

## CERTIFICATE OF ANALYSIS

## HGH

Somatropin (Recombinant Human Growth Hormone) · 36 IU / 12mg Lyophilised

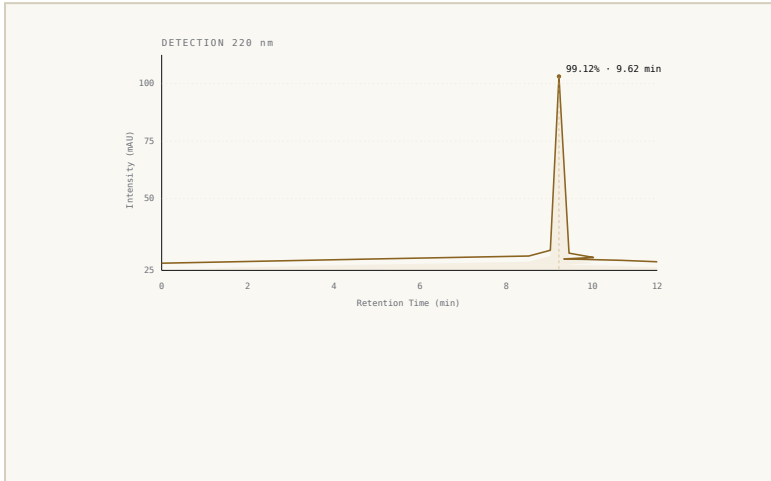
## 01 PRODUCT INFORMATION

PRODUCT	HGH	CAS NUMBER	12629-01-5
CHEMICAL NAME	Somatropin (rhGH, 191 amino acid residues)	MOL. FORMULA	C <sub>990</sub> H <sub>1529</sub> N <sub>263</sub> O <sub>299</sub> S <sub>7</sub>
QUANTITY	12mg (36 IU) per vial	MOL. WEIGHT	22124.10 g/mol
BATCH / LOT	HGH250703	APPEARANCE	White lyophilised powder
MFG. DATE	03 July 2026	RETEST DATE	03 July 2028
STORAGE	2–8°C, dark, dry	INTENDED USE	Research Use Only

## 02 ANALYTICAL RESULTS

TEST ITEM	SPECIFICATION	RESULT	METHOD
Appearance	White to off-white lyophilised powder	✓ COMPLIES	Visual
Identification	Positive	✓ COMPLIES	HPLC / MS
Identity (SDS-PAGE)	Matches reference standard	✓ COMPLIES	SDS-PAGE
Purity (HPLC)	≥ 98.0%	99.12%	RP-HPLC
Purity (SDS-PAGE)	≥ 97.0%	98.7%	SDS-PAGE
Biological Potency	≥ 3.0 IU/mg	3.12 IU/mg	Bioassay
Dimer & Related Proteins	≤ 5.0%	1.8%	SEC-HPLC
Host Cell Proteins	≤ 100 ng/mg	< 50 ng/mg	ELISA
Water Content	≤ 8.0%	2.4%	Karl Fischer
Bacterial Endotoxins	≤ 10 EU/mg	< 2 EU/mg	LAL Test
Residual Solvents	Meets USP / EP requirements	✓ COMPLIES	GC
Heavy Metals	≤ 10 ppm	< 1 ppm	ICP-MS
Sterility	Sterile	✓ COMPLIES	USP <71>
pH (Reconstituted)	4.0 – 7.0	7.6	pH Meter

## 03 HPLC CHROMATOGRAM SUMMARY



MAIN PEAK RT	9.62 min
PEAK AREA	99.12%
TOTAL IMPURITIES	0.88%
DETECTION	UV 220 nm
COLUMN	C4 reversed-phase

## 04 MASS SPECTROMETRY SUMMARY

EXPECTED MOLECULAR MASS	22124.10 Da
OBSERVED MOLECULAR MASS	22124.18 Da
MASS DEVIATION	+ 0.08 Da (within tolerance)
RESULT	✓ IDENTITY CONFIRMED

## 05 QUALITY ASSURANCE &amp; AUTHORISATION

"This batch has been manufactured and tested in accordance with internal quality control procedures and complies with all specifications listed in this Certificate of Analysis."

RELEASED  
QC APPROVED

APPROVED BY

Daniel Hughes

QUALITY ASSURANCE MANAGER

SIGNATURE

D. Hughes

AUTHORISED DIGITALLY

DATE OF ISSUE

03 July 2026

ISSUED DIGITALLY

## 06 LABORATORY INFORMATION

ANALYTICAL TESTING BY

**Hongbai Technology Co.**

Independent third-party laboratory · RP-HPLC · SEC-HPLC · SDS-PAGE · Bioassay · LAL

ISO/IEC  
17025  
ACCREDITED

ISSUED BY

Nexapep Ltd

DOCUMENT TYPE

Independent Third-Party CoA

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TEST REPORT NO.

HB-HGH250703

WEBSITE

nexapep.co.uk

SAMPLE REFERENCE

HGH250703



DOCUMENT VERIFICATION REFERENCE

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