



Solvipurity

ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00274

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ISO/IEC 17025 · GMP · GLP

## CERTIFICATE OF ANALYSIS



AUTHENTIC

## HCG 5000 IU

Björn Healthcare ehf. · Sterile lyophilizate, 5000 IU per 3 ml clear glass vial, rubber stopper + aluminium flip-off (white cake)

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



## BATCH NO.

BJRN-20FASRY

## 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

2027-01-11

## EXPIRY

2028-10-11

## RECEIVED

2026-03-16

## RELEASE

2026-03-16

## DECLARED COMPOSITION

HCG 5000 IU — recombinant glycoprotein; sequence:  $\alpha$ -subunit (92 aa) +  $\beta$ -subunit (145 aa), glycosylated; CAS 9002-61-3; theoretical MW 36700.00 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
+ SOLVIPURITY · CERTIFICATE SVP-2026-00274 +				
● Identification — sequence / mass match	<b>Confirmed</b> CAS 9002-61-3	—	Match theoretical within ±1 Da	LC-MALDI-TOF
● Molecular weight (measured)	<b>36699.76 Da</b> Δ = -0.24 Da	0.5 Da	36700.00 Da ± 1.0 Da (theoretical)	MALDI-TOF
● Chromatographic purity (main peak)	<b>97.31 %</b>	0.05 %	≥ 95.0 %	RP-HPLC-UV 220 nm
● Any single impurity (max)	<b>0.44 %</b>	0.05 %	≤ 1.00 %	RP-HPLC-UV 220 nm
● Peptide content (amino acid analysis)	<b>84.8 % w/w</b>	0.5 %	≥ 80.0 % w/w	AAA (6 N HCl, 110 °C, 24 h)
● Biological potency (in-vitro)	<b>12788.56 IU/mg</b>	—	≥ 10800.00 IU/mg (≥ 90 % reference)	Nb2 cell proliferation (HGH) / Leydig cAMP (HCG)
● Water content (Karl Fischer)	<b>1.57 % w/w</b>	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
● Residual acetonitrile	<b>138 ppm</b>	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Residual DMF	<b>31 ppm</b>	10 ppm	≤ 880 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Lead (Pb)	<b>0.049 ppm</b>	0.02 ppm	≤ 0.5 ppm (ICH Q3D parenteral)	ICP-MS
● Arsenic + Cadmium + Mercury (total)	<b>0.138 ppm</b>	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
● Bacterial endotoxins (LAL)	<b>0.84 EU/mg</b>	0.125 EU/mg	< 5.0 EU/mg	Kinetic chromogenic LAL (Ph. Eur. 2.6.14)
● TAMC (aerobic bacteria, pre-lyophilization bulk)	<b>1 CFU/g</b>	1 CFU/g	≤ 10 <sup>2</sup> CFU/g	Ph. Eur. 2.6.12
● TYMC (yeast / molds, pre-lyophilization bulk)	<b>3 CFU/g</b>	1 CFU/g	≤ 10 <sup>1</sup> CFU/g	Ph. Eur. 2.6.12
● Sterility (final lyophilized vial)	<b>Complies — no growth</b>	—	No growth, 14 d incubation	Ph. Eur. 2.6.1 (direct inoculation)
● Container closure integrity	<b>Pass</b>	—	No dye uptake	Dye ingress (0.05 % methylene blue, 2 h vacuum)



