

METAPHARMACEUTICAL

N DE LOTE:

0120323

16/03/2023
DSM

D-Panthenol

Coversheet for Certificate of Analysis

Productcode : 0413852
Lot No. : TL02210099
Analysis No. : L30666



C/ La Terra, 42 - P.I. Els Bellots
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CfC Number : 05021155
Articlecode : 0413852331
Sales Name : 20 KG PAIL PE D-Panthenol
Manufacturing Date : 16-OCT-2022
Best Use Before Date : 15-OCT-2025
Delivery Note No. 2422082385
Destination : Spain
Customer Ref. No : PC2201679
Customer Article No: .045
Customer Name: DISPROQUIMA,S.A.
C/Terra 42, Pol. Ind. Els Bellots
Terrassa
Article desc. CoA
Comment

CERTIFICATE OF ANALYSIS

D-Panthenol

Product Code:	0413852	Manufacturing Date:	16-Oct-2022
Analysis Number:	30666	Release Date:	06-Dec-2022
Lot Number:	TL02210099	Best Use Before:	15-Oct-2025

Test	Test Method	Result	Limits/Specification
Appearance:	Visual	viscous liquid	viscous liquid
Colour:	Visual	colorless	colorless, slightly yellow
Solution in water 5%:	Spectroscopy	clear	clear
Colour of solution in water 5%:	Visual	complies	not more coloured than Ph. Eur. B6
pH of 5% solution in water:	Potentiometry	9.8	9.0 - 10.5
Identity by specific rotation and IR:	Visual	corresponds	corresponds
Refractive Index (589nm, 20 deg. C):		1.500	1.497 - 1.501
Specific Optical Rotation (589nm, 20 deg C, c=5):	Polarimetry	30.4 °	+29.0 - +31.5 °
Water:	Karl Fischer titration	0.1 %	≤ 1.0 %
Sulfated Ash:	Gravimetric analysis	corresponds*	≤ 0.1 %
Heavy Metals colourimetric:	Visual	corresponds*	≤ 10 ppm
Lead:	AAS	corresponds*	≤ 1.0 ppm
Impurity A (3-Aminopropan-1-ol) and other amino compounds:	Titration	0.4 %	≤ 0.5 %
Impurities by HPLC:	HPLC		
Impurity B (Pantoic acid)		0.30 %	≤ 0.5 %
Impurity C (Pantolactone)		0.79 %	≤ 1.0 %
Unspecified Impurities		0.07 %	≤ 0.10 %
Total Impurities		1.2 %	≤ 2.0 %

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Test	Test Method	Result	Limits/Specification
Residual Solvents:	Gas chromatography		
Dichloromethane		corresponds*	≤ 50 ppm
Methanol		corresponds*	≤ 200 ppm
Assay (anhydrous substance) non aqueous titration:	Titration	99.4 %	98.0 - 101.0 %
Microbiological Purity:	Test for microbiological quality		
Total Aerobic Microbial Count adapted Ph. Eur. 2.6.12		corresponds*	≤ 100 CFU/g
Total Comined Yeasts and Moulds adapted Ph. Eur. 2.6.12		corresponds*	≤ 100 CFU/g
Enterobacteria PH. Eur. 2.6.13		corresponds*	≤ 10 CFU/g
Salmonella spp Ph. Eur. 2.6.13		corresponds*	negative in 25 g
Escherichia coli Ph. Eur. 2.6.13		corresponds*	negative in 10 g
Staphylococcus aureus Ph. Eur. 2.6.13		corresponds*	negative in 10 g
Pseudomonas aeruginosa Ph. Eur. 2.6.13		corresponds*	negative in 10 g
Candida albicans Ph. Eur. 2.6.13		corresponds*	negative in 10 g

*) checked at regular intervals

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This lot has been analyzed against the substance specifications given above and released. The manufacturing and control records have been reviewed by our authorized Quality organization. The lot has been produced in conformity with applicable regulations and Good Manufacturing Practices for the uses stated in DSM Product Data sheet. A QA comment will be presented below if there is any deviation requiring restriction in the use of this lot.

Please consult your local representative or visit the DSM Customer Portal online for further compendial and compliance documentation.

Mark Cusack, Designated Quality Assurance Manager
(This document has been generated and signed electronically)

DSM Nutritional Products (UK) Ltd
Quality Assurance

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