

PRODUCT SPECIFICATION SHEET

SWEETPEARL® P200

Definition

Product identifier

Product name: SWEETPEARL® P200

Specifications

Description (characters)

D-MALTITOL; D-GLUCOPYRANOSYL-D-GLUCITOL.

INCI: MALTITOL

Aspect	Crystalline powder
Colour	White or almost white
Solubility	Very soluble in water, practically insoluble in anhydrous ethanol

Identification

Identification test A	EP / NF	Complies
Identification test B	NF	Complies

Physical and chemical values (tests)

D-Maltitol (on DS)	EP	98,0 – 102,0 %
D-Maltitol (on DS)	NF	92,0 – 100,5 %
Appearance of solution	EP	Complies
Conductivity	EP / NF	20 µS/cm max.
Reducing sugars	EP	0,2 % max.
Reducing sugars	NF	0,3 % max.

Related substances:

- D-Sorbitol (on DS)	EP	1,0 % max.
- Maltotriitol (on DS)	EP	1,0 % max.
- Total of related substances	EP	2,0 % max.

Nickel	NF	1 mg/kg max.
Water content	EP / NF	1,0 % max.

Particle size (Sieve) :

- Residue on 500 microns	5 % max.
- Residue on 100 microns	40 % min.

Microbiological values

Total aerobic microbial count	EP / NF	1 000 CFU/g max.
Total yeasts and moulds count	EP / NF	100 CFU/g max.
Escherichia coli	EP	Not detected in 1g
Salmonellae	EP	Not detected in 10g

Additional data

Comments

Not intended for use in manufacture of parenteral dosage forms.

Methods used by Roquette may be the Pharmacopoeia methods or alternative validated methods.

Caption:

- "EP" stands for European Pharmacopoeia
- "NF" stands for National Formulary from USP-NF

Conformity

Legislation / specific regulations

Meets the requirements of the current monograph of:

- European Pharmacopoeia : MALTITOL(1235)
- National Formulary from USP - NF : MALTITOL

Please contact us for any statement regarding compliance to the General Chapters (elemental impurities, residual solvents, organic volatile impurities, metal catalyst, metal reagent).

Storage

The product durability may vary according to packaging type and manufacturing plant.
Proper information is shown on labelling and CoA.

Storage conditions - We recommend preserving 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. 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. 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.

This Product Specification Sheet has been edited from a non-productive environment. Minor modifications could occur when edited from the final productive environment.