

Certificate of Analysis

Productname: Gelatina pulv.
Number of analysis/Inspection Code: 1 / KEUR-187730B
Batchnumber: 20E11-F03-374444
Reference code / No.: 2177 / 106623
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	Faintly yellow or light yellowish-brown powder	Conform		
Identification A	Violet	Conform		
Identification B	Conform	Conform		Gel forming
pH	3,8 - 7,6	5,5		1%m/V; 55 °C
Conductivity	<=1	0	mS / cm	1%m/V; 30 °C
Sulphur dioxide	<=50	Conform	ppm	
Peroxides	<=10	Conform	ppm	
Gel strength	100 - 120	118	GF	
Iron	<=30	Conform	ppm	
Chromium	<=10	Conform	ppm	
Zinc	<=30	Conform	ppm	
Loss on drying	<=15,0	12,3	%	105°C, 16h
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Total aerobic microbial count (TAMC)	<=1000	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=100	Conform	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 laboratory Eurofins.

Release:
Paul Hofman
Pharmacist - Qualified Person

12/16/20

Expiration: 04-2025

Conclusion: APPROVED

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