

CERTIFICATE OF ANALYSIS

			GENERAL DATA	
Article Number		02.02.30		
Article description		Dermatophagoides farinae Mite Bodies		
Storage		-20 °C		
Production Date		December, 2014		
Charge Number		18M03		
50		RAW MAT	ERIAL / PRODUCTION PROCES	
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 HAI	RVEST PROCESSING OF MITES	
Harvesting of mite bodies		The mites have been sieved after cultivation After sieving, the mites are separated from the medium by physical separation methods		
Freeze drying		The mite bodies are subsequently killed and freeze dried		
			ANALYSES	
		Result	Specifications	
Species		Ok	Dermatophagoides farinae	Literature
Character material		Ok	Brown woolly powder	Visual determination
Purity		> 99%	Other mite species < 1% Foreign material < 1%	Microscopic determination
Allergenic pattern (mg/g)	Der f 1 Der f 2 Der p 1	0.25 0.69 < 0.05	0.05 - 1.5 0.10 - 2.0 < 0.05	ELISA
Protein content (mg/g)		98 148	50-200 100-400	Bradford assay BCA assay
Protein pattern		Ok	Clear bands	SDS-PAGE gel; CBB & silver staining
Bioburden (Cfu/g)	SDA TSA	192 4.2 x 10 ⁴	$SDA < 1 \times 10^{11}$ $TSA < 1 \times 10^{11}$	Ph. Eur.
Water content (%)		6.3	< 8	Loss on Dryness

January 8, 2019

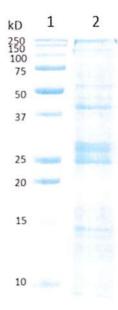
Head of Production

HQA

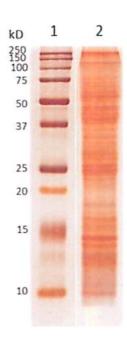


SDS-PAGE analysis

CBB Stain:



Silver Stain:



1: Marker, 2: 18M03