



## 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 — 10mg

Elamipretide

## 1. PRODUCT IDENTIFICATION

|                      |                                                               |                  |                          |
|----------------------|---------------------------------------------------------------|------------------|--------------------------|
| Synonym              | Elamipretide                                                  | Label claim      | 10mg                     |
| Sequence / structure | D-Arg-Dmt-Lys-Phe-NH <sub>2</sub>                             | Lot / Batch      | ZX260512-299 / B51885    |
| Mol. formula         | C <sub>32</sub> H <sub>49</sub> N <sub>9</sub> O <sub>5</sub> | Manufacture date | 24 May 2026              |
| Mol. weight          | 639.79 g/mol                                                  | Date of analysis | 30 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 ( $\Delta$ 0 ppm)           | PASS    |
| Purity               | RP-HPLC, UV 220 nm       | $\geq 98.0\%$ area                     | 99.52%                                | PASS    |
| Related substances   | RP-HPLC                  | Single $\leq 1.0$ / Total $\leq 2.0\%$ | 0.24 / 0.48%                          | PASS    |
| Water content        | Karl Fischer (USP <921>) | $\leq 8.0\%$                           | 1.4%                                  | PASS    |
| Counter-ion: acetate | Ion chromatography       | Report (3.0–15.0%)                     | 5.1%                                  | PASS    |
| Net peptide content  | Amino-acid analysis      | $\geq 80.0\%$                          | 91.7%                                 | PASS    |
| Bacterial endotoxin  | LAL kinetic (USP <85>)   | $< 5.0$ EU/mg                          | 0.08 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.

DLW.

Dr. Li Wenhua

Analyst · 30 May 2026 · Zhongxi Research Institute

DFH.

Dr. Fang Hong (QC Manager)

Approved by · 30 May 2026 · Zhongxi Research Institute



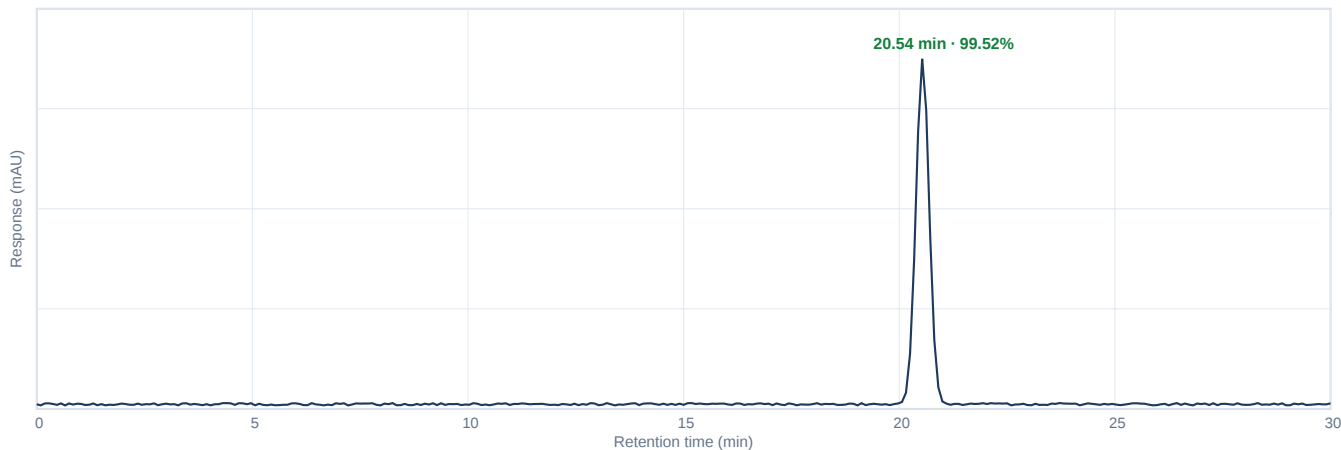
## APPENDIX — ANALYTICAL RAW DATA

SS-31 10mg · Lot ZX260512-299 · Cert. ZXR-COA-2026-60796



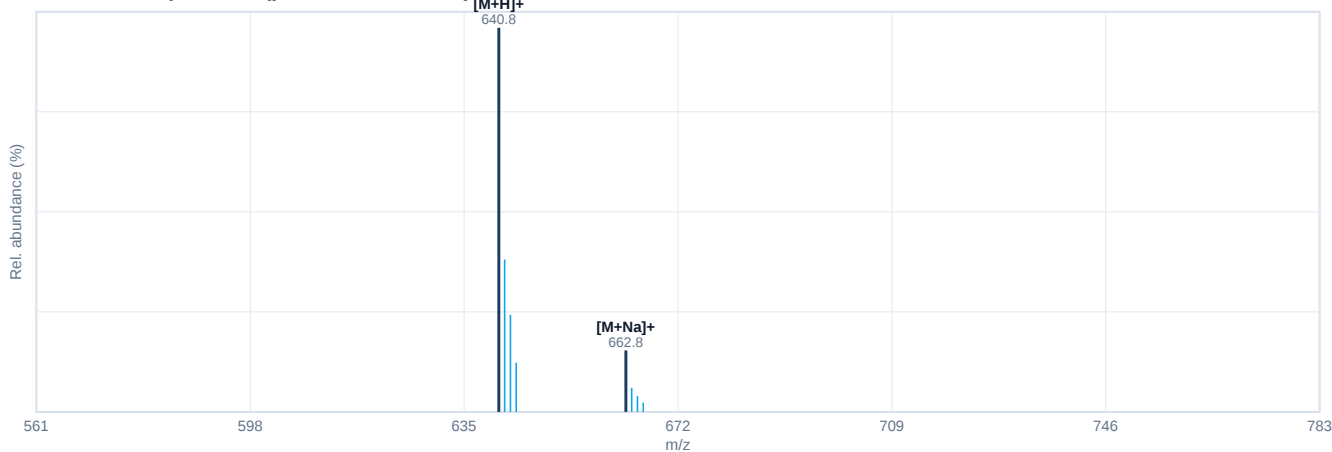
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Figure 1. RP-HPLC Chromatogram (UV 220 nm)



| Peak # | RT (min) | Area (μV·s) | Area % | Assignment                   |
|--------|----------|-------------|--------|------------------------------|
| 1      | 20.54    | 1069143     | 99.52  | Main (target)                |
| 2      | 16.77    | 2382        | 0.22   | Impurity / related substance |
| 3      | 23.82    | 1884        | 0.18   | Impurity / related substance |
| 4      | 2.66     | 565         | 0.06   | Impurity / related substance |
| 5      | 9.06     | 192         | 0.02   | Impurity / related substance |

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



## Interpretation

Identity confirmed by ESI-MS. Observed ions [M+H]<sup>+</sup> 640.8, [M+Na]<sup>+</sup> 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.