



Solvipurity

ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00385

ISSUED 2026-03-16 · ACCREDITATION AL-1142
ISO/IEC 17025 · GMP · GLP

CERTIFICATE OF ANALYSIS



AUTHENTIC

HGH 100 IU (10× 10IU)

Björn Healthcare ehf. · Sterile lyophilizate, 100 IU per 3 ml clear glass vial, rubber s
topper + aluminium flip-off (white cake)

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



BATCH NO.

BJRN-20LXDxEC0

ANALYTICAL METHODS

RP-HPLC-UV 220 nm · LC-MALDI-TOF · AAA
(amino acid analysis) · Ion chromatography
(counter-ion) · Karl Fischer 2.5.32 · GC-MS
(headspace) · ICP-MS · Kinetic chromogenic
LAL 2.6.14 · Ph. Eur. 2.6.1 sterility · Ph. Eur. 2.6.12
microbial limits · In-vitro cell-based bioassay

MANUFACTURED

2026-12-21

EXPIRY

2028-09-21

RECEIVED

2026-03-16

RELEASE

2026-03-16

DECLARED COMPOSITION

HGH 100 IU (10× 10IU) — recombinant glycoprotein; sequence: rhGH 191 aa (somatropin); CAS
12629-01-5; theoretical MW 22125.00 Da

Analytical results

19 TESTS · ALL METHODS VALIDATED

SUBSTANCE / PARAMETER	RESULT	LOQ	LIMIT	METHOD
● Appearance — sterile lyophilized cake, white to off-white	Conforms	—	homogeneous white cake, no particulates	Visual
● Solubility (water for injection, 2 mg/ml, 25 °C)	Complete within 60 s — clear colourless solution	—	Clear, no visible particles	Visual (Ph. Eur. 2.2.1)

Identification — HPLC retention time	Matches reference	—	±2.0 % of ref	RP-HPLC-UV 220 nm SVP-2026-00385 +
● Identification — sequence / mass match	Confirmed CAS 12629-01-5	—	Match theoretical within ±1 Da	LC-MALDI-TOF
● Molecular weight (measured)	22125.08 Da Δ = +0.08 Da	0.5 Da	22125.00 Da ± 1.0 Da (theoretical)	MALDI-TOF
● Chromatographic purity (main peak)	98.36 %	0.05 %	≥ 95.0 %	RP-HPLC-UV 220 nm
● Any single impurity (max)	0.29 %	0.05 %	≤ 1.00 %	RP-HPLC-UV 220 nm
● Peptide content (amino acid analysis)	89.5 % w/w	0.5 %	≥ 80.0 % w/w	AAA (6 N HCl, 110 °C, 24 h)
● Biological potency (in-vitro)	3.00 IU/mg	—	≥ 2.70 IU/mg (≥ 90 % reference)	Nb2 cell proliferation (HGH) / Leydig cAMP (HCG)
● Water content (Karl Fischer)	2.84 % w/w	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
● Residual acetonitrile	71 ppm	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Residual DMF	131 ppm	10 ppm	≤ 880 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Lead (Pb)	0.066 ppm	0.02 ppm	≤ 0.5 ppm (ICH Q3D parenteral)	ICP-MS
● Arsenic + Cadmium + Mercury (total)	0.096 ppm	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
● Bacterial endotoxins (LAL)	1.13 EU/mg	0.125 EU/mg	< 5.0 EU/mg	Kinetic chromogenic LAL (Ph. Eur. 2.6.14)
● TAMC (aerobic bacteria, pre-lyophilization bulk)	3 CFU/g	1 CFU/g	≤ 10 ² CFU/g	Ph. Eur. 2.6.12
● TYMC (yeast / molds, pre-lyophilization bulk)	2 CFU/g	1 CFU/g	≤ 10 ¹ CFU/g	Ph. Eur. 2.6.12
● Sterility (final lyophilized vial)	Complies — no growth	—	No growth, 14 d incubation	Ph. Eur. 2.6.1 (direct inoculation)
● Container closure integrity	Pass	—	No dye uptake	Dye ingress (0.05 % methylene blue, 2 h vacuum)

