

Certificate of Analysis

Product name: **Zinci gluconas**
Batch number / Weight: **22A21-B08-225410 / 50 G**
Analysed according to: **Ph. Eur.**
Number of analysis / Inspection Code **22A21-B08 / INS-22-2324**
Reference Code / No.: **V01201 / 7500080182**

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	0,04	ppm	
Lead	<=2,00	0,55	ppm	
Thallium	<=2,00	<0,01	ppm	
Water (Karl Fischer)	<=12,0	7,04	%	
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	99,2	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

fagron.pl

Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, Poland
 tel.: +48 12 3343 512
 e-mail: biuro@fagron.pl

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 EL Spol

Release:

Agnieszka Pszczółka

Qualified Person

28-11-2022

Expiration: 13-09-2026

Conclusion: APPROVED

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

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl