

Certificate of Analysis

Product name: **Calcii gluconas**

Batch number / Weight: **23G19-B04-229715 / 1 KG**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23G19-B04 / INS-23-6144**

Reference Code / No.: **V01201 / 7500114974**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) White, crystalline or granular powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Colour ≤Y6	Conform		
Appearance of solution	≤ref. susp. II	Conform		
Organic substances and boric ac	Conform	Conform		
Sucrose and reducing sugars	Conform	Conform		
Chlorides	≤200	<200	ppm	
Sulphates	≤100	<100	ppm	
Magnesium and alkaline metals	≤0,4	0,20	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Calcium (D-)Gluconate monohyd	98,5 - 102,0	99,58	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer

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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:
Dominika Soltysik
Qualified Person

08-09-2023

Expiration: 09-05-2027

Conclusion: APPROVED

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