ROQUETTE
Offering the best of nature™

PRODUCT SPECIFICATIONS SHEET

PEARLITOL® 200 SD - MANNITOL

Definition

Product Identifier

Product name: PEARLITOL® 200 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 (IMPURITY B:D-MALTITOL - IMPURITY C:ISOMALT)	EP / USP / JP	2.0 % max.
- 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. > 315 microns (BECKMAN)		10 % max.
- PART. > 300 microns (SYMPATEC)		10 % max.
- PART. > 150 microns (BECKMAN)		45 % min.
- PART. > 140 microns (SYMPATEC)		45 % min.

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- PART. > 75 microns (BECKMAN)		90 % min.
- PART. > 30 microns (SYMPATEC)		90 % 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.

- 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 (EP) MANNITOL (0559)

- US Pharmacopeia (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

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

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.