

PEARLITOL® 160 C - MANNITOL

Definition

Product Identifier

Product name: PEARLITOL® 160 C - MANNITOL

D-MANNITOL

CAS No. 69-65-8

INCI: MANNITOL

Specifications

A) CHARACTERS

APPEARANCE	White, crystalline powder.
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B) IDENTIFICATION

IDENTIFICATION TEST-A	IP	COMPLIES
IDENTIFICATION TEST-B(*)	IP	COMPLIES
IDENTIFICATION TEST-C(*)	IP	COMPLIES
IDENTIFICATION TEST-D	IP	COMPLIES

C) TESTS

D-MANNITOL (on DS)	IP	97.0 to 102.0 %
APPEARANCE IN SOLUTION	IP	clear, colourless
ACIDITY (NaOH 0.01M)(*)	IP	0.2 mL max.
SPECIFIC OPTICAL ROTATION(*)	IP	+23.0 to +25.0°
ARSENIC(**)	IP	2 mg/kg max.
CHLORIDES	IP	50 mg/kg max.
SULPHATES	IP	100 mg/kg max.
REDUCING SUGARS(Na ₂ SO ₃)	IP	12.8 mL min.
SORBITOL(*)	IP	COMPLIES
SULPHATED ASH	IP	0.1 % max.
LOSS ON DRYING	IP	0.5 % max.
PARTICLE SIZE (laser)		
- PART. > 500 microns		10 % max.
- PART. > 315 microns		25 % max.

PRODUCT SPECIFICATIONS SHEET

PEARLITOL® 160 C - MANNITOL

- PART. > 40 microns	60 % 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

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

Conformity

Conforms to the current edition of

- Indian Pharmacopoeia (IP) MANNITOL

Storage

Expiry date Manufacturing date + 3 years, in its unopened packaging.

We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations of temperature and humidity.

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.