



CERTIFICATE OF ANALYSIS

Issued by an ISO/IEC 17025-accredited laboratory · raw data appended (page 2)

PASS

QC released for dispatch



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SS-31 — 40mg

Elamipretide

1. PRODUCT IDENTIFICATION

Synonym	Elamipretide	Label claim	40mg
Sequence / structure	D-Arg-Dmt-Lys-Phe-NH ₂	Lot / Batch	ZX260512-629 / B83603
Mol. formula	C ₃₂ H ₄₉ N ₉ O ₅	Manufacture date	13 May 2026
Mol. weight	639.79 g/mol	Date of analysis	16 May 2026
CAS number	736992-21-5	Storage	-20 °C, dark, desiccated
Salt form	Acetate salt		

2. ANALYTICAL TEST RESULTS

Test	Method	Specification	Result	Verdict
Appearance	Visual	White/off-white powder	White to off-white lyophilized powder	PASS
Identity (ESI-MS)	LC-MS	Matches 639.79 Da	639.79 Da (Δ 0 ppm)	PASS
Purity	RP-HPLC, UV 220 nm	$\geq 98.0\%$ area	98.41%	PASS
Related substances	RP-HPLC	Single ≤ 1.0 / Total $\leq 2.0\%$	0.90 / 1.59%	PASS
Water content	Karl Fischer (USP <921>)	$\leq 8.0\%$	2.7%	PASS
Counter-ion: acetate	Ion chromatography	Report (3.0–15.0%)	9.2%	PASS
Net peptide content	Amino-acid analysis	$\geq 80.0\%$	86.4%	PASS
Bacterial endotoxin	LAL kinetic (USP <85>)	< 5.0 EU/mg	0.06 EU/mg	PASS
Heavy metals	ICP-MS (ICH Q3D)	Conforms	Conforms	PASS

CONCLUSION

All tested parameters CONFORM to the acceptance specifications. The batch is of high chromatographic purity ($\geq 98\%$) with an impurity profile, identity and residual/contaminant results meeting pharmaceutical-grade quality requirements. Material released. Supporting RP-HPLC chromatogram and ESI-MS spectrum are appended on page 2.

DHR.

Dr. Huang Rui

Analyst · 16 May 2026 · Zhongxi Research Institute

DFH.

Dr. Fang Hong (QC Manager)

Approved by · 16 May 2026 · Zhongxi Research Institute



APPENDIX — ANALYTICAL RAW DATA

SS-31 40mg · Lot ZX260512-629 · Cert. ZXR-COA-2026-90116



Scan to verify

Figure 1. RP-HPLC Chromatogram (UV 220 nm)

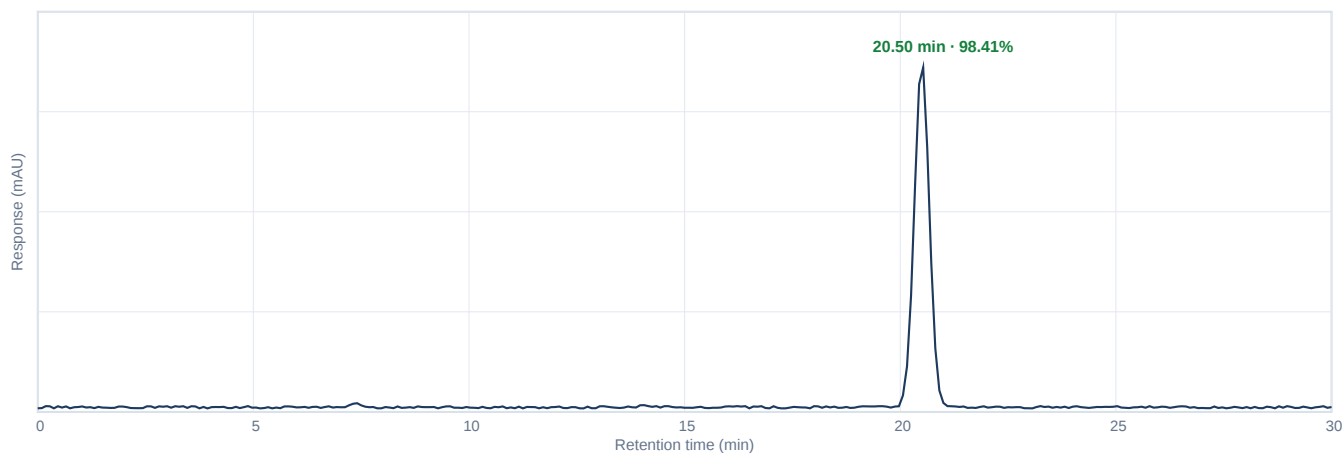
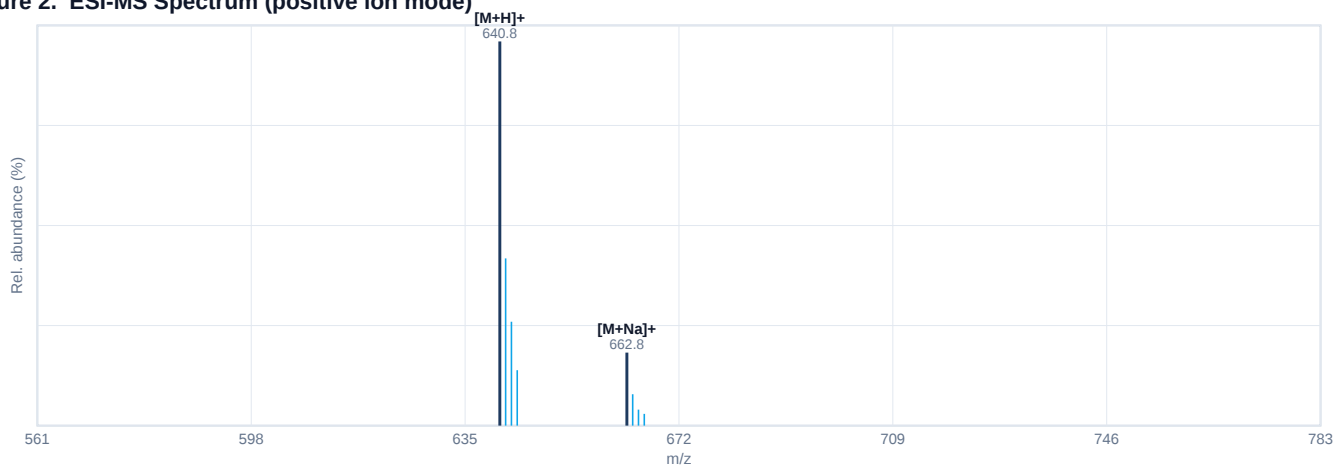


Figure 2. ESI-MS Spectrum (positive ion mode)



Interpretation

Identity confirmed by ESI-MS. Observed ions [M+H]⁺ 640.8, [M+Na]⁺ 662.8 deconvolute to a neutral monoisotopic-average mass of 639.79 Da (theoretical 639.79 Da; mass error 0 ppm), consistent with SS-31. No co-eluting species above 0.5% indicative of misidentification.

Methods — RP-HPLC: Agilent 1260 Infinity II; Zorbax SB-C18 4.6×250 mm, 5 μm; A: 0.1% TFA in water, B: 0.1% TFA in MeCN; 10–70% B over 30 min; 1.0 mL/min; 25 °C; 20 μL injection. MS: AB Sciex TripleTOF, ESI+, capillary 4.5 kV, deconvolution by Bio Tool Kit. KF: Metrohm 901. IC: Thermo Dionex ICS-6000. ICP-MS: Agilent 7900.