

NEOSORB® PF - SORBITOL

Definition

Product Identifier

Product name: NEOSORB® PF - SORBITOL

D-GLUCITOL(D-SORBITOL) (EP).

D-GLUCITOL (NF).

INCI : SORBITOL

Specifications

A) CHARACTERS

APPEARANCE	White or almost white, crystalline powder
SOLUBILITY	Very soluble in water, practically insoluble in ethanol (96%).

B) IDENTIFICATION

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

C) TESTS

D-SORBITOL on DS	EP	97.0 - 102.0 %
D-SORBITOL on DS	NF	91.0 - 100.5 %
APPEARANCE IN SOLUTION	EP / NF	Clear, colourless
CONDUCTIVITY	EP	20 microS/cm max.
pH	NF	3.5 - 7.0
RESIDUE ON IGNITION	NF	0.1 % max.
REDUCING SUGARS	EP	0.2 % max.
REDUCING SUGARS	NF	0.3 % max.
RELATED SUBSTANCES:		
- IMPURITY A: D-MANNITOL	EP	2.0 % max.
- IMPURITY B: D-IDITOL	EP	2.0 % max.
- IMPURITY C: D-MALTITOL	EP	2.0 % max.
- IMP BETWEEN MALTITOL & MANNITOL		1.0 % max.
- ANY UNSPECIFIED IMPURITY		0.10 % max.
- AMOUNT OF RELATED SUBSTANCES	EP	3.0 % max.

PRODUCT SPECIFICATIONS SHEET

NEOSORB® PF - SORBITOL

NICKEL (**)	NF	1 mg/kg max.
WATER	EP / NF	1.5 % max.
CHLORIDE	NF	50 mg/kg max.
SULPHATE	NF	100 mg/kg max.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT	EP / NF	100 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	EP / NF	100 CFU/g max.
- ESCHERICHIA COLI(**)	EP	Not detected in 1 g
- SALMONELLA(**)	EP	Not detected in 10 g
BACTERIAL ENDOTOXINS	EP / NF	<2.5 IU/g

Comments

Neosorb PF is intended for use in preparing 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** SORBITOL (0435)
- **National Formulary from USP-NF** SORBITOL

Please contact us for any statement regarding compliance to the General Chapters (elemental impurities, residual solvents, organic volatile impurities, metal catalyst, metal reagent).

Storage

Retest Date

Manufacturing date + 3 years, in its unopened packaging.

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



PRODUCT SPECIFICATIONS SHEET

NEOSORB® PF - SORBITOL

- Upon opening, use the product as quickly as possible to prevent moisture regain.

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 its possession, handling and use.

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