

CERTIFICATE OF ANALYSIS



DSM

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D-Panthenol

Product Code:	0413852	Manufacturing Date:	27-Jul-2024
Analysis Number:	84205	Release Date:	08-Oct-2024
Lot Number:	TL02407064	Best Use Before:	27-Jul-2027

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	9.7	9.0 - 10.5
Identity by specific rotation and IR:	Visual	corresponds	corresponds
Refractive Index (589nm, 20 deg. C):		1.498	1.497 - 1.501
Specific Optical Rotation (589nm, 20 deg C, c=5):	Polarimetry	30.8 °	+29.0 - +31.5 °
Water:	Karl Fischer titration	0.3 %	≤ 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)		0.31 %	≤ 0.5 %
Impurity C (Pantolactone)		0.92 %	≤ 1.0 %
Unspecified Impurities		<0.05 %	≤ 0.10 %
Total Impurities		1.2 %	≤ 2.0 %

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Residual Solvents:	Gas chromatography		
Dichloromethane		corresponds*	≤ 50 ppm
Methanol		corresponds*	≤ 200 ppm
Assay (anhydrous substance) non aqueous titration:	Titration	100.1 %	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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