

PRODUCT SPECIFICATIONS SHEET

NEOSORB® 70/70 B

Definition

Product Identifier

Product name: NEOSORB® 70/70 B

Sorbitol, liquid (non crystallising)

Aqueous solution of a hydrogenated, partly hydrolysed starch.

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 IN SOLUTION	EP	COMPLIES
CONDUCTIVITY	EP	10 microS/cm max.
REDUCING SUGARS	EP	0.2 % max.
RED.SUGARS AFTER HYDROLYSIS	EP	9.3 % max.
WATER	EP	28.0 - 32.0 %
DRY SUBSTANCE	EP	68.0 - 72.0 %
D-SORBITOL(ON DS)	EP	72.0 - 92.0 %
D-SORBITOL(AS IS)	NF	45.0 % min.
RESIDUE ON IGNITION(*)	NF	0.1 % max.
NICKEL	NF	1 mg/kg max.
REDUCING SUGARS(ON DS)	NF	0.3 % max.
pH	NF	5.0 - 7.5

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WATER	NF	28.5 - 31.5 %
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 1g
- SALMONELLA(**)		Not detected in 10g

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(EP)** SORBITOL, LIQUID (NON CRYSTALLISING)
- **National Formulary from USP-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

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.

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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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.