

Certificate of Analysis

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

Batch number / Weight: **22B02-B06-222169 / 100 G**

Analysed according to: **Ph.Eur.10**

Number of analysis / Inspection Code **22B02-B06 / INS-22-4980**

Reference Code / No.: **V01465 / 223.784**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Slightly brown, amorphous powder with a characteristic odour	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Fat content	$\leq 5,0$	0,7	%	
Loss on drying	$\leq 5,0$	2,4	%	
Total proteolytic activity	$\geq 1,0$	1,48	PE U/mg	
Total proteolytic activity	x 62,5 PE	92,5	NF U/mg	
Lipolytic activity	≥ 15	20,0	PE U/mg	
Lipolytic activity	x 1 PE	20,0	NF U/mg	
Amylolytic activity	≥ 12	16,6	PE U/mg	
Amylolytic activity	x 4,15 PE	68,89	NF U/mg	
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10 gram	Conform		
Total aerobic microbial count (TA)		750	CFU/g	
Total yeasts and moulds (TYMC)		70	CFU/g	
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
Residual solvents				
Acetone		<5000	ppm	

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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 EL Spol

Release:

Agnieszka Pszczółka

Qualified Person

14-09-2022

Expiration: 31-12-2023

Conclusion: APPROVED

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