

CERTIFICATE OF ANALYSIS

CTS™ VITRONECTIN (VTN-N) RECOMBINANT HUMAN PROTEIN IN PARTNERSHIP WITH CDI™

Catalog Number:

CTS279S3

Lot Number:

D1-042110G 2021-10-06

Manufacturing Date: Expiry Date:

2024-09-26

CoA Issue No.:

498

Volume:

1 mL

Storage temperature:

-70 ± 10 °C

Composition: 20 mM K₂HPO₄ 20 mM KH₂PO₄ pH 7.40 (NaOH),135 mM NaCl,15 mM KCl, 0.5 mM EDTA,150 mM L-Arginine, 250 mM Acetyl-L-cysteine, 20% (v/v) Glycerol, DNA-free WMB

This L-Alginine, 200 mis Acetyl-L-cysteine, 20% (viv) Glycerol, DIVA-nee visib

For Research Use or Manufacturing of Cell, Gene, or Tissue-Based Products. CAUTION: Not intended for direct administration into humans or animals.

Testing is listed in alphabetica	order					
PARAMETER	SPECIFICATION	RESULT	UNIT			
¹ Biological activity	Concentration of Test sample at which half maximal attachment of BALB/3T3 cells in serum-free medium is observed (ED₅₀) ≤1.000 µg/ml	0.539	μg/ml			_
	Ratio of ED50 values between IRS and Test samples: 55.00-145.00 %	107.46	%			
² Color and clarity	Color: not more intense than Y6 (Yellow palette) Clarity: <30 NTU	Conforms 3	NTU			
³ Concentration	0.81-0.99 mg/ml	0.98	mg/ml			
⁴ Endotoxins	< 25 EU/mg protein	Conforms				
⁵ Host cell gDNA	<100.00 pg/mg (LOQ — 12 pg/mg)	< LOQ	(LOQ	_	12	– pg/mg)
⁶ Identity by RP-HPLC	The intact protein chromatographic profiles of the Sample solution are similar to those of the IRS	Conforms				
⁷ Identity by SDS-PAGE	Main band of the test sample corresponds to position of the main band of IRS (≈55 kDa)	Conforms				_
⁸ Mycoplasmas	<lod (lod="" 10="" cfu="" ml)<="" td="" –=""><td>Conforms</td><td></td><td></td><td><u> </u></td><td></td></lod>	Conforms			<u> </u>	
⁹ pH	7.4 (7.0 – 7.8)	7.4				
¹⁰ Purity by RP-HPLC	> 95.0 %	98.6	%			_
¹¹ Sterility	No growth	Conforms				



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Lot No. D1-042110G is approved

498

CoA is issued by

uality Assurance Department Magnan collie

Signature No 23

CoA is verified and approved by

Quality Assurance Manager

Signature

Date

REFERENCES:

1Biological activity: Thermo Fisher Scientific Baltics, In-house method.

²Color and clarity: Color: acc. Ph. Eur. 2.2.2. Degree of coloration of liquids. Method I. Clarity: acc. Ph. Eur. 2.2.1. Clarity and degree of opalescence of liquids", Instrumental method.

³Concentration, ⁶Identity, ¹⁰Purity: Thermo Fisher Scientific Baltics, In-house method.

4Endotoxin testing: USP <85> Bacterial Endotoxins and Ph. Eur. 2.6.14. Bacterial endotoxins. Method A. Gelclot method: limit test.

⁵Host cell gDNA: Contract Laboratory, In-house method.

7Identity by SDS-PAGE: Thermo Fisher Scientific Baltics, In-house method.

⁸Mycoplasmas: Contract Laboratory, In-house method.

⁹pH: USP <791> pH and Ph. Eur. 2.2.3. Potentiometric determination of pH.

11Sterility: Contract Laboratory, Ph. Eur. 2.6.1. Sterility and USP/NF <71> Sterility Test.