

Certificate of Analysis

Product name: **Cholecalciferolum 1g=40ME**

Batch number / Weight: **22I23-B06-213412 / 1 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22I23-B06 / INS-22-8472**

Reference Code / No.: **/ UE02102007**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
IR-spectrum	Conform	Conform		
Specific optical rotation	+105 - +112	+109,6		
Related substances	Conform	Conform		
Impurity A	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,0	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Cholecalciferol	97,0 - 102,0	101,51	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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:
Ewelina Gadzinowska
Qualified Person

26-01-2023

Expiration: 07-02-2026

Conclusion: APPROVED

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