

**PEARLITOL® 100 SD - MANNITOL**

Definition

Product Identifier

**Product name:** PEARLITOL® 100 SD - MANNITOL

D-MANNITOL

INCI: MANNITOL

Specifications

A) CHARACTERS

**APPEARANCE**

White or almost white crystals or powder.

**SOLUBILITY**

Freely soluble in water, practically insoluble in ethanol(96%).

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.

**PARTICLE SIZE (laser)**

- **PART. > 150 microns (BECKMAN)**

35 % max.

- **PART. > 140 microns (SYMPATEC)**

35 % max.

- **PART. > 75 microns (BECKMAN)**

70 % min.

- **PART. > 30 microns (SYMPATEC)**

70 % min.

PRODUCT SPECIFICATIONS SHEET

**PEARLITOL® 100 SD - MANNITOL**

**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**

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- Not intended for use in manufacture of parenteral dosage forms.

**- NOTE FOR LASER PARTICLE SIZE DESCRIPTION**

As part of continuous improvement, ROQUETTE decided to replace its current laser particle size device BECKMAN brand by the new technology SYMPATEC brand. To support this evolution, the specification has slightly evolved for particle size description, the acceptance criteria remain the same and the sieve size shows the both technology brand name and equivalency. The new expression with SYMPATEC technology is shown in this product specification sheet. ROQUETTE is currently in a transition period during which batches can be tested by BECKMAN device or SYMPATEC device.

**Conformity**

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**Conforms to the requirements of the current monograph**

- 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).

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

**Storage**

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**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.



PRODUCT SPECIFICATIONS SHEET

**PEARLITOL® 100 SD - MANNITOL**

Disclaimer

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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.