

CERTIFICATE OF ANALYSIS (For research use only)

GENERAL DATA			
Article Number	02.01.85		
Article description	<i>Dermatophagoides pteronyssinus</i> extract FD		
Storage	Upon arrival store at -20 °C		
Production Date	July 30, 2018		
Charge Number	18G08		
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 / PURITY			
Identity	Result	Specifications	Reference
Species	Ok	<i>Dermatophagoides pteronyssinus</i>	Literature
Character material	Ok	Light brown powder	Visual determination
Allergenic pattern (mg/g)	Der p 1	38	10 – 100
	Der p 2	3,4	1 – 10
	Der f 1	0,01	< 0.1
Protein content (mg/g)	72	25 – 250	Bradford assay
	233	100 – 750	BCA assay
Protein pattern	Pictures added (page 2)	Clear bands	SDS PAGE gel; CBB & silver staining
Endotoxin (EU/mg)	301	TBD	Endotoxin assay
Bioburden (Cfu/mg)	TSA	28	< 1 x 10 ⁶
	SDA	< 0,2	< 1 x 10 ⁶
Water content (%)	1,9	< 8	Karl Fischer

March 4, 2020

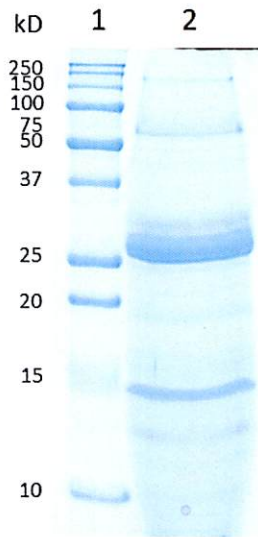
Head of Production

Head Quality Assurance

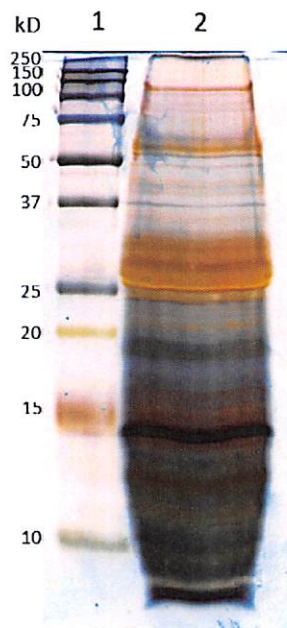
ba HAA

SDS-PAGE analysis

CBB Stain:



Silver Stain:



1: Marker, 2: 18G08