ROQUETTE
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PRODUCT SPECIFICATIONS SHEET

NEOSORB® P 550 SD

Definition

Product Identifier

Product name: NEOSORB® P 550 SD

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 (SIEVE):		
- RESIDUE ON 800 microns		10 % max.
- RESIDUE ON 200 microns		90 % 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.

Indicatives Values

MEAN DIAMETER(LASER)	550 microns approx.

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

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.

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

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.