

Certificate of Analysis

Product name: Coffeinum
Batch number: 19B12-B06-191048
Base unit: 25g
Expiration date: 31.01.2022
Quality: Ph.Eur.
Manufacturing date: 17.04.2019
Inspection report no.: INS-19-00872
IIN: 100341-114-91

Description	Claim	Result	Unit	Laboratory
Appearance	white or almost white, crystalline powder or silky, white or almost white, crystals	conform		Fagron Poland
Identification A, B, E	acc. to Ph. Eur.	conform		Fagron Poland
Appearance of solution	acc. to Ph. Eur.	conform		Eurofins
Acidity	acc. to Ph. Eur.	conform		Eurofins
Related substances	unspecified impurities: max. 0,10% total impurities: max. 0,10%	<0,05 <0,10	%	Eurofins
Sulfates	max. 500 ppm	<500	ppm	Eurofins
Loss on drying	max. 0,5%	0,07	%	Fagron Poland
Sulphated ash	max. 0,1%	0,0	%	Eurofins
Assay	98,5 - 101,5%	101,1	%	Eurofins
Elemental impurities	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 Eurofins.

Release:
 Aleksandra Mazanek
 Qualified Person

Date of releasing: 29.04.2019

Conclusion: Approved


Fagron sp. z o.o.
Aleksandra Mazanek
Aleksandra Mazanek
 Qualified Person