

Certificate of Analysis

Product name: **Pancreatis pulvis 3xUSP-NF**

Batch number / Weight: **23K20-B05-235907 / 100 G**

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

Number of analysis / Inspection Code **23K20-B05 / INS-23-9597**

Reference Code / No.: **V01465 / 224.158**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Slightly brown, amorphous powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Fat content	$\leq 5,0$	1,7	%	
Loss on drying	$\leq 5,0$	1,25	%	
Total proteolytic activity	$\geq 1,0$	1,38	PE U/mg	
Lipolytic activity	≥ 15	19,4	PE U/mg	
Amylolytic activity	≥ 12	15,9	PE U/mg	
Total aerobic microbial count (TA)	$\leq 10^4$	$7,0 \times 10^2$	CFU/g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	< 10	CFU/g	
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10 gram	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

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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:
Dominika Soltysik
Qualified Person

05-03-2024

Expiration: 31-10-2025

Conclusion: APPROVED

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