

PRODUCT SPECIFICATIONS SHEET

**NEOSORB® 70/90 B**

Definition

Product Identifier

**Product name:** NEOSORB® 70/90 B

NONCRYSTALLIZING SORBITOL SOLUTION (NF)

Aqueous solution of a hydrogenated, partly hydrolysed starch.

INCI: SORBITOL / HYDROGENATED STARCH HYDROLYSATE

Specifications

A) CHARACTERS

APPEARANCE

Syrupy liquid

COLOUR

Clear, colourless

B) IDENTIFICATION

IDENTIFICATION A(\*)

NF

Complies

IDENTIFICATION B

NF

Complies

IDENTIFICATION TEST C(\*\*)

NF

Complies

C) TESTS

D-SORBITOL(AS IS)

NF

45.0 % min.

RESIDUE ON IGNITION(\*)

NF

0.1 % max.

NICKEL

NF

1 ppm max.

REDUCING SUGARS (ON DS)

NF

0.3 % max.

pH

NF

5.0 - 7.5

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.

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

## NEOSORB® 70/90 B

- "NF" stands for National Formulary from USP-NF

-(\*) Compliance data - Tests not performed

-(\*\*) Monitoring plan

### Conformity

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**Conforms to the requirements of the current monograph**

- **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

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**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.

### Disclaimer

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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.