

Dexpanthenol

CODE ARTICLE: 90670	BATCH: 0132859
TEST DATE: 05/12/2024	TEST: QC-00270688
EXPIRY DATE: 27/07/2027	FABRICATION DATE: 27/07/2024
CAS: [81-13-0]	FORMULA: C9H19NO4
SYNONYMS / BOTANICAL NAME: D-Pantenol; Alcohol D-Pantotenilico	
STORAGE: Store in tightly closed containers in a cool, dry place.	

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS -			Viscous liquid	PH.EUR.*
COLOUR	PASS -			Colourless	PH.EUR.*
SOLUBILITY					
SOLUBLE	PASS -			Very soluble in water	PH.EUR.*
SOLUBLE	PASS -			Freely soluble in ethanol (96 per cent)	PH.EUR.*
SOLUBLE	PASS -			Practically insoluble in heptane	PH.EUR.*
IDENTIFICATION					
IDENTIFICACION ROTACIÓN ÓPTICA [A]	30,8 DEGREES		29	31,5	PH.EUR.
IDENTIFICACION POR IR [B]	PASS				PH.EUR.*
DISSOLUTION ASPECT	PASS -			Solution S clear and not more coloured than B6	PH.EUR.
PH (5%)	9,6 -		9	10,5	PH.EUR.*
IMPUREZA A Y OTROS AMINO COMPUESTOS	0,4 %		-	0,5	PH.EUR.
RELATED SUBSTANCES					
IMPURITY B	0,31 %		-	0,5	PH.EUR.
IMPURITY C	0,92 %		-	1	PH.EUR.
TOTAL IMPURITIES	1,2 %		-	2	PH.EUR.
UNSPECIFIED IMPURITIES	<0,05 %			0,10	PH.EUR.
WATER	0,3 %		-	1	PH.EUR.
SULPHATED ASHES	PASS %		-	0,1	PH.EUR.
ASSAY (ANHYDROUS BASIS)	100,1 %		98	101	PH.EUR.
REFRACTION INDEX	1,498 -		1,497	1,501	Manufacture's Standard
HEAVY METALS	PASS ppm		-	10	Manufacture's Standard
LEAD	PASS ppm		-	1,0	Manufacture's Standard
RESIDUAL SOLVENTS					
DICHLOROMETHANE	PASS ppm			50	Manufacture's Standard
METHANOL	PASS ppm			200	Manufacture's Standard
MICROBIOLOGICAL CONTROL					
TOTAL AEROBICS	PASS UFC/G			100	Manufacture's Standard
MOLDS AND YEASTS	PASS UFC/G			100	Manufacture's Standard
ENTEROBACTERS	PASS UFC/G			10	Manufacture's Standard

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer Batch: TL02407064 Manufacturer Code: 56839 Supplier Code: 405159

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
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TEST	RESULTS	Units	MIN	MAX	METHOD
SALMONELLA	ABSENT	25g			Manufacture's Standard
E. COLI	ABSENT	10g			Manufacture's Standard
STAPHYLOCOCCUS AUREUS	ABSENT	10g			Manufacture's Standard
PSEUDOMONAS AERUGINOSA	ABSENT	10g			Manufacture's Standard
C. ALBICANS	ABSENT	10g			Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11, USP				Manufacture's Standard

NON-sterile



Silvia Sancho-Tello Ripoll
Technical Director.

The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE

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