



CERTIFICATE NO.	LAB SAMPLE ID	ISSUE DATE	REPORT STATUS
COA-2026-0185	20260800224	03 SEP 2026	FINAL

01 CLIENT & PRODUCT INFORMATION

Client organization	ROEHN LABS	Client contact	support@roehn.com
Product name	TB-500	Client lot / batch	00011/0011
Label claim	5 mg	Lab sample ID	20260800224 (A, B, C)
Sample matrix	Lyophilized	Quantity received	3
Container / closure	Vial w/Crimp	Condition on receipt	Intact
Date received	21 Aug 2026	Testing period	28 Aug 2026
Storage condition	Ambient	Route / intended use	RUO

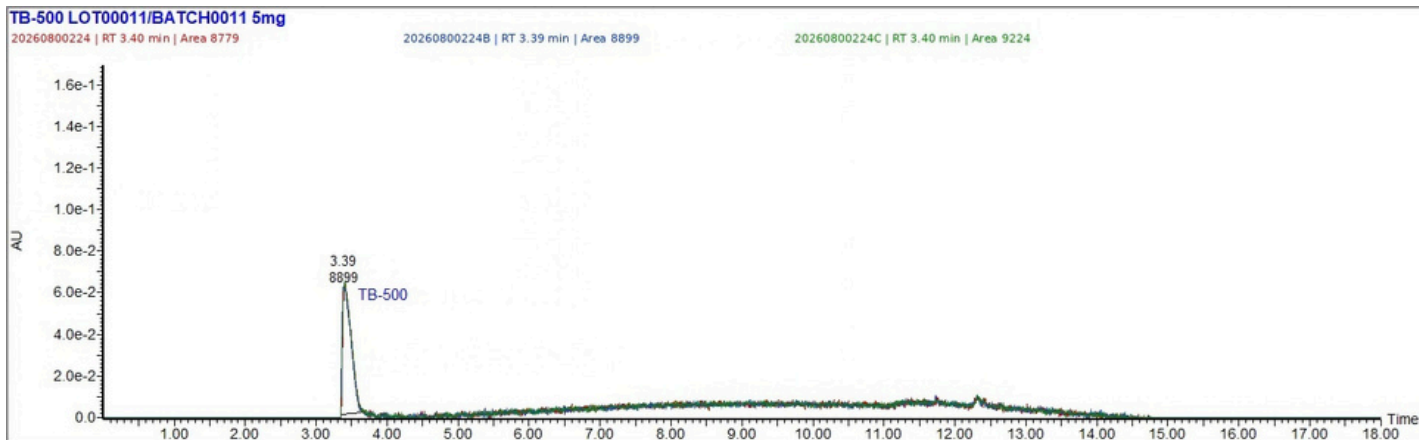
02 ANALYTICAL TEST RESULTS | Purity, identification and net content

Analysis	Method / SOP	Instrumentation	Result	Units	Acceptance criterion	Status
Purity (Average purity calculated from 3 vials)	UPLC-UV	Acquity UPLC/PDA	99.69 AVG	% area	>99%	PASS
Identification	UPLC-MS	Waters Quattro Series	Conforms	—	Ionization profile match w/standard across all vials tested	PASS
Net content	Quantitative UPLC	Acquity UPLC/PDA	Vial1—5.01 Vial2—5.12 Vial3-5.18	mg/vial	±10%	PASS

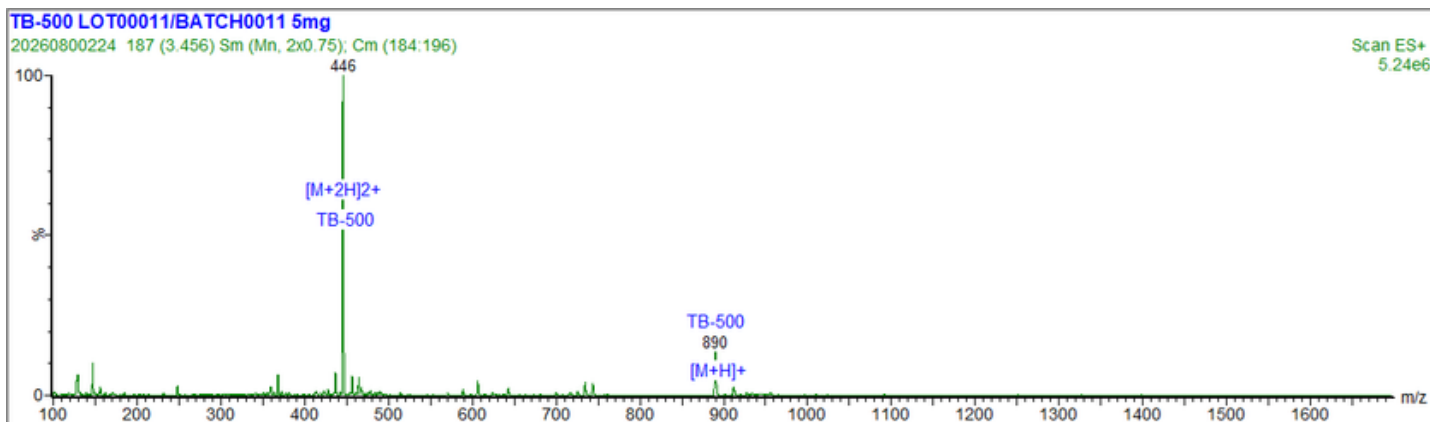
03 SUPPORTING ANALYTICAL EVIDENCE



PRODUCT AS RECEIVED



UV CHROMATOGRAM



MASS SPECTRUM / SPECTRA



04 ENDOTOXIN ANALYSIS | Recombinant Factor C (rFC) fluorescence assay

Method	Recombinant Factor-c	Instrument / asset ID	Molecular Devices Gemini XPS
Assay / reagent	bioMerieux EndoZyme II	Standard	Kit-integrated
Sample preparation	Reconstitution in Endotoxin Free Water	Run / plate ID	0828P1-AVQC20260800224
Product limit	0.5 EU/mL (AV Analytics applies 2x USP limit for H2O, no USP endotoxin limit applies to RUO products)	Maximum valid dilution	1:100

Parameter	Result	Acceptance criterion	Units	Status
Endotoxin	Vial 1 0.10 Vial 2 0.08 Vial 3 0.09	<0.5	EU/mL	PASS
Positive product control recovery	74 Non-	50-200	%	PASS
Negative control	Detect	<0.005	EU/mL	PASS
Standard curve / assay validity	98	Correlation factor >0.94	R ²	PASS

05 AUTHORIZATION | Review, decision rule and release

Analyst	Jason Snitker	Technical reviewer	Vanessa Montoya, PhD
Authorized signatory	Vanessa Montoya, PhD	Decision rule	Document complete, fields correct, analysis reviewed
Deviations / qualifiers	None	Amendment history	NA

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