

## Certificate of Analysis

**Product name:** **Pancreatis pulvis 3xUSP-NF**  
**Batch number / Weight:** **22B02-B06-220026 / 250 G**  
**Analysed according to:** **Ph. Eur. 10.8**

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	$\geq 15$	20,0	PE U/mg	
Lipolytic activity	x 1 PE	20,0	NF U/mg	
Amylolytic activity	$\geq 12$	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)	$\leq 20000$	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

Analysis performed by the authorized lab.

Release:  
 Ewelina Gadzinowska  
 Qualified Person

16-08-2022

Expiration: 31-12-2023

Conclusion: APPROVED

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