

PRODUCT SPECIFICATIONS SHEET

NEOSORB® 70/20 B

Definition

Product Identifier

Product name: NEOSORB® 70/20 B

Sorbitol, liquid (crystallising)

Aqueous solution of a hydrogenated, partly hydrolysed starch.

INCI : SORBITOL

Specifications

A) CHARACTERS

APPEARANCE	Syrupy liquid
COLOUR	Clear, Colourless
SOLUBILITY	Miscible with water

B) IDENTIFICATION

IDENTIFICATION-A	EP	Complies
IDENTIFICATION-A(*)	USP-NF	Complies
IDENTIFICATION-B	EP	Complies
IDENTIFICATION-B	USP-NF	Complies
IDENTIFICATION-C	EP	Complies
IDENTIFICATION-C(**)	USP-NF	Complies

C) TESTS

D-SORBITOL (on DS)	EP	92.0 - 101.0 %
D-SORBITOL	USP-NF	64.0 % min.
APPEARANCE OF SOLUTION	EP	Complies
CONDUCTIVITY	EP/USP-NF	10 microS/cm max.
REDUCING SUGARS	EP	0.2 % max
REDUCING SUGARS	USP-NF	0.3 % max.
NICKEL	USP-NF	1 mg/kg max.
WATER CONTENT	EP	28.0 - 32.0 %
WATER CONTENT	USP-NF	28.5 - 31.5 %
SULPHATED ASH/(ROI)	USP-NF	0.1 % max.

MICROBIOLOGICAL VALUES:

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- TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	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
- "USP-NF" stands for USP-NF Pharmacopoeia
- (*) Compliance data - Tests not performed
- (**) Monitoring plan

Conformity

Conforms to the current edition of

- **European Pharmacopoeia** SORBITOL, LIQUID (CRYSTALLISING) (0436)
- **USP-NF Pharmacopoeia** 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.

NEOSORB® 70/20 B shows a tendency to crystallise.

Unheated deliveries (drums or containers) can be affected by crystallisation phenomena, therefore reheating before use can be required. Please contact us to receive the related documentation.

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

All information and instructions provided in this Product Specification Sheet are based on the current state of our knowledge at the



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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.