

LYCADEX® BIOPHARMA - DEXTROSE MONOHYDRATE

Definition

Product Identifier

Product name: LYCADEX® BIOPHARMA - DEXTROSE MONOHYDRATE

GLUCOSE MONOHYDRATE(EP) - DEXTROSE MONOHYDRATE(USP)

EINECS : 200-075-1

INCI: GLUCOSE

Product code : 361125

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

C) TESTS

APPEARANCE OF SOLUTION	EP	Complies
COLOR AND CLARITY OF SOLUTION	USP	Complies
CONDUCTIVITY	EP / USP	20 microS/cm max.
RELATED SUBSTANCES :		EP / USP
- 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.
- Total impurities		0.5 % max.
DEXTRIN	EP / USP	Complies

PRODUCT SPECIFICATIONS SHEET

LYCADEX® BIOPHARMA - DEXTROSE MONOHYDRATE

SOLUBLE STARCH, SULFITES	EP / USP	15 ppm max.
WATER	EP / USP	7.5 - 9.5 %
ASSAY (DEXTROSE)	EP / USP	97.5 - 102.0 %
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
- STAPHYLOCOCCUS AUREUS		Not detected in 10g
- PSEUDOMONAS AERUGINOSA		Not detected in 10g
BIOLOGICAL VALUES:		
- BACTERIAL ENDOTOXINS		<=1 IU/g

- * Compliance data - Tests not performed

Comments

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

Methods of analysis used by Roquette are listed in Analytical Dossier.

Suitable for use in biopharmaceutical manufacturing.

Conformity

Conforms to the current edition of

- European Pharmacopoeia (EP)
- US Pharmacopoeia (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

- 5 years in its original packaging.

We recommend to preserve the product in its unopened original packaging, preferably protected from wide variations in temperature and humidity.



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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.