

Certificate of Analysis

Productname: Solani amylum
Number of analysis/Inspection Code: 1 / KEUR-184725B
Batchnumber: 20C11-F02-371102
Reference code / No.: 1998 / VNL98
Analysed according to: PH.EUR10.0

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	6,8		5 g / 25 ml
Foreign matter	Conform	Conform		
Oxidising substances	<=20	4	ppm	
Sulphur dioxide	<=50	6	ppm	
Iron	<= 10	Conform	ppm	
Loss on drying	<=20,0	18,3	%	1.5 h 130 °C
Sulphated ash	<=0,6	0,3	%	
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:
Paul Hofman
Pharmacist - Qualified Person

08/05/20

Expiration: 10-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.