

Certificate of Analysis

Product name: **Zinci oxidum**
Batch number / Weight: **22G07-B11-226360 / 200 G**
Analysed according to: **Ph. Eur. 10.8**
Number of analysis / Inspection Code **22G07-B11 / INS-22-6046**
Reference Code / No.: **V00625 / 48/21**

Tests	Requirement	Result	Unit	Standard remark
Appearance	soft, white or faintly yellowish-white, amorphous powder	Conform		
Appearance	free from gritty particles			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Particle size	99%<90 µm	Conform		
Alcalinity	Conform	0,00	ml	
Carbonates and substances inso insoluble in acids	Conform	Conform		
Iron	<=200	<200	ppm	
Cadmium	<=10	<0,01	ppm	
Lead	<=10	3,59	ppm	
Thallium	<=5	2,62	ppm	
Loss on ignition	<=1,0	0,27	%	
Assay	99,0 - 100,5	100,15	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA		<10	CFU/g	
Total yeasts and moulds (TYMC)		<10	CFU/g	

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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 lab,CBMiA

Release:
Ewelina Gadzinowska
Qualified Person

30-11-2022

Expiration: 27-11-2026

Conclusion: APPROVED

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