

**NEOSORB® P 30/60 - SORBITOL**

Definition

Product Identifier

**Product name:** NEOSORB® P 30/60 - 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	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-MALTTITOL	EP	2.0 % max.

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- AMOUNT OF RELATED SUBSTANCES	EP	3.0 % max.
NICKEL(**)	NF	1 mg/kg max.
WATER	EP / NF	1.5 % max.
<b>PARTICLE SIZE(SIEVE):</b>		
- RESIDUE ON 800 microns		5 % max.
- RESIDUE ON 200 microns		98 % min.
<b>MICROBIOLOGICAL VALUES:</b>		
- TOTAL AEROBIC MICROBIAL COUNT(**)	EP / NF	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT(**)	EP / NF	100 CFU/g max.
- ESCHERICHIA COLI(**)	EP	Not detected in 1g
- SALMONELLA(**)	EP	Not detected in 10g

## Comments

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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

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### 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

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**Expiry Date** Manufacturing date + 5 years, in its unopened packaging.

- These dates are indicative and may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA.



## PRODUCT SPECIFICATIONS SHEET

# NEOSORB® P 30/60 - SORBITOL

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

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

### 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.