

## Certificate of Analysis

**Product name:** **Calcii gluconas**  
**Batch number / Weight:** **20I16-B06-202725 / 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 acid	Conform	Conform		
Sucrose and reducing sugars	Conform	Conform		
Chlorides	≤200	Conform	ppm	
Sulphates	≤100	Conform	ppm	
Magnesium and alkaline metals	≤0,4	0,36		
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Calcium (D-)Gluconate monohydrate	98,5 - 102,0	99,57	%m/m	
Total aerobic microbial count (TAMC)	≤1000	Conform	CFU / g	
Total yeasts and moulds (TYMC)	≤100	Conform	CFU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
TAMC	≤ 10 <sup>3</sup>	<10	CFU/g	
TYMC	≤10 <sup>2</sup>	<10	CFU/g	

Analysis performed by the authorized lab.

Release:  
 Ewelina Gadzinowska  
 Qualified Person

30-10-2020

Expiration: 05-04-2024

Conclusion: APPROVED

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