

PRODUCT SPECIFICATIONS SHEET

PEARLITOL® 100 SD - MANNITOL

Definition

Product Identifier

Product name: PEARLITOL® 100 SD - MANNITOL

D-MANNITOL

INCI: MANNITOL

Specifications

A) CHARACTERS

APPEARANCE	White crystals or a crystalline powder.
SOLUBILITY	Freely soluble in water; sparingly soluble in ethanol; practically insoluble in ether.
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B) IDENTIFICATION

IDENTIFICATION TEST-1 (*)	ChP	Complies
IDENTIFICATION TEST-2 (*)	ChP	Complies

C) TESTS

ASSAY (on DS)	ChP	98.0 - 102.0 %
MELTING POINT	ChP	166 - 170 °C
SPECIFIC OPTICAL ROTATION	ChP	+137° to +145°
ACIDITY	ChP	Complies
CLARITY AND COLOR OF SOLUTION	ChP	Complies
TOTAL IMPURITIES	ChP	2.0 % max.
REDUCING SUGARS	ChP	Complies
CHLORIDES	ChP	30 mg/kg.
SULFATES	ChP	100 mg/kg.
OXALATE(*)	ChP	0.02% max.
LOSS ON DRYING	ChP	0.5 % max.
RESIDUE ON IGNITION	ChP	0.1% max.
HEAVY METALS(*)	ChP	10 mg/kg max.
ARSENIC	ChP	2 mg/kg max.
PARTICLE SIZE (laser)		
- PART. > 150 microns (BECKMAN)		35 % max.
- PART. > 140 microns (SYMPATEC)		35 % max.

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- PART. > 75 microns (BECKMAN)	70 % min.
- PART. > 30 microns (SYMPATEC)	70 % min.
MICROBIOLOGICAL VALUES:	
- TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	100 CFU/g max.
- ESCHERICHIA COLI(**)	Not detected in 1g
- SALMONELLA(**)	Not detected in 10g

- * Compliance data - Tests not performed
- ** Monitoring plan

Comments

- 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

Conforms to the requirements of the current monograph

- Chinese Pharmacopoeia (ChP) 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

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.

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- 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.