

Certificate of Analysis

Product name: **Calcii gluconas**
Batch number / Weight: **20116-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 ³	<10	CFU/g	
TYMC	<=10 ²	<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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