

Dexpanthenol

CODE ARTICLE: 96483	BATCH: 0131651
TEST DATE: 28/10/2024	TEST: QC-00269313
EXPIRY DATE: 20/06/2027	FABRICATION DATE: 20/06/2024
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]	30,6 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%)	10,3 -		9	10,5	PH.EUR.*
IMPUREZA A Y OTROS AMINO COMPUESTOS	0,4 %		-	0,5	PH.EUR.
RELATED SUBSTANCES					
IMPURITY B	0,26 %		-	0,5	PH.EUR.
IMPURITY C	0,69 %		-	1	PH.EUR.
TOTAL IMPURITIES	1 %		-	2	PH.EUR.
UNSPECIFIED IMPURITIES	<0,05 %			0,10	PH.EUR.
WATER	0,2 %		-	1	PH.EUR.
SULPHATED ASHES	PASS %		-	0,1	PH.EUR.
ASSAY (ANHYDROUS BASIS)	100 %		98	101	PH.EUR.
REFRACTION INDEX	1,499 -		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: TL02406052 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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