

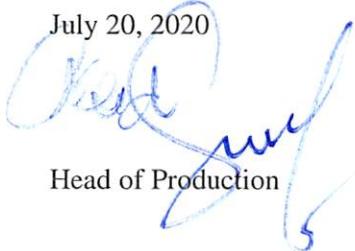
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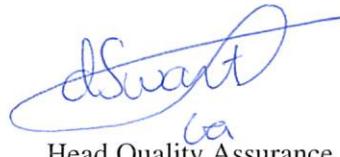
CERTIFICATE OF ANALYSIS (For research use only)

GENERAL DATA				
Article Number	02.02.85			
Article description	<i>Dermatophagoides farinae</i> extract FD			
Storage	Upon arrival store at -20 °C			
Production Date	November 12, 2019			
Charge Number	19K10			
RAW MATERIAL / PRODUCTION PROCESS				
Cultivation location	Groningen, the Netherlands			
Cultivation method	The mites are cultivated separately at constant temperature and humidity			
Source of mites	Source described, identified, selected and purified by Citeq Biologics Source confirmed by external specialist			
Inoculation	The mites are grown in a continuous culture, i.e. a portion of a previous lot becomes the starting material for the next lot			
Medium	Main components not of human and animal origin (starch/yeast) Additives (< 0.1%) contain no human or animal components			
POST HARVEST PROCESSING OF MITES				
Extraction	The mite culture is extracted, followed by filtration and dialysis			
Freeze drying	The extract is freeze dried after dialysis			
ANALYSIS				
Identity	Result	Specifications	Reference	
Species	Ok	<i>Dermatophagoides farinae</i>	Literature	
Character material	Ok	Light brown fluffy powder	Visual determination	
Allergenic pattern (mg/g)	Der f 1 Der f 2 Der p 1	19.2 – 21.7 1.8 0,01	5 – 100 0.5 – 10 < 0.1	ELISA
Protein content (mg/g)	107 – 109 405 - 410		25 – 250 100 – 750	Bradford assay BCA assay
Protein pattern	Ok		Clear bands	SDS-PAGE gel; CBB & silver staining
Endotoxin (EU/mg)	2.9 x 10 ³ – 9.7 x 10 ³		500 – 7500	Endotoxin assay
Bioburden (CFU/g)	SDA TSA	1 x 10 ³ - 4 x 10 ³ 1 x 10 ³ - 3 x 10 ³	< 1 x 10 ⁶ < 1 x 10 ⁶	Ph. Eur.
Protease activity	Serine (mU/mg) Cysteine (U/mg)	4.3 x 10 ² – 1.2 x 10 ⁴ 2.5 x 10 ³ – 5.9 x 10 ³	TBD	Serine protease assay Cysteine protease assay
Mycoplasma DNA presence	Negative		Negative	PCR analysis
Water content (%)	1.3 - 4		TBD	Karl Fischer

July 20, 2020



Head of Production



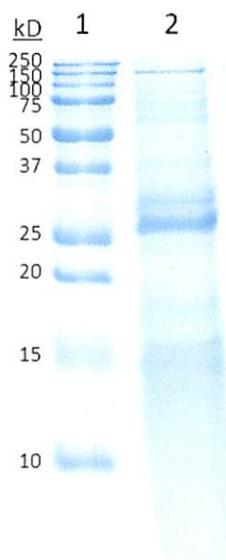
Head Quality Assurance

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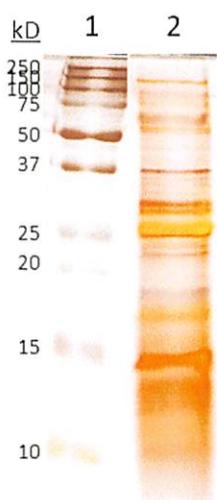
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SDS-PAGE analysis

CBB Stain:



Silver Stain:



1: Marker, 2: 19K10



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Tested on the presence of Mycoplasma DNA from:

M. arginini
M. orale
M. hyorhinis
M. fermentans
M. genitalium
A laidlawii
M. hominis
M. pirum
M. pneumoniae
M. salivarium
U urealyticum
M. synoviae
M. bovis