

Certificate of Analysis

Product name: Zinci oxidum
Batch number: 19G03-B03-194154
Base unit: 1kg
Expiration date: 16.02.2024
Quality: Ph.Eur.
Manufacturing date: 09.08.2019
Inspection report no.: INS-19-02844
IIN: 101213-114-91

Description	Claim	Result	Unit	Laboratory
Appearance	soft, white or faintly yellowish-white, amorphous powder	conform		Fagron Poland
Identification A,B	acc. to Ph. Eur.	conform		Fagron Poland
Alkalinity	acc. to Ph. Eur.	conform		Fagron Poland
Carbonates and substances insoluble in acids	acc. to Ph. Eur.	conform		Fagron Poland
Arsenic	max. 5 ppm	<5	ppm	Fagron Poland
Cadmium	max. 10 ppm	0,9	ppm	El spol
Iron	max. 200 ppm	<200	ppm	Fagron Poland
Lead	max. 50 ppm	4	ppm	El spol
Loss on ignition	max. 1,0 %	0,15	%	Fagron Poland
Assay	99,0 - 100,5 %	100,18	%	Fagron Poland
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

Analysis performed by the laboratory: Fagron Poland and El spol.

Release:
Dominika Sołtysik
Qualified Person



Fagron sp. z o.o.
Dominika Sołtysik
osoba wykwalifikowana
qualified person

Date of releasing: 22.08.2019

Conclusion: Approved