ROQUETTE
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PRODUCT SPECIFICATIONS SHEET

ANHYDROUS DEXTROSE C

Definition

Product Identifier

Product name: ANHYDROUS DEXTROSE C

GLUCOSE (EP) - DEXTROSE (USP)
INCI: GLUCOSE

Specifications

A) CHARACTERS

APPEARANCE		White or almost white, crystalline powder.
SOLUBILITY		Freely soluble in water, very slightly soluble in ethanol (96%).

B) IDENTIFICATION

IDENTIFICATION TEST-A	EP	Complies
IDENTIFICATION TEST-A(*)	USP-NF	Complies
IDENTIFICATION TEST-B	EP / USP-NF	Complies
IDENTIFICATION TEST-C	USP-NF	Complies
IDENTIFICATION TEST-E	EP	Complies

C) TESTS

APPEARANCE OF SOLUTION	EP / USP-NF	Complies
CONDUCTIVITY	EP / USP-NF	20 microS/cm max.
DEXTRIN	EP / USP-NF	Complies
SOLUBLE STARCH, SULFITES	EP / USP-NF	15 ppm max.
WATER	EP / USP-NF	1.0 % max.
ASSAY	EP / USP-NF	97.5 - 102.0 %
RELATED SUBSTANCES:		EP / USP-NF
- Sum of impurities A and B, Maltose and Isomaltose		0.4 % max.
- Impurity C, Maltotriose		0.2 % max.
- Impurity D, Fructose		0.15 % max.
- Unspecified impurities		0.10% max

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- Total impurities	0.5 % max.
PARTICLE SIZE (LASER):	
- PART. > 1000 microns	5 % max.
- PART. > 250 microns	70 % max.
- PART. > 40 microns	90 % min.
MICROBIOLOGICAL VALUES:	
- TOTAL AEROBIC MICROBIAL COUNT(**)	1000 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT(**)	100 CFU/g max.
- ESCHERICHIA COLI(**)	Not detected in 1g
- SALMONELLA(**)	Not detected in 10g

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

Indicatives Values

AVERAGE PARTICLE SIZE (laser)	300 microns
BULK DENSITY	0.85 kg/l approx.

Comments

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

Conformity

Conforms to the current edition of

- European Pharmacopoeia (EP)
- US Pharmacopeia (USP)

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 in temperature and humidity.

Disclaimer

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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.