

Calcium-D-Pantothenate



Coversheet for Certificate of Analysis

Productcode : 0412678
Lot No. : TL01608719
Analysis No. : 06187950

CfC Number : 03011775
Articlecode : 0412678366
Sales Name : CALCIO D-PANTOTENATO USP
Manufacturing Date : 17-AUG-2016
Best Use Before Date : 17-AUG-2019
Delivery Note No. 1922101930
Destination : Italy
Customer Ref. No : 2016 5214
Customer Article No: 001608-25
Customer Name: ACEF S P A
VIA UMBRIA
FIORENZUOLA D'ARDA

Comment

CALCIUM D-PANTOTHENATE

CERTIFICATE OF ANALYSIS

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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	6.9	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 (as dry) 589nm, 20 deg.C, c=5	26.5	+25.5 to +27.5	deg.
Loss on Drying Ph. Eur.	2.4	0.0 to 3.0	%
Heavy Metals colourimetric comparison to Pb standard	corresponds*	0 to 10	ppm
Lead atomic absorption	corresponds*	0 to 2	ppm
Chloride turbidimetric comparison to standard	corresponds*	0 to 200	ppm
Alkaloids visual	corresponds*	no turbidity produced	
3-Aminopropionic Acid non-aqueous titration	0.15	0 to 0.5	%
Nitrogen content digestion/titration	5.7	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*	0 to 600	ppm
Methanol Headspace GC	corresponds*	0 to 3000	ppm

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Calcium Pantoate	0.49	0.0 to 0.80	%
HPLC			
Pantolactone	0.07	0.0 to 0.20	%
HPLC			
Methyl Pantothenate	0.01	0.0 to 0.15	%
HPLC			
Impurity 1	0.04	0.0 to 0.15	%
HPLC			
Impurity 2	0.06	0.0 to 0.15	%
HPLC			
Unspecified Impurities >0.10 percent	not present	not present	
HPLC			
Total Impurities	0.8	0.0 to 1.5	%
HPLC			
Microbiology			
Total Aerobic Microbial Count adapted Ph. Eur. 2.6.12	less than 10 ³ cfu/g	less than 10 ³ cfu/g	
Total combined Yeasts/Moulds adapted Ph. Eur. 2.6.12	less than 10 ² cfu/g	less than 10 ² cfu/g	
Enterobacteria Ph. Eur. 2.6.13	less than 10 ¹ cfu/g	less than 10 ¹ cfu/g	
Escherichia coli Ph. Eur. 2.6.13	negative in 10g	negative in 10g	
Salmonella spp. adapted Ph.Eur. 2.6.13	negative in 25g	negative in 25g	
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	

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*) 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:

Ph.Eur. + USP + FCC

DSM Nutritional Products (UK) Ltd.

The Quality Assurance Manager



Strachan Fraser