

Certificate of Analysis

Product name: **Calcii gluconas**
Batch number / Weight: **21D02-B05-210992 / 250 G**
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 $\leq Y6$	Conform		
Appearance of solution	\leq ref. susp. II	Conform		
Organic substances and boric acid	Conform	Conform		
Sucrose and reducing sugars	Conform	Conform		
Chlorides	≤ 200	Conform	ppm	
Sulphates	≤ 100	≤ 100	ppm	
Magnesium and alkaline metals	$\leq 0,4$	0,30		
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Calcium (D-)Gluconate monohydrate	98,5 - 102,0	99,39	%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	$\leq 10^3$	$2,0 \times 10^1$	CFU/g	
TYMC	$\leq 10^2$	< 10	CFU/g	

Analysis performed by the authorized lab.

Release:

CE } a • : \ a • : & 5 } æ

Qualified Person

28-06-2021

Expiration: 31-03-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.