

PEARLITOL® 200 GT-EXP-MANNITOL

Definition

Product Identifier

Product name: PEARLITOL® 200 GT-EXP-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.

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. > 300 microns		25 % max.
- PART. > 140 microns		40 % min.

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- PART. > 30 microns	90 % 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

Comments

- This product should be considered as an experimental product. Product specifications and related analytical methods may evolve.
- 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.

Caption

- "ChP" stands for Chinese Pharmacopoeia
- (*) Compliance data - Tests not performed
- (**) Monitoring plan

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).

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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.



PRODUCT SPECIFICATIONS SHEET

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Disclaimer

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.