

Certificate of Analysis

Productname: Solani amylum
Number of analysis/Inspection Code: 1 / KEUR-179955B
Batchnumber: 19112-F03-365059
Reference code / No.: 1998 / VNL95
Analysed according to: PH.EUR 9.8

Tests	Requirement	Result	Unit	Standard remark
Appearance	Very fine, (almost) white powder	Conform		
Identification A	Conform	Conform		Microscopy
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	5,0 - 8,0	7,0		5 g / 25 ml
Foreign matter	Conform	Conform		
Oxidising substances	<=20	0,85	ppm	
Sulphur dioxide	<=50	12,2	ppm	
Iron	<= 10	Conform	ppm	
Loss on drying	<=20,0	15,8	%	1.5 h 130 °C
Sulphated ash	<=0,6	0,2	%	
Total aerobic microbial count (TAMC)	<=10 ³	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=10 ²	Conform	CFU / g	
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10g	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic + microbiel.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

01/29/20

Expiration: 10-2023

Conclusion: APPROVED

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