

Certificate of Analysis

Product name: **Maydis amylum**

Batch number / Weight: **22K04-B12-236621 / 1 KG**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **22K04-B12 / INS-22-9957**

Reference Code / No.: **V01176 / E3602**

Tests	Requirement	Result	Unit	Standard remark
Appearance	matt, white to slightly yellowish, very fine powder that creaks when pressed between the fingers	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	4,0 - 7,0	5,51		
Foreign matter	Conform	Conform		
Oxidising substances	<=20	Conform	ppm	
Sulphur dioxide	<=50	6,4	ppm	
Iron	<=10	<10	ppm	
Loss on drying	<=15,0	12,57	%	
Sulphated ash	<=0,6	0,09	%	
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	5,0x10 ¹	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 Fagron PL lab,CBMiA

Release:
Dominika Soltysik
Qualified Person

24-01-2024

Expiration: 20-11-2026

Conclusion: APPROVED

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