

PEARLITOL® 400 DC - MANNITOL

Definition

Product Identifier

Product name: PEARLITOL® 400 DC - MANNITOL

D-MANNITOL

CAS No.: 69-65-8

INCI: MANNITOL

Specifications

A) CHARACTERS

APPEARANCE

White or almost white, crystalline powder.

SOLUBILITY

Very soluble in water, practically insoluble in ethanol.

B) IDENTIFICATION

INFRA RED ABSORPTION

EP / USP / JP

COMPLIES

C) TESTS

D-MANNITOL (on DS)

EP / USP / JP

97.0 - 102.0 %

APPEARANCE IN SOLUTION

EP / USP / JP

Clear, colourless

CONDUCTIVITY

EP / USP / JP

20 microS/cm max.

MELTING POINT(**)

EP / USP / JP

165 - 170 °C

REDUCING SUGARS

EP / USP / JP

0.1 % max.

RELATED SUBSTANCES:

- IMPURITY A:D-SORBITOL

EP / USP / JP

2.0 % max.

- SUM OF IMPURITIES B and C

EP / USP / JP

2.0 % max.

(IMPURITY B:D-MALTTITOL - IMPURITY C:ISOMALT)

- UNSPECIFIED IMPURITIES

EP / USP / JP

0.10 % max.

- TOTAL IMPURITIES

EP / USP / JP

2.0 % max.

HEAVY METALS(**)

JP

5 mg/kg max.

NICKEL(**)

USP / JP

1 mg/kg max.

LOSS ON DRYING

EP / USP / JP

0.5 % max.

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PARTICLE SIZE (sieve)

- RESIDUE on 500 microns 20 % max.
- RESIDUE on 100 microns 85 % min.

MICROBIOLOGICAL VALUES:

- | | | |
|---------------------------------|----------|---------------------|
| - TOTAL AEROBIC MICROBIAL COUNT | EP / USP | 1000 CFU/g max. |
| - TOTAL YEASTS AND MOULDS COUNT | EP / USP | 100 CFU/g max. |
| - ESCHERICHIA COLI(**) | EP / USP | 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 (EP) MANNITOL (0559)
- US Pharmacopoeia (USP) MANNITOL
- Japanese Pharmacopoeia (JP) 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.

- These dates are 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



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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.