

Certificate of Analysis

Product name: **Tritici amyllum**
Batch number / Weight: **21F22-B03-225806 / 1 KG**
Analysed according to: **Ph. Eur.**
Number of analysis / Inspection Code **21F22-B03 / INS-21-4267**
Reference Code / No.: **V01176 / E3227**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Very fine, white powder	Conform		
Appearance	that cracks when pressed between the fingers			
Appearance	not contain granules of any other origin			
Appearance	It may contain quantity of tissue plant.			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	4,5 - 7,0	6,6		
Foreign matter	Conform	Conform		
Iron	<= 10	Conform	ppm	
Total protein	<= 0,3	Conform	%	
Total protein	(corresponding to 0.048 % of nitrogen)			
Oxidising substances	<=20	Conform	ppm	
Sulphur dioxide	<= 50	Conform	ppm	
Loss on drying	<=15,0	12,5	%	
Sulphated ash	<=0,6	0,20	%	
E. coli	Negatief / g	Conform		
Salmonella	Negatief / 10 g	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count	<=10 ³	<10	CFU/g	
Total yeasts and moulds	<=10 ²	<10	CFU/g	

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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, EI Spol, CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

28-11-2022

Expiration: 07-04-2026

Conclusion: APPROVED

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