

Certificate of Analysis

Product name: **Gelatina pulv.**

Batch number / Weight: **21H03-B01-215319 / 100 G**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Brown) yellow powder	Conform		
Identification A	Violet	Conform		
Identification B	Conform	Conform		
pH	3,8 - 7,6	5,5		
Conductivity	<=1	0,2	mS / cm	
Sulphur dioxide	<=50	Conform	ppm	
Peroxides	<=10	Conform	ppm	
Gel strength	100 - 120	117	%	
		135	g	
Iron	<=30	Conform	ppm	
Chromium	<=10	Conform	ppm	
Zinc	<=30	Conform	ppm	
Loss on drying	<=15,0	12,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Total aerobic microbial count (TA)	<=1000	<10	CFU / g	
Total yeasts and moulds (TYMC)	<=100	<10	CFU / g	
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10 gram	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

28-12-2021

Expiration: 30-11-2024

Conclusion: APPROVED

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