

PRODUCT SPECIFICATIONS SHEET

POLYSORB® 85/70/00

Definition

Product Identifier

Product name: POLYSORB® 85/70/00

Sorbitol, liquid, partially deshydrated (EP)

Anhydriized liquid sorbitol (USP) - Sorbitol sorbitan solution (USP)

INCI : SORBITOL

Specifications

A) CHARACTERS

APPEARANCE

Clear, colourless, syrupy
liquid

SOLUBILITY

Miscible with water,
Practically insoluble in
meneral oil and vegetable
oils

B) IDENTIFICATION

IDENTIFICATION TEST	EP	See tests
IDENTIFICATION TEST-A(*)	USP/NF	Conforms
IDENTIFICATION TEST-B	USP/NF	See tests
IDENTIFICATION TEST-C(**)	USP/NF	See tests

C) TESTS

1,4-SORBITAN/D.S.	EP-USP/NF	15.0 % min.
D-SORBITOL/D.S	EP-USP/NF	25.0 % min.
APPEARANCE OF SOLUTION	EP	Clear,colourless
CONDUCTIVITY	EP	20 microS/cm max.
REDUCING SUGARS	EP-USP/NF	0.3 % max.
NICKEL(**)	EP-USP/NF	1 ppm max.
WATER CONTENT	EP	15.0 - 32.0 %
WATER CONTENT	USP/NF	31.5 % max.
PH	USP/NF	4.0 - 7.0
RESIDUE ON IGNITION	USP/NF	0.20 % max.
ETHYLENE GLYCOL(**)	USP/NF	1000 ppm max.

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DIETHYLENE GLYCOL(**)	USP/NF	1000 ppm max.
- MICROBIAL CONTAMINATION:		
TOTAL AEROBIC MICROBIAL COUNT		1000 CFU/g max.
TOTAL YEASTS AND MOULDS COUNT		100 CFU/g max.
ESCHERICHIA COLI		Absence in 10g.
SALMONELLA		Absence in 10g.

- * Compliance data - Tests not performed
- ** Monitoring plan

Indicatives Values

- Content of D-Sorbitol / D.S. : 35 % to 45 %
- Content of 1,4-Sorbitan / D.S. : 24 % to 28 %

Comments

The Certificate of Analysis states the content of D-sorbitol and the content of 1,4-sorbitan (=nominal value).

Methods used by Roquette may be EP or USP or internal validated method which have been compared to the pharmacopeia monograph.

Conformity

- **Current pharmacopeias** E.P. (2048) and U.S.P./NF

Storage

STORAGE

Store at room temperature, in a dry place and in its unopened original packaging.

SHELF LIFE

Chemical stability 2 years in its original packaging.

STANDARD PACKAGING

275 Kg steel drum

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.