

Certificate of Analysis

Productname: **Calcii pantothenas**
Number of analysis/Inspection Code: 1 / KEUR-187039B
Batchnumber: **20I02-F01-374200**
Reference code / No.: 3162 / 93275888Q0
Analysed according to: **PH.EUR10.2**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		Slightly hygroscopic !
Identification A	+25,5 - +27,5	Conform		Specific optical rotation
Identification B	Conform	Conform		HPLC
Identification C	Blue	Conform		
Identification D	Red	Conform		Calcium
Appearance of solution	Clear and colourless	Conform		5%m/V
pH	6,8 - 8,0	7,3		5%m/V
Specific optical rotation	+25,5 - +27,5	27,3		Dried
Imp A+other aminocarb. imp	<=0,50	0,29	%	
Related substances	Conform	Conform		
Impurity B	<=0,8	<0,05	%	
Impurity C	<=0,5	<0,05	%	
Impurity E	<=0,25	0,11	%	
Impurity H	<=0,15	n.d.	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,5	0,1	%	
Chlorides	<=200	Conform	ppm	
Loss on drying	<=3,0	2,4	%	105°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Calcium pantothenate	98,0 - 101,0	100,0	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer



Analysis performed by the authorized laboratory Proxylabs.

Release:

Paul Hofman

Pharmacist - Qualified Person

11/13/20

Expiration: 05-2023

Conclusion: APPROVED

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