



biologics
CERTIFICATE OF ANALYSIS
(For research use only)

GENERAL DATA			
Article Number	02.02.71		
Article description	Der f 1, purified > 95%, Freeze Dried		
Storage	-20 °C		
Production Date	May 31, 2021		
Charge Number	21E01		
RAW MATERIAL / PRODUCTION PROCES			
Cultivation location	Groningen, the Netherlands		
Cultivation method	<i>Dermatophagoides farinae</i> whole culture on defined medium.		
POST HARVEST PROCESSING OF MITES			
02.01.65 in house extract	Extract, freeze dried after purification		
ANALYSES			
IDENTITY / PURITY			
Identity	Result	Specifications	Reference
Protein	Der f 1	Cysteine protease	Literature
Sample	Der f 1	Der f 1 and Der f 1 fragments	Literature
Material	Der f 1	White powder	Literature
Contains lactose			
(BIO)CHEMICAL ANALYSES			
Analysis	Result	Specifications	Method
Allergenic pattern Der f 1(µg/vial)	250	t.b.d.	ELISA
Protein content (µg/vial)	529	t.b.d.	UV absorption (OD ₂₈₀)
Protein pattern	Picture added (page 2)	Major protein band 25 kDa	SDS PAGE + CBB/Silver staining
Bioburden (Cfu/vial)	TSA	1.5 x 10 ²	Eur Pharm method
	SDA	3	
Protease activity (U/mg protein)	Serine	4.7 x 10 ⁻³	Protein activity assay
	Cysteine	4.0 x 10 ⁻³	

October 17, 2022

Head of Production

Head Quality Assurance

b.a. HAA

CITEQ

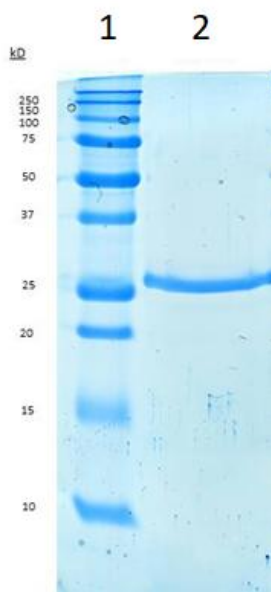
biologics

CERTIFICATE OF ANALYSIS

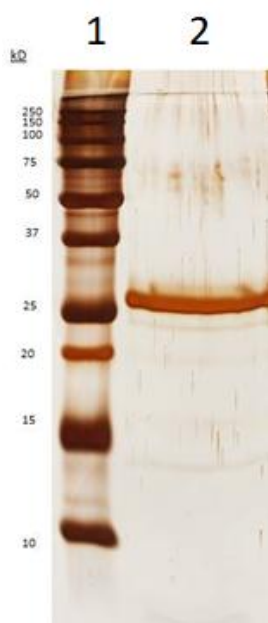
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SDS-PAGE analysis

CBB Stain



Silver Stain



1: Marker, 2: 21E01