

PEARLITOL® PF - MANNITOL

Definition

Product Identifier

Product name: PEARLITOL® PF - MANNITOL

D-MANNITOL
INCI: MANNITOL

Specifications

A) CHARACTERS

APPEARANCE White or almost white, crystalline powder.
SOLUBILITY Very soluble in water, practically insoluble in ethanol.

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	Complies
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.
RELATED SUBSTANCES:		
- IMPURITY A:D-SORBITOL	EP/USP-NF/JP	2.0 % max.
- SUM OF IMPURITIES B and C	EP/USP-NF/JP	2.0 % max.
(IMPURITY B:D-MALTTITOL - IMPURITY C:ISOMALT)		
- 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.

MICROBIOLOGICAL VALUES:

- TOTAL AEROBIC MICROBIAL COUNT	EP/USP-NF	100 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT	EP/USP-NF	100 CFU/g max.

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- ESCHERICHIA COLI(**)	EP/USP-NF	Not detected in 1g
- SALMONELLA(**)	EP	Not detected in 10g
BACTERIAL ENDOTOXINS	EP/USP-NF	<2.5 IU/g

Comments

-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

- "EP" stands for European Pharmacopoeia
- "USP-NF" stands for USP-NF Pharmacopoeia
- "JP" stands for JP Pharmacopoeia
- (**) Monitoring plan

Conformity

Conforms to the current edition of

- **European Pharmacopoeia (EP)** MANNITOL (0559)
- **USP-NF Pharmacopoeia** 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).

Storage

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

-These dates are indicative and 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



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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.