

CERTIFICATE OF ANALYSIS

 Date
 07-Jul-2020

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Pancreatin (Pancreas powder)

 Material
1003248

 Batch
212714

 Prod. date
 08.2019

 Expiry date
 07.2022

Characteristic	Unit	Result	Specification
Appearance slightly brown amorphous powder		complies	see characteristic
Ident.: Amylase (enzyme activity test)		positive ident.	positive Identification
Ident.: Lipase (enzyme activity test)		positive ident.	positive Identification
Ident.: Proteases (enzyme activity test)		positive ident.	positive Identification
Amylase	Ph.Eur.U/g	97587	>= 12000
Lipase	Ph.Eur.U/g	85673	>= 15000
Proteases	Ph.Eur.U/g	5810	>= 1000
Fat	%	0.1	<= 5.0
Water	%	2.7	<= 5.0
Residual solvents: Isopropyl alcohol	%	0.3	<= 3.0
Total aerobic microbial count (TAMC)	cfu/g	70	<= 10000
Total combined yeast/moulds count (TYMC)	cfu/g	10	<= 100
Bile-tolerant gram-negative bacteria	/g	< 10	<= 100
Salmonella		absent / 10 g	absent / 10 g
Escherichia coli		absent / 1 g	absent / 1 g
Staphylococcus aureus		absent / 1 g	absent / 1 g

Specification: SOLID 0000096804 Version 4.0

The batch has been manufactured and released in accordance with our internal instruction resp. specification and in compliance with Good Manufacturing Practices.

This certificate was generated by a validated system and signed electronically.

07.07.2020 / 10:14:00 CET e-sign: Guido Schicksnus, Qualified Person,
 Certificate checked and approved

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