AV ANALYTICS
Analytical Precision - Operational Excellence
INDEPENDENT ANALYTICAL LABORATORY

CERTIFICATE OF ANALYSIS

Analytical results | Controlled laboratory report

CERTIFICATE NO.	LAB SAMPLE ID	ISSUE DATE	REPORT STATUS
COA-2026-0174	*20260800213*	*03 SEP 2026*	*FINAL*

01 CLIENT & PRODUCT INFORMATION

Client organization	*Aurevia Bioscience*	**Client contact**	*support@aureviabio.com*
Product name	*Tirzepatide*	**Client lot / batch**	*00011/0011*
Label claim	*20 mg*	**Lab sample ID**	*20260800213 (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*

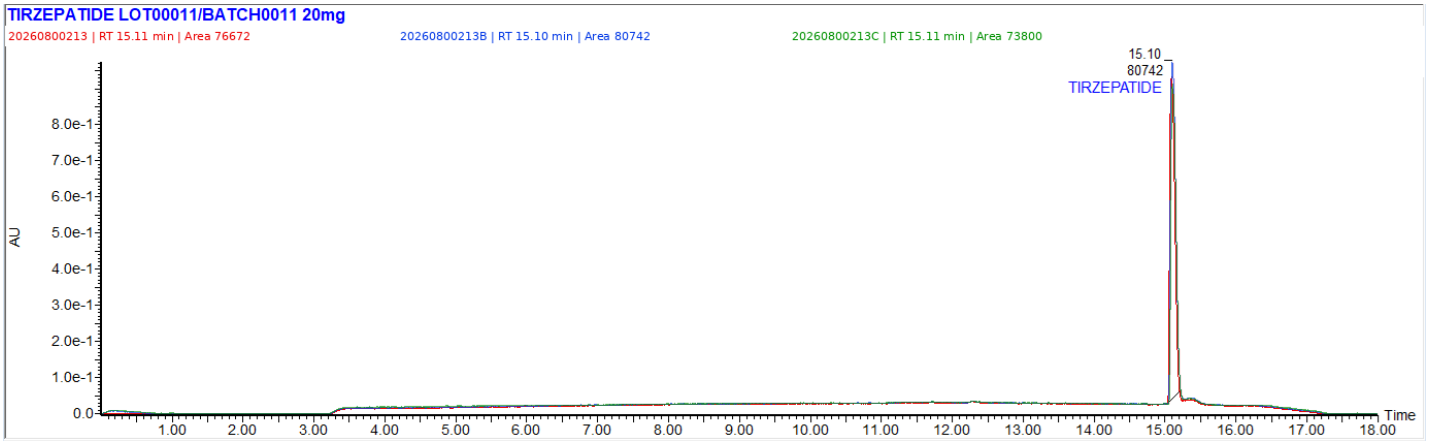
02 ANALYTICAL TEST RESULTS | Purity, identification and net content

Analysis	Method / SOP	Instrumentation	Result	Units	Acceptance criterion	Status
Purity (Average purity calculated from 3 vials)	*UPLC-UV*	*Acquity UPLC/PDA*	*99.80 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*	*Vial 1 – 20.16* *Vial 2 – 20.88* *Vial 3- 19.87*	*mg/vial*	*±10%*	*PASS*

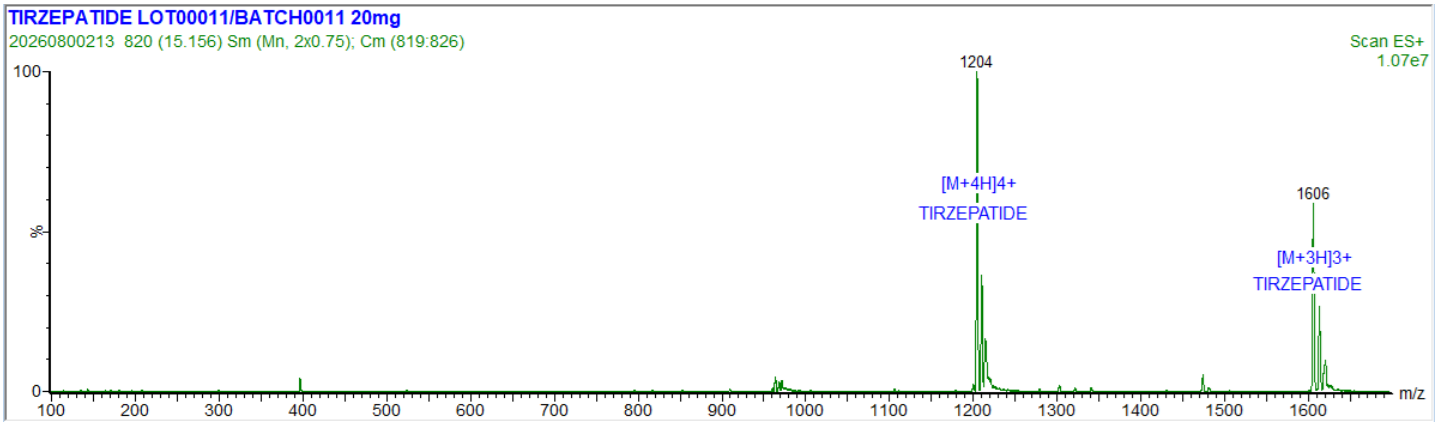
03 SUPPORTING ANALYTICAL EVIDENCE



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-AVQC20260800213*
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 0.11 Vial 2 0.09 Vial 3 0.02*	*<0.5*	*EU/mL*	*PASS*
Positive product control recovery	*77*	*50-200*	*%*	*PASS*
Negative control	*Non-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*

Report conditions: Results are analytical findings for the item tested and do not constitute an endorsement of product safety, efficacy or regulatory status. Unless otherwise stated, this certificate may be reproduced only in full with written approval from AV Analytics.