

Certificate of Analysis

Product name: **Zinci gluconas**

Batch number / Weight: **22L30-B04-230408 / 50 G**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **22L30-B04 / INS-23-1282**

Reference Code / No.: **V01201 / 7500095370**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	<=ref. susp. II / <=Y6	Conform		
Sucrose and reducing sugars	Conform	Conform		
Chlorides	<=500	<500	ppm	
Sulphates	<=500	<500	ppm	
Cadmium	<=2	0,08	ppm	
Lead	<=2,00	0,55	ppm	
Thallium	<=2,00	<0,01	ppm	
Water (Karl Fischer)	<=12,0	7,18	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Zinc gluconate	98,0 - 102,0	101,25	%m/m	
Total aerobic microbial count (TA)	<=1000	<1	CFU / g	
Total yeasts and moulds (TYMC)	<=100	<1	CFU/g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	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, EI Spol, CBMiA

Release:
Dominika Soltysik
Qualified Person

23-06-2023

Expiration: 29-11-2026

Conclusion: APPROVED

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