

LYCADEX® PF / DEXTROSE MONOHYDRATE

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DEFINITION :

Glucose monohydrate

CAS n° : 14431-43-7

EINECS : 200-075-1

White, crystalline, odourless, sweet taste.

SPECIFICATIONS :

APPEARANCE OF SOLUTION	EP	clear, colourless
APPEARANCE OF SOLUTION	USP	Conforms
ACIDITY	EP NaOH 0.1N	0.15 ml max.
ACIDITY	USP NaOH 0.020N	0.30 ml max.
SPECIFIC OPTICAL ROTATION	EP	+52.5° à +53.3°
SPECIFIC ROTATION	USP	+52.6° à +53.2°
FOREIGN SUGARS, SOLUBLE STARCH, DEXTRIN	EP	Conforms
DEXTRIN	USP	Conforms
SOLUBLE STARCH, SULPHITE	USP	Conforms
SULPHITE (SO ₂)	EP	15 ppm max.
CHLORIDE	EP - USP	125 ppm max.
SULPHATE	EP - USP	200 ppm max.
ARSENIC	EP - USP	1 ppm max.
BARIUM	EP	Conforms
CALCIUM	EP	200 ppm max.
LEAD	EP	0.5 ppm max.
HEAVY METALS	USP	5 ppm max.
WATER CONTENT	EP	7.0 - 9.5 %
LOSS ON DRYING	USP	7.5 - 9.5 %
SULPHATED ASH	EP - USP	0.1 % max.
PYROGEN TEST	EP	conform
- solute at 100 g/l		
- sterilized 10 mn at 110 D.C		
- injection 10 ml/kg		
BACTERIAL ENDOTOXINS	LAL TEST	2.5 IU/g max.
TOTAL COUNT	internal Method	100/g max.
YEASTS + MOULDS	internal Method	20/g max.
ESCHERICHIA COLI	internal Method	abs. in 10g

MCL,MMC: ROQUETTE Methods

QUALITY ASSURANCE / PHARMA COSMETICS

Lestrem,
December 27, 2002

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SALMONELLA

internal Method

abs. in 10g

CONFORMITY :

- European Pharmacopoeia 2002 (EP)
- USP 25/NF 20 (USP)

STORAGE :

SHELF LIFE :

- chemical stability : 3 years in its original packaging.

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