

## Certificate of Analysis

**Product name:** **Calcii pantothenas**

**Batch number / Weight:** **22C23-B02-223693 / 25 G**

**Analysed according to:** **Ph. Eur. 10**

**Number of analysis / Inspection Code** **22C23-B02 / INS-22-3043**

**Reference Code / No.:** **V01782 / 75379568E0**

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		
pH	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	<=3000	<3000	ppm	

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Fagron Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail:biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.  
ul. Pasternik 26, 31-354 Kraków, Poland  
tel.: +48 12 3343 512  
e-mail: biuro@fagron.pl

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:

Agnieszka Pszczółka

Qualified Person

21-09-2022

Expiration: 05-10-2024

Conclusion: APPROVED

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Fagron Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail:biuro@fagron.pl