

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

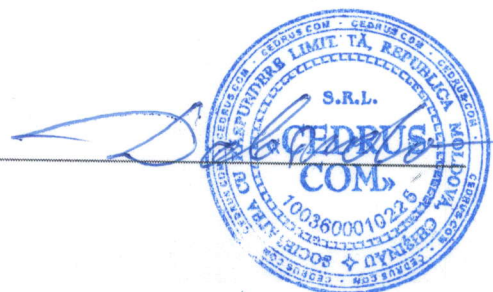
APPEARANCE White or almost white, crystalline powder.
SOLUBILITY Very soluble in water, practically insoluble in ethanol (96%).

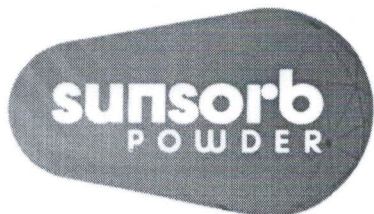
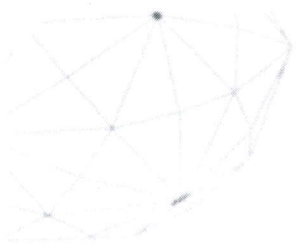
B) IDENTIFICATION

IDENTIFICATION TEST-A	EP	Complies
IDENTIFICATION TEST-A(*)	NF	Complies
IDENTIFICATION TEST-B	NF	Complies
IDENTIFICATION TEST-C	EP	Complies
IDENTIFICATION TEST-C	NF	Complies
IDENTIFICATION TEST-D	EP	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.
WATER CONTENT	EP/NF	1.5 % max.
MELTING POINT	GB/T 617, JECFA	96-101 °C





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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

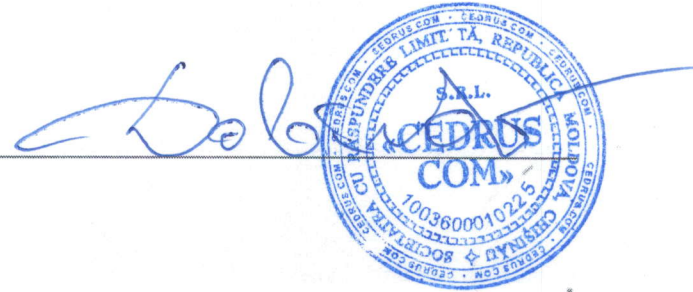
Conformity

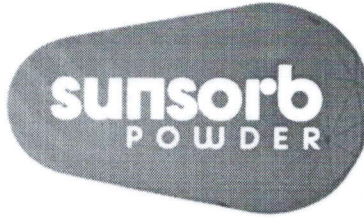
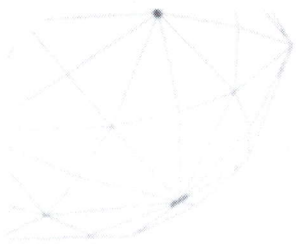
Conforms to the requirements of the current monograph

- 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).

DOCUMENT NO: GMP.SUS.KY.001
 REVISION DATE/NO: 27.12.2021/0





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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.

