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PRODUCT SPECIFICATIONS SHEET

DEXTROSE ANHYDROUS BIOPHARMA

Definition

Product Identifier

Product name: DEXTROSE ANHYDROUS BIOPHARMA

GLUCOSE ANHYDROUS(EP) - DEXTROSE ANHYDROUS(USP / FCC)
PURIFIED GLUCOSE (JP)
INCI: GLUCOSE
Product code : 361417

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	Complies
IDENTIFICATION TEST-B	EP / USP	Complies
IDENTIFICATION TEST-C	USP	Complies
IDENTIFICATION TEST-E	EP	Complies
IDENTIFICATION TEST-1(*)	JP	Complies
IDENTIFICATION TEST-2	JP	Complies

C) TESTS

APPEARANCE OF SOLUTION	EP	Complies
COLOR AND CLARITY OF SOLUTION	USP / JP	Complies
CONDUCTIVITY	EP / USP / JP	20 microS/cm max.
RELATED SUBSTANCES:	EP / USP / JP	.
- sum of impurities A and B		
Maltose and Isomaltose	EP / USP / JP	0.4 % max.
- impurity C, Maltotriose	EP / USP / JP	0.2 % max.
- impurity D, Fructose	EP / USP / JP	0.15 % max.

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- unspecified impurities	EP / USP / JP	0.10 % max.
- total impurities	EP / USP / JP	0.5 % max.
DEXTRIN	EP / USP / JP	Complies
SOLUBLE STARCH, SULFITES	EP / USP / JP	15 ppm max.
WATER	EP / USP / JP	1.0 % max.
HEAVY METALS	JP	4 ppm max.
ASSAY (DEXTROSE)	EP / USP / JP	97.5 - 102.0 %
ASSAY - REDUCING SUGARS (*)	FCC	99.5 - 100.5 %
ARSENIC	FCC	1 ppm max.
CHLORIDE	FCC	0.018 % max.
LEAD	FCC	0.1 ppm max.
SULFUR DIOXIDE	FCC	0.002 % max.
LOSS ON DRYING	FCC	2.0 % max.
OPTICAL SPECIFIC ROTATION	FCC	+52.6 to +53.2 DEG.
STARCH	FCC	Complies
RESIDUE ON IGNITION	FCC	0.1 % max.
MICROBIOLOGICAL VALUES:		
- TOTAL AEROBIC MICROBIAL COUNT		100 CFU/g max.
- TOTAL YEASTS AND MOULDS COUNT(**)		100 CFU/g max.
- ESCHERICHIA COLI(**)		Not detected in 1g
- SALMONELLA(**)		Not detected in 10g
- PSEUDOMONAS AERUGINOSA		Not detected in 10g

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

Comments

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

Suitable for use in upstream Biopharmaceutical manufacturing. Not suitable for injection.

Conformity

Conforms to the current edition of

- European Pharmacopoeia (EP), GLUCOSE (0177)

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- US Pharmacopeia (USP), DEXTROSE

- Japanese Pharmacopoeia (JP), PURIFIED GLUCOSE

- Food Chemical Codex (FCC), DEXTROSE

Please contact us for any statement regarding compliance to the General Chapters (elemental impurities, residual solvents, organic volatile impurities, metal catalyst, metal reagent).

Storage

Retest date manufacturing date + 3 years.

-Those date is indicative and 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

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.