

ANALYTICKÝ CERTIFIKÁT / CERTIFICATE OF ANALYSIS

Calcium-D-Pantothenate

Coversheet for Certificate of Analysis

Productcode : 0412678
 Lot No. : TL01909788
 Analysis No. : 06213439

CfC Number : 03882549
 Articlecode : 0412678366
 Sales Name : 25 KG BOX Calcium D-
 Pantothenate

Manufacturing Date : 10-SEP-2019
 Best Use Before Date : 09-SEP-2022
 Delivery Note No. 8222063776
 Destination : Netherlands
 Customer Ref. No : 8048864
 Customer Article No: 52231

Test	Result	Limits / Specifications	Dimension / Units
Appearance visual	free flowing powder	free flowing powder	
Colour visual	white	white	
Solution in Water (c = 5) visual	clear and colourless	clear and colourless	
pH (c = 5 in water) of 5% solution in water	6.8	6.8 to 8.0	
Alkalinity visual	corresponds*	no pink colouration	
Identity Calcium, rotation and chromatography Ca, rotation, chromatography	corresponds*	corresponds	
Identity Copper Sulphate	corresponds*	complies	
Specific Rotation(c=5 in Water) 589nm,20deg,c=5	26.6	+25.5 to +27.5	deg.
Loss on Drying Ph.Eur.	2.29	0.0 to 3.0	%
Heavy Metals colourimetric comparison to Pb standard	corresponds*	0 to 10	ppm
Lead atomic absorption	corresponds*	max. 1.0	ppm
Chloride turbidimetric comparison to standard	corresponds*	0 to 200	ppm
Alkaloids visual	corresponds*	no turbidity produced	
3-Aminopropionic Acid non-aqueous titration	0.16	0.0 to 0.5	%
Nitrogen content digestion/titration	5.8	5.7 to 6.0	%
Calcium content titration	8.3	8.2 to 8.6	%
Assay as Dry non-aqueous titration	99.3	98.0 to 101.0	%
Dichloromethane Headspace GC	corresponds*	max. 50	ppm
Methanol Headspace GC	corresponds*	max. 200	ppm



CALCIUM D-PANTOTHENATE

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Test	Result	Limits / Specifications	Dimension / Units
Microbiology			
Total Aerobic Microbial Count adapted Ph. Eur. 2.6.12	max 10 ³ cfu/g	max 10 ³ cfu/g	
Total combined Yeasts/Moulds adapted Ph. Eur. 2.6.12	max 10 ² cfu/g	max 10 ² cfu/g	
Enterobacteria Ph. Eur. 2.6.13	max 10 ¹ cfu/g	max 10 ¹ cfu/g	
Salmonella spp. Ph. Eur. 2.6.13	negative in 25g	negative in 25g	
Escherichia coli Ph. Eur. 2.6.13	negative in 10g	negative in 10g	
Staphylococcus aureus Ph. Eur. 2.6.13	negative in 10g	negative in 10g	
Pseudomonas aeruginosa Ph. Eur. 2.6.13	negative in 10g	negative in 10g	
Impurity B HPLC	0.5	max. 0.8	%
Impurity C HPLC	0.1	max. 0.5	%
Impurity E HPLC	0.07	max. 0.25	%
Impurity H HPLC	0.06	max. 0.15	%
Unspecified Impurities >0.10 percent HPLC	not present	not present	
Total Impurities HPLC	0.9	max. 1.5	%

*) checked at regular intervals

This lot was analysed and released by our authorized Quality Control Department and was found to meet the specifications as given above.

The product meets all requirements of the following valid compendia when tested accordingly:

USP, FCC, Ph.Eur.

