CERTIFICATE OF ANALYSIS

DSM
BRIGHT SCIENCE. BRIGHTER LIVING.

Calcium D-Pantothenate

Product Code:	0412678	**Manufacturing Date:**	16-Dec-2023
Analysis Number:	63949	**Release Date:**	07-Feb-2024
Lot Number:	TL02312875	**Best Use Before:**	15-Dec-2026

Test	Test Method	Result	Limits/Specification
Appearance:	Visual	free flowing powder	free flowing powder
Colour:	Visual	white	white
Clarity of solution, 5% in water:	Visual	clear	clear
Colour of solution, 5% in water:	Visual	colorless	colorless
pH of solution, 5% in water:	Potentiometry	7.0	6.8 - 8.0
Alkalinity:	Visual	corresponds*	complies with USP regulations
Identity (Rotation, Calcium):		corresponds	corresponds
Identity (IR):	IR spectroscopy	corresponds	corresponds
Specific Optical Rotation, dry (589nm, 20°C, c=5):	Polarimetry	25.9 °	25.5 - 27.5 °
Loss on drying (105°C, 4 hours):	Gravimetric analysis	1.99 %	≤ 3.0 %
Heavy Metals as Pb, colourometric:	Visual	corresponds*	≤ 10 ppm
Lead:	AAS	corresponds*	≤ 1.0 ppm
Chloride:	Spectroscopy	<200 ppm	≤ 200 ppm
Alkaloids, by FCC:	Visual	corresponds*	complies
Impurity A (3-Aminopropionic Acid) and other aminocarboxylic acid impurities:	Titration	0.11 %	≤ 0.50 %
Nitrogen content, dry:	Titration	corresponds*	5.7 - 6.0 %
Calcium content, dry:	Titration	8.3 %	8.2 - 8.6 %

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Test	Test Method	Result	Limits/Specification
Assay, dry:	Titration	99.1 %	98.0 - 101.0 %
Residual Solvents:	Gas chromatography		
Dichloromethane		corresponds*	≤ 50 ppm
Methanol		corresponds*	≤ 200 ppm
Microbiological Purity:	Test for microbiological quality		
Total Aerobic Microbial Count adapted Ph. Eur. 2.6.12		<10^3 CFU/g	max. 10^3 CFU/g
Total combined Yeast/Moulds Count adapted Ph. Eur. 2.6.12		<10^2 CFU/g	max. 10^2 CFU/g
Enterobacteria Ph. Eur. 2.6.13		<10 CFU/g	< 10 CFU/g
Salmonella spp Ph. Eur. 2.6.13		negative in 25 g	negative in 25 g
Escherichia coli Ph. Eur. 2.6.13		negative in 10 g	negative in 10 g
Staphylococcus aureus Ph. Eur. 2.6.13		negative in 10 g	negative in 10 g
Pseudomonas aeruginosa Ph. Eur. 2.6.13		negative in 10 g	negative in 10 g
Related Impurities:	HPLC		
Impurity B		0.66 %	≤ 0.8 %
Impurity C		0.25 %	≤ 0.3 %
Impurity E		0.03 %	≤ 0.25 %
Impurity H		0.06 %	≤ 0.15 %
Unspecified Impurities		<0.05 %	≤ 0.10 %
Total Impurities		1.01 %	≤ 1.2 %

*) 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.

Matthew Brown, Designated Quality Assurance Manager
(This document has been generated and signed electronically)

DSM Nutritional Products (UK) Ltd
Quality Assurance

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