

PRODUCT SPECIFICATIONS SHEET

SWEETPEARL® P200

Definition

Product Identifier

Product name: SWEETPEARL® P200

D-MALTITOL

INCI : MALTITOL

Specifications

A) CHARACTERS

APPEARANCE

White or almost white,
crystalline powder.

SOLUBILITY

Very soluble in water,
practically insoluble in
anhydrous ethanol.

B) IDENTIFICATION

IDENTIFICATION TEST-A(*)

EP / NF

COMPLIES

IDENTIFICATION TEST-B

NF

COMPLIES

C) TESTS

D-MALTITOL on DS

EP

98.0 - 102.0 %

D-MALTITOL on DS

NF

92.0 - 100.5 %

APPEARANCE IN SOLUTION

EP

COMPLIES

CONDUCTIVITY

EP / NF

20 microS/cm max.

REDUCING SUGARS

EP

0.2 % max.

REDUCING SUGARS

NF

0.3 % max.

RELATED SUBSTANCES:

- D-SORBITOL

EP

1.0 % max.

- MALTOTRIITOL (DP3H)

EP

1.0 % max.

- AMOUNT 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.

SWEETPEARL® P200

- RESIDUE on 100 microns

40 % min.

MICROBIOLOGICAL VALUES:

- TOTAL AEROBIC MICROBIAL COUNT(**)

EP / NF

1000 CFU/g max.

- TOTAL YEASTS AND MOULDS(**)

EP / NF

100 CFU/g max.

- ESCHERICHIA COLI(**)

EP

Not detected in 1g

- SALMONELLA(**)

EP

Not detected in 10g

Comments

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

- "EP" stands for European Pharmacopoeia

- "NF" stands for National Formulary from USP-NF

- (*) Compliance data - Tests not performed

- (**) Monitoring plan

Conformity

Conforms to the requirements of the current monograph

- **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

Expiry date Manufacturing date + 3 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.

Disclaimer



SWEETPEARL® P200

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.