



Solvipurity

ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00317

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

## CERTIFICATE OF ANALYSIS



AUTHENTIC

## Gonadorelin (GnRH) 10mg

Björn Healthcare ehf. · Sterile lyophilizate, 10 mg per 3 ml clear glass vial, rubber s  
topper + aluminium flip-off (white cake)

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



## BATCH NO.

BJRN-20E3NYY

## ANALYTICAL METHODS

RP-HPLC-UV 220 nm · LC-ESI-MS · 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

## MANUFACTURED

2026-06-05

## EXPIRY

2028-03-05

## RECEIVED

2026-03-16

## RELEASE

2026-03-16

## DECLARED COMPOSITION

Gonadorelin (GnRH) 10mg — synthetic peptide; sequence:  
pGlu-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly-NH<sub>2</sub>; CAS 33515-09-2; theoretical MW 1182.31 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-2026-00317 +
Identification — sequence / mass match	<b>Confirmed</b> CAS 33515-09-2	—	Match theoretical within ±1 Da	LC-ESI-MS
Molecular weight (measured)	<b>1182.77 Da</b> Δ = +0.46 Da	0.5 Da	1182.31 Da ± 1.0 Da (theoretical)	ESI-MS
Chromatographic purity (main peak)	<b>98.15 %</b>	0.05 %	≥ 98.0 %	RP-HPLC-UV 220 nm
Any single impurity (max)	<b>0.36 %</b>	0.05 %	≤ 1.00 %	RP-HPLC-UV 220 nm
Peptide content (amino acid analysis)	<b>88.4 % w/w</b>	0.5 %	≥ 80.0 % w/w	AAA (6 N HCl, 110 °C, 24 h)
Trifluoroacetate (TFA counter-ion)	<b>0.64 % w/w</b>	0.05 %	≤ 1.00 % w/w	IC (ion chromatography)
Water content (Karl Fischer)	<b>1.92 % w/w</b>	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
Residual acetonitrile	<b>222 ppm</b>	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
Residual DMF	<b>81 ppm</b>	10 ppm	≤ 880 ppm (ICH Q3C Class 2)	GC-MS (headspace)
Lead (Pb)	<b>0.036 ppm</b>	0.02 ppm	≤ 0.5 ppm (ICH Q3D parenteral)	ICP-MS
Arsenic + Cadmium + Mercury (total)	<b>0.043 ppm</b>	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
Bacterial endotoxins (LAL)	<b>1.99 EU/mg</b>	0.125 EU/mg	< 10.0 EU/mg	Kinetic chromogenic LAL (Ph. Eur. 2.6.14)
TAMC (aerobic bacteria, pre-lyophilization bulk)	<b>4 CFU/g</b>	1 CFU/g	≤ 10 <sup>2</sup> CFU/g	Ph. Eur. 2.6.12
TYMC (yeast / molds, pre-lyophilization bulk)	<b>0 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)



