

LAB 3794 - SWEETPEARL P300 DC

Definition

Product Identifier

Product name: LAB 3794 - SWEETPEARL P300 DC

D-Maltitol (EP) ; D-Glucopyranosyl-D-glucitol (NF).

CAS : 585-88-6

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(*)	EP	COMPLIES
IDENTIFICATION TEST-B	NF	COMPLIES
IDENTIFICATION TEST-C(*)	EP	COMPLIES
IDENTIFICATION TEST-D(*)	EP	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.
LEAD(**)	EP	0.5 ppm max.

LAB 3794 - SWEETPEARL P300 DC

NICKEL(**)	EP / NF	1 ppm max.
WATER CONTENT	EP / NF	1.0 % max.
PARTICLE SIZE (sieve)		
- RESIDUE ON 500 microns		5.0 % max.
- RESIDUE ON 100 microns		80 % min.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT(**) EP / NF		1000/g max.
- TOTAL YEASTS AND MOLDS(**)	EP / NF	100/g max.
- ESCHERICHIA COLI(**)	EP / NF	Not detected in 10g
- SALMONELLAE(**)	EP / NF	Not detected in 10g

Comments

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

Not intended for use in manufacture of parenteral dosage forms.

Conformity

Conforms to the current edition of

- European Pharmacopoeia (EP) MALTITOL (1235)

- National Formulary (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 + 5 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.

- * Compliance data - Tests not performed .

- ** Monitoring plan

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

LAB 3794 - SWEETPEARL P300 DC

its possession, handling and use.

Notes : All the dates are formatted like YYYY/MM/DD.