

Certificate of Analysis

Product name: **Talcum**
Batch number / Weight: **19J16-B09-195199 / 5 KG**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	light, homogeneous, white or almost white powder	Conform		
Identification	Conform	Conform		
Acidity or alkalinity	Conform	Conform		
Water soluble substances	$\leq 0,2$	0,05	%	
Aluminium	$\leq 2,0$	0,2	%	
Calcium	$\leq 0,9$	0,07	%	
Iron	$\leq 0,25$	0,01	%	
Lead	≤ 10	<2	ppm	
Magnesium	17,0-19,5	19,0	%	
Loss on ignition	$\leq 7,0$	5,20	%	
Microbial contamination	TAMC - max. 10^3 CFU/g TYMC - max. 10^2 CFU/g	<10 <10	CFU/g 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:
Dorota Sutkowska
Qualified Person

08-01-2020

Expiration: 15-04-2024

Conclusion: APPROVED

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