

Certificate of Analysis

Product name: **Pancreatis pulvis 3xUSP-NF**
Batch number / Weight: **21H12-B07-213389 / 250 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
	with a characteristic odour			
Appearance	Slightly brown, amorphous powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Fat content	<=5,0	2,6	%	
Loss on drying	<=5,0	1,1	%	
Total proteolytic activity	>=1,0	1,24	PE U/mg	
Total proteolytic activity	x 62,5 PE	77,5	NF U/mg	
Lipolytic activity	>=15	21,0	PE U/mg	
Lipolytic activity	x 1 PE	21,0	NF U/mg	
Amylolytic activity	>=12	17,0	PE U/mg	
Amylolytic activity	x 4,15 PE	70,55	NF U/mg	
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10 gram	Conform		
Total aerobic microbial count (TAMC)	<=20000	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=200	Conform	CFU/g	
Excipient	Lactosum Ph. Eur	67	%	
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

09-12-2021

Expiration: 30-06-2023

Conclusion: APPROVED

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