

Certificate of Analysis

Product name: **Bromelaina (> 1200 GDU/g)**

Batch number / Weight: **21H12-B05-219891 / 10 G**

Analysed according to: **Monograph**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Creamy-)white powder	Conform		
Identification A	Conform	Conform		UV-spectrum
Identification B	Blue	Conform		
Heavy metals	<=50	Conform	ppm	
Loss on drying	<=5	2,7	%	4 h 60 °C, vacuum
Sulphated ash	<=5	1,5	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Bromelain	> 1200	1203	GDU / g	1 GDU = 2 FIP-units, data producer
Total aerobic microbial count (TA)	<=20000	<10	CFU / g	
Total yeasts and moulds (TYMC)	<=200	<10	CFU/g	
St. aureus	Negative / gram	Conform		
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10 gram	Conform		
Bile-tolerant gram-neg. bacteria	<=200	<10	CFU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

05-04-2022

Expiration: 31-05-2023

Conclusion: APPROVED

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