



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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HGH (Somatropin) — 10mg

Recombinant Human Growth Hormone (Somatropin, 191aa)

1. PRODUCT IDENTIFICATION

Synonym	Recombinant Human Growth Hormone (Somatropin, 191aa)	Label claim	10mg
Sequence / structure	Single-chain 191-amino-acid polypeptide — sequence identical to human pituitary growth hormone (two disulfide bridges: Cys53–Cys165, Cys182–Cys189)	Lot / Batch	ZX260512-567 / B25589
Mol. formula	C990H1528N262O300S7	Manufacture date	20 May 2026
Mol. weight	22124.76 g/mol	Date of analysis	26 May 2026
CAS number	12629-01-5	Storage	–20 °C, dark, desiccated
Salt form	Lyophilised protein (no counter-ion)		

2. ANALYTICAL TEST RESULTS

Test	Method	Specification	Result	Verdict
Appearance	Visual	White lyophilized powder	White to off-white lyophilized powder	PASS
Identity (intact mass)	LC-MS (ESI, deconvoluted)	Matches 22124.76 Da	22124.83 Da (Δ 3 ppm)	PASS
Identity (peptide map)	Tryptic RP-HPLC-MS	Map matches reference	Conforms	PASS
Purity	RP-HPLC C4, UV 214 nm	$\geq$ 98.0% area	98.27%	PASS
Monomer content	SE-HPLC (UV 214 nm)	$\geq$ 98.0% monomer	99.37%	PASS
Related proteins	RP-HPLC + SE-HPLC	Total $\leq$ 2.0%	1.73%	PASS
Biological potency	Cell-proliferation bioassay	30 IU ($\pm$ 10%)	31.5 IU	PASS
Water content	Karl Fischer (USP <921>)	$\leq$ 5.0%	2.5%	PASS
Host-cell protein (E. coli)	ELISA	$\leq$ 100 ng/mg	31 ng/mg	PASS
Residual host-cell DNA	qPCR	$\leq$ 10 ng/mg	< 0.10 ng/mg	PASS
Bacterial endotoxin	LAL kinetic (USP <85>)	< 5.0 EU/mg	0.14 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.

DZK.

Dr. Zhou Kai

Analyst · 26 May 2026 · Zhongxi Research Institute

DLX.

Dr. Lin Xia (QC Manager)

