PRODUCT SPECIFICATIONS SHEET

# PEARLITOL® 150 SD - MANNITOL

## Definition

### Product Identifier

**Product name:** PEARLITOL® 150 SD - MANNITOL

Low Reducing Sugars D-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-NF/JP | COMPLIES |
| **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. |
| REDUCING SUGARS(Glucose+Mannose) | ROQUETTE | 0.03 % max. |
| RELATED SUBSTANCES: | | |
| - IMPURITY A:D-SORBITOL | EP/USP-NF/JP | 2.0 % max. |
| - SUM OF IMPURITIES B and C (IMPURITY B:D-MALTITOL - IMPURITY C:ISOMALT) | EP/USP-NF/JP | 2.0 % max. |
| - 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 (laser) | | |
| - PART. > 150 microns (BECKMAN) | | 45 % max. |
| - PART. > 140 microns (SYMPATEC) | | 45 % max. |
| - PART. > 75 microns (BECKMAN) | | 85 % min. |

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|---|---|---|
| - PART. > 30 microns (SYMPATEC) | | 85 % 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

## Indicative Values

PARTICLE SIZE DISTRIBUTION (laser):

| | |
|---|---|
| - D10 | 80 microns max. |
| - D50 | 95 - 135 microns |
| - D90 | 220 microns max. |

## Comments

- 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

Conforms to the requirements of the current monograph

- 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).

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

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## 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.

## Disclaimer

SPECIFIC DISCLAIMER:

Not intended for use in manufacture of parenteral dosage form, nor preparation for dialysis.
This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharma cGMPs.
Please contact us for further information.

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.