

APPEARANCE OF SOLUTION	EP	Conforms
CONDUCTIVITY	EP	10 microS/cm max.
REDUCING SUGARS	EP	0.2 % max.
RED. SUGARS AFTER HYDROLYSIS	EP	9.3 % max.
LEAD(**)	EP	0.5 ppm max.
NICKEL	EP	1 ppm max.
WATER	EP	28.0 - 32.0 %
D-SORBITOL ON DS	EP	72.0 - 92.0 %
D-SORBITOL	NF	45.0 % min.
RESIDUE ON IGNITION(*)	NF	0.1 % max.
NICKEL	NF	1 ppm max.

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REDUCING SUGARS ON DS	NF	0.3 % max.
pH	NF	5.0 - 7.5
WATER	NF	28.5 - 31.5 %
REDUCING SUGARS		0.03 % max.
DIETHYLENE GLYCOL(**)		1000 ppm max.
ETHYLENE GLYCOL		1000 ppm max.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT		1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT		100 CFU/g max.
- ESCHERICHIA COLI(**)		Not detected in 10g
- SALMONELLA(**)		Not detected in 10g

Comments

Methods used by Roquette may be the Pharmacopoeia methods or alternative validated methods which have been compared to the Pharmacopoeia methods.

Conformity

Conforms to the current edition of

- **European Pharmacopoeia (EP)** SORBITOL, LIQUID (NON CRYSTALLISING)
- **National Formulary (NF)** NONCRYSTALLIZING SORBITOL 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

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

Expiry date MD + 5 years, in its unopened packaging.

- * Compliance data - Tests not performed
- ** Monitoring plan

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



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its possession, handling and use.

Notes : All the dates are formatted like YYYY/MM/DD.