



Certificate of Analysis

Productname: Zinci oxidum

Inspection No: G05190/0519/536
Batchnumber: 19D29-T21-065879
Expiration date: 14.04.2022
Analysed according to: ČL 2017, Ph.Eur.9.0
Original Manuf. Date: 15.4.2019

Sample Unit: 2 x 50 g
Batch Size: 2 000 x 250 g

Identification of producer: V01172
Batch no. of vendor: D29099

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Bílý nebo slabě žlutobílý jemný amorfní amorphous powder, free from gritty particles.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	White /yellow /white	Conform			Fagron CZ
Identification B	White	Conform		Zinc	Fagron CZ
TESTS					
Alkalinity	<=0,3	0,1	ml	0,1 mol/l HCl	Fagron CZ
Carbonates and subs. insoluble in acids	Conform	Conform			Fagron CZ
Arsenic	<=5	Conform	µg/g		Fagron CZ
Cadmium	<=10	1	µg/g		Contract Lab
Iron	<=200	Conform	µg/g		Fagron CZ
Lead	<=50	7	µg/g		Contract Lab
Loss on ignition	<=1,0	0,1	%	500°C	Fagron CZ
Particle size	99%<90 µm	Conform			Data Producer
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	CHMP/ICH/353369/2013	Conform			Data Producer
ASSAY					
Zinc oxide	99,0 - 100,5	99,3	%	Ignited	Fagron CZ

Performed by: Dominika Stropková

Responsible: Mgr. Kateřina Jokešová, QC
 Ing. Martina Zemanová, QP

Date: 31.05.2019

Conclusion: APPROVED

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