

Certificate of Analysis

Product name: Talcum
Batch number / Weight: 20A08-B06-200589 / 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	Conform		
Identification	Conform	Conform		
Acidity or alkalinity	Conform	Conform		
Water soluble substances	<=0,2	0,02	%	
Aluminium	<=2,0	0,17	%	
Calcium	<=0,9	0,08	%	
Iron	<=0,25	0,01	%	
Lead	<=10	<2	ppm	
Magnesium	17,0-19,5	18,3	%	
Loss on ignition	<=7,0	5,02	%	
Microbial contamination	TAMC - max. 10 ³ CFU/g	<10	CFU/g	
	TYMC - max. 10 ² CFU/g	<10	CFU/g	
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 authorized lab.

Release:
Dominika Sołtysik
Qualified Person

03-03-2020

Expiration: 19-08-2024

Conclusion: APPROVED

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