

PEARLITOL® 300 DC - MANNITOL

Definition

Product Identifier

Product name: PEARLITOL® 300 DC - MANNITOL

D-MANNITOL

INCI: MANNITOL

Specifications

A) CHARACTERS

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

B) IDENTIFICATION

INFRA RED ABSORPTION	EP / USP-NF / JP	COMPLIES
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C) TESTS

D-MANNITOL (on DS)	EP / USP-NF / JP	97.0 - 102.0 %
APPEARANCE IN SOLUTION	EP / USP-NF / JP	Clear, colourless
CONDUCTIVITY	EP / USP-NF / JP	20 microS/cm max.
MELTING POINT(**)	EP / USP-NF / JP	165 - 170 °C
REDUCING SUGARS	EP / USP-NF / JP	0.1 % max.
RELATED SUBSTANCES:		
- IMPURITY A:D-SORBITOL	EP / USP-NF / JP	2.0 % max.
- SUM OF IMPURITIES B and C	EP / USP-NF / JP	2.0 % max.
(IMPURITY B:D-MALTTITOL - IMPURITY C:ISOMALT)		
- UNSPECIFIED IMPURITIES	EP / USP-NF / JP	0.10 % max.
- TOTAL IMPURITIES	EP / USP-NF / JP	2.0 % max.
HEAVY METALS(**)	JP	5 mg/kg max.
NICKEL(**)	USP-NF / JP	1 mg/kg max.
LOSS ON DRYING	EP / USP-NF / JP	0.5 % max.

PARTICLE SIZE (sieve)

- RESIDUE on 500 microns	0.5 % max.
- RESIDUE on 315 microns	55 % max.

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- RESIDUE on 200 microns		70 % min.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT	EP / USP-NF	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	EP / USP-NF	100 CFU/g max.
- ESCHERICHIA COLI(**)	EP / USP-NF	Not detected in 1g
- SALMONELLA(**)	EP	Not detected in 10g

- ** Monitoring plan

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.

Conformity

Conforms to the current edition of

- European Pharmacopoeia MANNITOL (0559)
- USP-NF Pharmacopoeia MANNITOL
- Japanese Pharmacopoeia D-MANNITOL

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.

- The product durability 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.



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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.