

**PRODUCT SPECIFICATION SHEET**  
**SWEETPEARL® P200**

**Definition**

**Product identifier**

**Product name:** SWEETPEARL® P200

**Specifications**

**Description (characters)**

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

INCI: MALTITOL

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

**Identification**

<b>Identification test A</b>	EP / NF	Complies
<b>Identification test B</b>	NF	Complies

**Physical and chemical values (tests)**

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

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

**Particle size (Sieve) :**

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

## Microbiological values

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