Approved by · 26 May 2026 · Zhongxi Research Institute



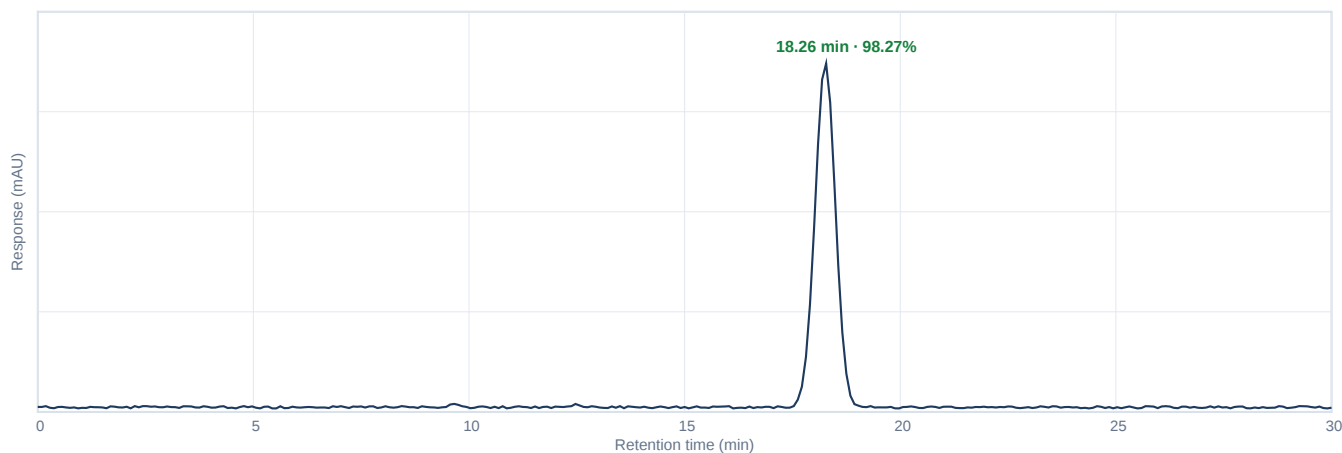
APPENDIX — ANALYTICAL RAW DATA

HGH (Somatropin) 10mg · Lot ZX260512-567 · Cert. ZXR-COA-2026-37719



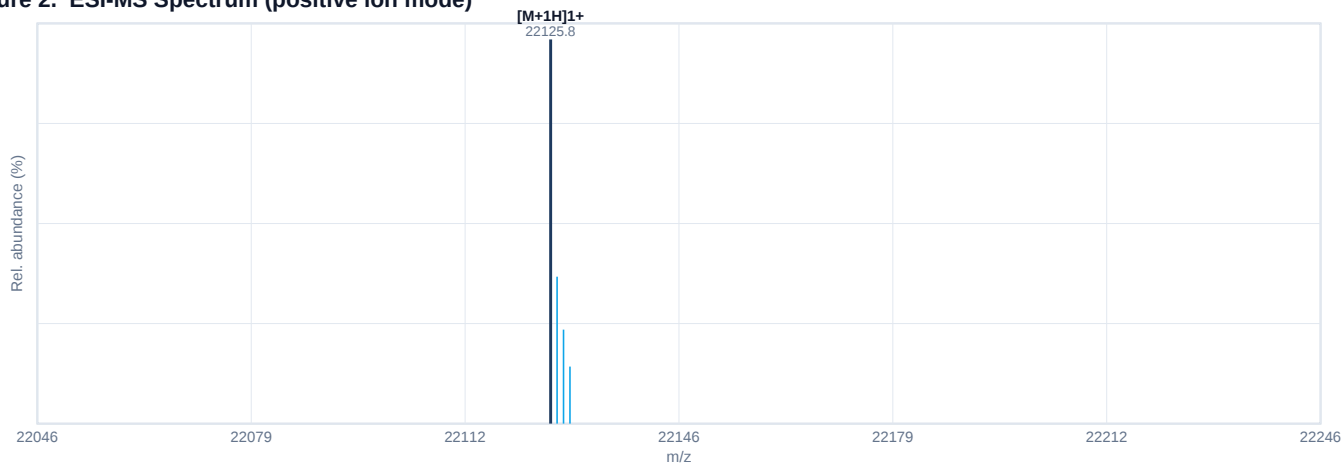
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Figure 1. RP-HPLC Purity Chromatogram — intact somatropin (UV 214 nm)



Peak #	RT (min)	Area (μV·s)	Area %	Assignment
1	18.26	1042877	98.27	Main (target)
2	12.50	8770	0.90	Impurity / related substance
3	9.67	7886	0.83	Impurity / related substance

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



Interpretation

Identity confirmed by ESI-MS. Observed ions [M+1H]¹⁺ 22125.8 deconvolute to a neutral monoisotopic-average mass of 22124.83 Da (theoretical 22124.76 Da; mass error 3 ppm), consistent with HGH (Somatropin). No co-eluting species above 0.5% indicative of misidentification.

Methods — RP-HPLC: Agilent 1260 Infinity II; C4 wide-pore 4.6×250 mm, 5 μm, 300 Å; A: 0.1% TFA in water, B: 0.1% TFA in MeCN; 30–65% B gradient; 0.7 mL/min; 45 °C; UV 214 nm (a C4 wide-pore phase is used because standard C18 is unsuitable for a 22 kDa protein). Purity / monomer by SE-HPLC (TSKgel G2000SWxl, phosphate pH 7.0). Identity by intact-mass ESI-MS (LC-MS) plus tryptic peptide mapping vs the somatropin reference standard. Potency by cell-proliferation bioassay (Nb2 / rat) reported in IU (1 mg = 3 IU). Host-cell protein by ELISA; residual E. coli DNA by qPCR. KF: Metrohm 901. Endotoxin: LAL kinetic. Sterility: USP <71>.