

## Certificate of Analysis

**Product name:** **Gelatina pulv.**

**Batch number / Weight:** **21H03-B01-222305 / 100 G**

**Analysed according to:** **Ph. Eur. 10.8**

**Number of analysis / Inspection Code** **21H03-B01 / INS-21-5139**

**Reference Code / No.:** **V01538 / 107153**

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

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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 EI Spol, CBMiA

Release:  
Ewelina Gadzinowska  
Qualified Person

29-08-2022

Expiration: 31-07-2025

Conclusion: APPROVED

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