

Certificate of Analysis

Product name:	Calcii pantothenas		
Batch number / Weight:	22C23-B02-219448 / 100 G		
Analysed according to:	Ph. Eur.		

Tests	Requirement	Result	Unit	Standard remark
Appearance	White powder	Conform		
Identification A	+25,5 - +27,5	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
рН	6,8 - 8,0	7,30		
Specific optical rotation	+25,5 - +27,5	+27,4		
3-Aminopropionic acid	<=0,5	Conform	%	
Related substances	Conform	Conform		
Impurity B	<=0,8	0,43	%	
Impurity C	<=0,3	0,09	%	
Impurity E	<=0,25	0,132	%	
Impurity H	<=0,15	0,000	%	
Individual unspecified impurity	<=0,10	<0,05	%	
Total impurities	<=1,2	0,65	%	
Chlorides	<=200	<200	ppm	
Loss on drying	<=3,0	2,54	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Calcium pantothenate	98,0 - 101,0	99,95	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	not more than 1500 ppm	<3000	ppm	

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Release: Agnieszka Pszczółka Qualified Person

30-05-2022

Expiration: 05-10-2024

Conclusion: APPROVED

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