

NEOSORB® BIOPHARMA - SORBITOL

Definition

Product Identifier

Product name: NEOSORB® BIOPHARMA - SORBITOL

D-GLUCITOL (D-SORBITOL) (EP)

D-GLUCITOL (NF / JP)

INCI : SORBITOL

Product code : 423127

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 %
D-SORBITOL on DS	JP	97.0 % min.
APPEARANCE IN SOLUTION	EP / JP	Clear, colourless
CLARITY AND COLOR OF SOLUTION	NF	Clear, colorless
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	EP	0.2 % max.

PRODUCT SPECIFICATIONS SHEET

NEOSORB® BIOPHARMA - SORBITOL

REDUCING SUGARS	NF	0.3 % max.
GLUCOSE	JP	Complies
SUGARS	JP	Complies
RELATED SUBSTANCES:		
IMPURITY A : D-MANNITOL	EP	2 % max.
IMPURITY B : D-IDITOL	EP	2 % max.
IMPURITY C : D-MALTITOL	EP	2 % max.
AMOUNT OF RELATED SUBSTANCES	EP	3 % max.
LEAD	EP	0.5 ppm max.
ARSENIC	JP	1.3 ppm max.
NICKEL	EP / NF	1 ppm max.
NICKEL	JP	Complies
WATER	EP / NF	1.5 % max.
LOSS ON DRYING(*)	JP	2.0 % max.
CHLORIDE	NF / JP	50 ppm max.
SULFATE	NF	100 ppm max.
SULFATE	JP	60 ppm max.
HEAVY METALS	JP	5 ppm max.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT		100 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT		100 CFU/g max.
- ESCHERICHIA COLI		Not detected in 10g
- SALMONELLA		Not detected in 10g
- PSEUDOMONAS AERUGINOSA		Not detected in 10g
- STAPHYLOCOCCUS AUREUS		Not detected in 10g
BIOLOGICAL VALUES:		
- BACTERIAL ENDOTOXINS		1 IU/g max.

- * Compliance data - Tests not performed

Comments

Methods used by Roquette may be the Pharmacopoeia methods or alternative validated methods which have been compared to the Pharmacopoeia methods.

Methods of analysis used by Roquette are listed in Analytical Dossier.

NEOSORB® BIOPHARMA - SORBITOL

Suitable for use in biopharmaceutical manufacturing and as an excipient for injectable dosage form.

Conformity

Conforms to the current edition of

- European Pharmacopoeia (EP)
- National Formulary (NF)
- **Japanese Pharmacopoeia (JP) 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.

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

Disclaimer

GENERAL 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. Analytical criteria are tested either on each batch or monitored or guaranteed, based on the Product Risk Analysis. For each batch, the status of the analysis may be indicated in the Certificate of Analysis. 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. The ultimate use of this Product in any finished product is the responsibility of the purchaser.

This Product may have restrictions with respect to its use and/or usage levels, and such may vary on a country-by-country basis. The purchaser is responsible for its use of the Product and for its finished product, and that any claims made regarding its use of the Product and/or the finished product comply with applicable laws and regulations.