

## Certificate of Analysis

**Productname:** Pancreatis pulvis 3xUSP-NF  
**Number of analysis/Inspection Code:** 1 / KEUR-182076B  
**Batchnumber:** 20A31-F05-369472  
**Reference code / No.:** 1053 / 223.302  
**Analysed according to:** PH.EUR10.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	Slightly brown, amorphous powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Fat content	<=5,0	1,4	%	
Loss on drying	<=5,0	0,8	%	4 h 60 °C; vacuum
Total proteolytic activity	>=1,0	1,5	EP U/mg	Data producer
Total proteolytic activity	>= 62,5	93,8	USP U/mg	1Ph.Eur U=62.5USP U, Data producer
Lipolytic activity	>=15	21,5	EP U/mg	Data producer
Lipolytic activity	>=15,0	21,5	USP U/mg	1Ph.Eur U=1 USP U, Data producer
Amylolytic activity	>=12	17,0	EP U/mg	Data producer
Amylolytic activity	>=49,8	70,6	USP U/mg	1Ph.Eur U=4,15 USP U, Data producer
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	%	Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:  
Wai Lung Chung  
Pharmacist - Qualified Person

04/17/20

Expiration: 12-2021

Conclusion: APPROVED

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