

PRODUCT SPECIFICATIONS SHEET

SUNSORB® P 425 -SORBITOL

Definition

PRODUCT IDENTIFIER

Product name: SUNSORB® P 425 - SORBITOL POWDER

D-GLUCITOL(D-SORBITOL) (EP). D-GLUCITOL (NF). INCI : SORBITOL CAS No. 50-70-4

Specifications

A) CHARACTERS

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

B) IDENTIFICATION

Table with 3 columns: Test Name, Reference (EP/NF), and Result (Complies)

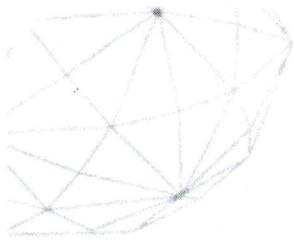
C) TESTS

Table with 3 columns: Test Name, Reference (EP/NF), and Value/Requirement



Handwritten signature





PRODUCT SPECIFICATIONS SHEET

SUNSORB® P 425 -SORBITOL

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.
- AMOUNT OF RELATED SUBSTANCES	EP	3.0 % max.
NICKEL(**)	NF	1 mg/kg max.

PARTICLE SIZE(SIEVE):

- RESIDUE ON 425 microns	5 % max.
- RESIDUE ON 100 microns	75 % min.

MICROBIOLOGICAL VALUES:

- 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 1 g
- SALMONELLA(**)	EP	Not detected in 10 g

Comments

Not intended for use in manufacture of parenteral dosage forms.

Methods used by Sunar Misir 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).

Rus





PRODUCT SPECIFICATIONS SHEET

SUNSORB® P 425 -SORBITOL

Storage

Expiry date is manufacturing date + 2 years, in its unopened packaging.

Best before date is manufacturing date +1 year, in its unopened packaging.

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

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

- Store in a well ventilated, clean and dry environment, away from odorous materials, at < 60 % relative humidity at ambient temperature. Avoid pressure on the bags. The pallets must not be piled up too high.

- To minimize the problem of product-lumping, it is highly recommended to avoid the stacking of pallets.

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 DD/MM/YYYY.

