

Certificate of Analysis

Product name: **Talcum**
Batch number / Weight: **20L08-B01-203419 / 5 KG**
Analysed according to: **Ph.Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	light, homogeneous, white or almost white powder greasy to the touch (non abrasive)	Conform		
Identification	Conform	Conform		
Acidity or alkalinity	Conform	Conform		
Water-soluble substances	<=0,2	0,03	%	
Aluminium	<=2,0	0,2	%	
Calcium	<=0,9	0,10	%	
Iron	<=0,25	<0,01	%	
Lead	<=10	<2	ppm	
Magnesium	17,0 - 19,5	19,1	%	
Loss on ignition	<=7,0	5,08	%	
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 (TAMC)	<=10 ²	Conform	CFU/g	
Total yeasts and moulds (TYMC)	<=10 ²	Conform	CFU/g	

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

25-01-2021

Expiration: 04-05-2025

Conclusion: APPROVED

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