

Certificate of Analysis

Product name: **Talcum**
Batch number / Weight: **22K10-B01-235352 / 5 KG**
Analysed according to: **Ph.Eur.11.2**
Number of analysis / Inspection Code **22K10-B01 / INS-22-9996**
Reference Code / No.: **V00623 / BFF1049W**

Tests	Requirement	Result	Unit	Standard remark
Appearance	light, homogeneous, white or almost white powder	Conform		
	greasy to the touch (non abrasive)			
Identification	Conform	Conform		
Acidity or alkalinity	Conform	Conform		
Water soluble substances	<=0,2	0,12	%	
Aluminium	<=2,0	0,2	%	
Calcium	<=0,9	0,08	%	
Iron	<=0,25	<0,01	%	
Lead	<=10	<2	ppm	
Magnesium	17,0 - 19,5	19,0	%	
Loss on ignition	<=7,0	4,83	%	
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 ²	<10	CFU/g	
Total yeasts and moulds (TYMC)	<=10 ²	<10	CFU/g	

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: fsne@fagron.pl

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, Poland
 tel.: +48 12 3343 512
 e-mail: biuro@fagron.pl

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, EI Spol

Release:

Ewelina Gadzinowska

Qualified Person

08-12-2023

Expiration: 18-02-2027

Conclusion: APPROVED

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

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@fagron.pl