

Certificate of Analysis

Product name: **Talcum**
Batch number / Weight: **22H09-B01-228747 / 5 KG**
Analysed according to: **Ph.Eur.11.0**
Number of analysis / Inspection Code **22H09-B01 / INS-22-8687**
Reference Code / No.: **V00623 / BFF1280V**

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	$\leq 0,2$	0,08	%	
Aluminium	$\leq 2,0$	0,2	%	
Calcium	$\leq 0,9$	0,06	%	
Iron	$\leq 0,25$	$< 0,01$	%	
Lead	≤ 10	< 2	ppm	
Magnesium	17,0 - 19,5	18,8	%	
Loss on ignition	$\leq 7,0$	5,07	%	
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)	$\leq 10^2$	< 10	CFU/g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	< 10	CFU/g	

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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, CBMiA

Release:
Dominika Soltysik
Qualified Person

31-03-2023

Expiration: 07-10-2026

Conclusion: APPROVED

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