



Certificate of Analysis

Productname: Zinci oxidum

Inspection No: G01937/0319/536
Batchnumber: 18G27-T01-064577
Expiration date: 23.06.2021
Analysed according to: ČL 2017, Ph.Eur.9.0

Sample Unit: 2 x 50 g
Batch Size: 800 x 250 g

Identification of producer: V01172
Batch no. of vendor: D58214

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Fine, (yellowish-)white powder.	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	0,05	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	2	µg/g		Contract Lab
Iron	<=200	Conform	µg/g		Fagron CZ
Lead	<=50	<5	µg/g		Contract Lab
Loss on ignition	<=1,0	0,2	%	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/82 260/06	Conform			Data Producer
Metallic residues	CHMP/ICH/353369/2013	Conform			Data Producer
ASSAY					
Zinc oxide	99,0 - 100,5	100,1	%	Ignited	Fagron CZ

Performed by: Alena Poláková

Responsible: Mgr. Kateřina Jokešová, QC
 PharmDr. Hana Běhalová, QP

Date: 14.03.2019

Conclusion: APPROVED

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