

Dexpanthenol

CODE ARTICLE: 90670	BATCH: 0127999
TEST DATE: 14/05/2024	TEST: QC-00264338
EXPIRY DATE: 29/08/2026	FABRICATION DATE: 30/08/2023
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.*
<u>SOLUBILITY</u>					
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.*
<u>IDENTIFICATION</u>					
IDENTIFICACION ROTACIÓN ÓPTICA [A]	30,2 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 -		9	10,5	PH.EUR.*
IMPUREZA A Y OTROS AMINO COMPUESTOS	0,4 %		-	0,5	PH.EUR.
<u>RELATED SUBSTANCES</u>					
IMPURITY B	0,24 %		-	0,5	PH.EUR.
IMPURITY C	0,97 %		-	1	PH.EUR.
TOTAL IMPURITIES	1,3 %		-	2	PH.EUR.
UNSPECIFIED IMPURITIES	0,08 %			0,10	PH.EUR.
WATER	0,1 %		-	1	PH.EUR.
SULPHATED ASHES	PASS %		-	0,1	PH.EUR.
ASSAY (ANHYDROUS BASIS)	99,3 %		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
<u>RESIDUAL SOLVENTS</u>					
DICHLOROMETHANE	PASS MG/KG			50	Manufacture's Standard
METHANOL	PASS MG/KG			200	Manufacture's Standard
<u>MICROBIOLOGICAL CONTROL</u>					
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
SALMONELLA	ABSENT/25g				Manufacture's Standard
E. COLI	ABSENT/10g				Manufacture's Standard
STAPHYLOCOCCUS AUREUS	ABSENT/10g				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.



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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, FCC				Manufacture's Standard

NON-sterile



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

Silvia Sancho-Tello Ripoll
Technical Director.

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Manufacturer Batch: TL02308130 Manufacturer Code: 56839 Supplier Code: 405159

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