

Certificate of Analysis

Product name: **Calcii gluconas**
Batch number / Weight: **21K04-B01-216189 / 1 KG**
Analysed according to: **Ph. Eur.**

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	0,11		
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Calcium (D-)Gluconate monohyd	98,5 - 102,0	99,0	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
TAMC	≤ 10 ³	<10	CFU/g	
TYMC	≤10 ²	<10	CFU/g	

Analysis performed by the authorized lab.

Release:
 Agnieszka Pszczółka
 Qualified Person

19-03-2022

Expiration: 31-03-2025

Conclusion: APPROVED

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