

Certificate of Analysis

Product name: **Gelatina pulv.**
Batch number / Weight: **23B23-B04-236043 / 100 G**
Analysed according to: **Ph.Eur.11.3**
Number of analysis / Inspection Code **23B23-B04 / INS-23-4005**
Reference Code / No.: **V01538 / 108430**

Tests	Requirement	Result	Unit	Standard remark
Appearance	faintly yellow or light yellowish-brown solid, usually occurring as	Conform		
Appearance	translucent sheets, shreds, granules or powder			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
pH	3,8 - 7,6	5,53		
Conductivity	<=1	0,14	mS / cm	
Sulphur dioxide	<=50	1	ppm	
Peroxides	<=10	0	ppm	
Gel strength	80 - 120 of the nominal value sted on label	112	%	
Gel strength		127	g	
Iron	<=30	<15,0	ppm	
Chromium	<=10	<5,0	ppm	
Zinc	<=30	<15,0	ppm	
Loss on drying	<=15,0	11,63	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Total aerobic microbial count (TA)	<=10 ³	<10	CFU / g	
Total yeasts and moulds (TYMC)	<=10 ²	<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 Eurofins, CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

25-03-2024

Expiration: 06-03-2027

Conclusion: APPROVED

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