Farmalabor PACK — Packaging for pharmaceutical and cosmetic use

FARMALABOR Farmacisti Associati — Raw materials for pharmaceutical cosmetic and food use

Farmalabor TECH — Equipment and furniture for galenic laboratory

CERTIFICATE OF ANALYSIS

Product 1216 Glucose monohydrate Ph. Eur.

Batch Number R1203053

Manufacturer

Retest date 12/03/2017

TECHNICAL DATA SHEET

PRODUCT	GLUCOSE MONOHYDRATE Ph. Eur.
CAS NUMBER	5996-10-1
MOLECULAR FORMULA	C6H12O6·H20
MOLECULAR WEIGHT	198,17
ASSAY	Min. 99,5%
OTHER NAMES	(+)-D-Glucopyranose monohydrate; Dextrose monohydrate
ORIGIN	Product derived from maize starch hydrolysis
TYPE OF PRODUCT AND USE	Food use
DESCRIPTION	Purified and crystallized D-glucose, containing a molecule of water of crystallization.
ALLERGENS	The product contains: maize and products thereof The product doesn't contain: eggs and products thereof; milk and dairy products; fish and products thereof; crustaceans and products thereof; fruits; legumes and products thereof; cocoa; yeast; meat (beef, pork, chicken), soya and products thereof, nuts and products thereof, groundnut and products thereof; other nuts; sesame and products thereof; mustard and products thereof; molluscs and products thereof; sorbates (E200/E203); benzoates (E210/E213); parabenes (E214/E219); gallates (E310/E312); BHA/BHT (E320/321); lactose; saccharose; lupin and products thereof; celery and products thereof; coriander; carrot; others umbellifers; glutamate (E620/625); gelatine; vanillin; cinnamon; azo colorants (E102/E110/E122/E123/E124/E151).
APPEARANCE	White crystalline powder
SOLUBILITY	Freely soluble in water; sparingly soluble in ethanol (96%)
pH	4-6 (sol. 50%)
STORAGE	Keep in well-closed containers, in a cool and dry place, protected from moisture
PROPERTIES	Dextrose is used as a tablet and capsule diluent; it is used in solution to adjust tonicity and as a sweetening agent; as a wet granulation diluent and binder, and as a direct-compression tablet diluent and binder, primarly in chewable tablets. The mildly reducing properties of dextrose may be used when tableting to improve the stability of active materials that are sensitive to oxidation. Dextrose is also a therapeutic agent: gelatinous and chewable tablets are used by diabetic subjects for mild hypoglycemic state.

ANALYSIS	LIMITS	RESULTS
IDENTITY	Identification test A: complies	Complies
	Identification test B: complies	Complies
	Identification test C: complies	Complies
APPEARANCE	White crystalline powder	Complies
ODOUR	Neutral	Complies
TASTE	Sweet	Complies
APPEARANCE OF SOLUTION	Complies	Complies
SIZE	Residue on 40 µ (400 mesh): min 85%	85%
	Residue on 315 µ (48 mesh): max 3%	0,5%
SPECIFIC ROTATION	+52,5°/+53,3° (EP)	53,1°
WATER	7-9,5% (EP)	8,2%
SULFATED ASH	Max 0,1% (EP)	< 0,10%
HEAVY METALS	Pb: max 0,50 ppm (EP)	< 0,50 ppm
	As: max 1,00 ppm (EP)	< 1,00 ppm
SULFATES	Max 200 ppm (EP)	< 10,0 ppm
SULPHITES	Max 15 ppm (EP)	< 15 ppm
CHLORIDES	Max 125 ppm (EP)	< 5,0 ppm

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ANALYSIS	LIMITS	RESULTS
CALCIUM	Max 200 ppm (EP)	< 200 ppm
BARIUM	Complies (EP)	Complies
IMPURITIES	Foreign sugars, soluble starch, dextrins: complies (EP)	Complies

NOTES

NOTES	Complies with: Codex Stan 212-1999; E.E.C. Dir. 2001/111/CE; FCC current edition; US code of Federal Regulations 21 CFR/168.111. OGM-free (Reg. EC 1829-1830/2003)
PHARMACOPOEIA	Complies with EP current edition

All specifications are as provided by the original manufacturer. They do not imply any exemption from identifying and inspecting the product before its use, the final user being fully responsible for the adoption and the correct usage of the product.

Technical director
Dr. Giovanni Summonte