

PRODUCT SPECIFICATIONS SHEET

NEOSORB® P 300C

Definition

Product Identifier

Product name: NEOSORB® P 300C

D-SORBITOL
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 |
| IDENTIFICATION TEST 1(*) | JP | Complies |
| IDENTIFICATION TEST 2(*) | JP | Complies |
| IDENTIFICATION TEST 3(*) | JP | Complies |

C) TESTS

| | | |
|-------------------------|-------|-------------------|
| D-SORBITOL on DS | EP | 97.0 - 102.0 % |
| D-SORBITOL on DS | NF | 91.0 - 100.5 % |
| ASSAY ON DS | JP | 97,0 % min. |
| APPEARANCE IN SOLUTION | EP,JP | Complies. |
| ACIDITY | JP | Complies. |
| CONDUCTIVITY | EP | 20 microS/cm max. |
| pH | NF | 3.5 - 7.0 |
| RESIDUE ON IGNITION | NF | 0.1 % max. |
| RESIDUE ON IGNITION | JP | 0.02 % max. |
| REDUCING SUGARS (AS IS) | EP | 0.2 % max. |
| REDUCING SUGARS (AS IS) | NF | 0.3 % max. |

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| | | |
|---|---------|----------------------|
| GLUCOSE | JP | 6,3 ml max. |
| SUGARS | JP | 6,3 ml 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. |
| - AMOUNT OF RELATED SUBSTANCES | EP | 3.0 % max. |
| CHLORIDE | JP | 50 mg/kg max. |
| SULFATE | JP | 60 mg/kg max. |
| HEAVY METALS(**) | JP | 5 mg/kg max. |
| NICKEL(**) | NF | 1 mg/kg max. |
| NICKEL(*) | JP | Complies. |
| ARSENIC(**) | JP | 1.3 mg/kg max. |
| WATER | EP / NF | 1.5 % max. |
| LOSS ON DRYING(*) | JP | 2.0 % max. |
| PARTICLE SIZE(LASER): | | |
| - PART.>710 microns | | 3 % max. |
| - PART.>220 microns | | 40 - 65 % |
| - PART.>15 microns | | 92 % 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 1g. |
| - SALMONELLA(**) | EP | 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
- "NF" stands for National Formulary from USP-NF
- "JP" stands for Japanese Pharmacopoeia
- (*) Compliance data - Tests not performed
- (**) Monitoring plan

NEOSORB® P 300C

Conformity

Conforms to the requirements of the current monograph

- **European Pharmacopoeia** SORBITOL (0435)
- **National Formulary from USP-NF** SORBITOL
- **Japanese Pharmacopoeia** D-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

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

- Those date is indicative and may vary according to packaging type and manufacturing plant. Proper information is shown on labelling and CoA.
- We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations of temperature and humidity.
- To minimise 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 YYYY/MM/DD.