

LYCADEX® PF / DEXTROSE MONOHYDRATE

Definition

Product Identifier

Product name: LYCADEX® PF / DEXTROSE MONOHYDRATE

GLUCOSE MONOHYDRATE (EP) - DEXTROSE (USP)- GLUCOSE HYDRATE (JP)

INCI: GLUCOSE

Manufacturing location : ROQUETTE FRERES, Lestrem (FRANCE)

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 / USP / JP	COMPLIES
CONDUCTIVITY	EP / USP / JP	20 microS/cm max.
DEXTRIN	EP / USP / JP	COMPLIES
SOLUBLE STARCH, SULFITES (**)	EP / USP / JP	15 mg/kg max.
WATER	EP / USP / JP	7.5 - 9.5 %.
HEAVY METALS (*)	JP	4 mg/kg max.
ASSAY (on DS)	EP / USP / JP	97.5 - 102.0 %.
RELATED SUBSTANCES:		
- SUM OF IMPURITIES A and B	EP - USP - JP	0.4 % max.
(IMPURITY A:MALTOSE - IMPURITY B:ISOMALTOSE)		
- IMPURITY C:MALTOTRIOSE	EP - USP - JP	0.2 % max.
- IMPURITY D:FRUCTOSE	EP - USP - JP	0.15 % max.
- UNSPECIFIED IMPURITIES	EP - USP - JP	0.10 % max.

PRODUCT SPECIFICATIONS SHEET

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- TOTAL IMPURITIES	EP - USP - JP	0.5 % 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
BIOLOGICAL VALUES:		
BACTERIAL ENDOTOXINS	LAL TEST	1.25 EU/G max.
PYROGEN TEST (**)	EP	COMPLIES
		-Solute at 150 g/L
		-Sterilized 10 mn at 110 D.C
		-Injection 10 mL/Kg

Comments

- Intended for use in manufacture of parenteral dosage forms.
- Methods used by Roquette may be the Pharmacopoeia methods or alternative validated methods which have been compared to the Pharmacopoeia methods.

Caption

- "EP" stands for European Pharmacopoeia
- "USP" stands for USP Pharmacopoeia
- "JP" stands for JP Pharmacopoeia
- (*) Compliance data - Tests not performed
- (**) Monitoring plan

Conformity

Conforms to the requirements of the current monograph

- European Pharmacopoeia (EP) GLUCOSE MONOHYDRATE (0178)
- US Pharmacopoeia (USP) DEXTROSE
- Japanese Pharmacopoeia (JP) Glucose Hydrate

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

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Storage

RETEST DATE Manufacturing date + 3 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.

- Upon opening, use the product as quickly as possible to prevent moisture regain.

Disclaimer

SPECIFIC DISCLAIMER:

ROQUETTE does not perform any retesting of the APIs batches beyond their retest date. Any use by the customer of any API batch beyond the retest date is subject to the customer's own determination of the suitability of the API continuing to comply with applicable specifications and ROQUETTE does not guaranty such compliance.

GENERAL 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. Analytical criteria are tested either on each batch or monitored or guaranteed, based on the Product Risk Analysis. For each batch, the status of the analysis may be indicated in the Certificate of Analysis. 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. The ultimate use of this Product in any finished product is the responsibility of the purchaser.

This Product may have restrictions with respect to its use and/or usage levels, and such may vary on a country-by-country basis. The purchaser is responsible for its use of the Product and for its finished product, and that any claims made regarding its use of the Product and/or the finished product comply with applicable laws and regulations.