Solvipurity
ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00379
ISSUED 2026-03-16 · ACCREDITATION AL-1142
ISO/IEC 17025 · GMP · GLP

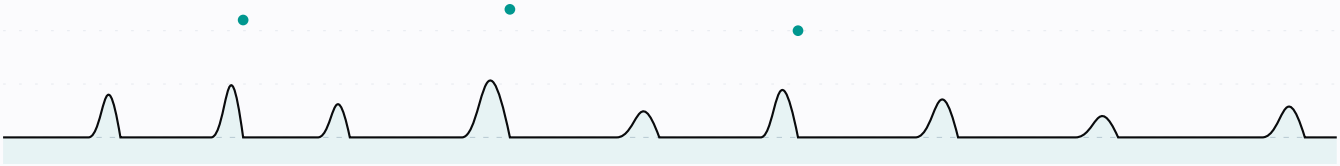
CERTIFICATE OF ANALYSIS

AUTHENTIC

Triptorelin 2mg

Björn Healthcare ehf. · Sterile lyophilizate, 2 mg per 3 ml clear glass vial, rubber s topper + aluminium flip-off (white cake)

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



BATCH NO.
BJRN-20HGQKY

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
2026-12-29

EXPIRY
2028-09-29

RECEIVED
2026-03-16

RELEASE
2026-03-16

DECLARED COMPOSITION
Triptorelin 2mg — synthetic peptide; sequence: pGlu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-Gly-NH_2; CAS 57773-63-4; theoretical MW 1311.45 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
Identification — sequence / mass match	**Confirmed** CAS 57773-63-4	—	Match theoretical within ±1 Da	LC-ESI-MS
Molecular weight (measured)	**1311.13 Da** Δ = -0.32 Da	0.5 Da	1311.45 Da ± 1.0 Da (theoretical)	ESI-MS
Chromatographic purity (main peak)	**99.33 %**	0.05 %	≥ 98.0 %	RP-HPLC-UV 220 nm
Any single impurity (max)	**0.32 %**	0.05 %	≤ 1.00 %	RP-HPLC-UV 220 nm
Peptide content (amino acid analysis)	**85.3 % w/w**	0.5 %	≥ 80.0 % w/w	AAA (6 N HCl, 110 °C, 24 h)
Trifluoroacetate (TFA counter-ion)	**0.17 % w/w**	0.05 %	≤ 1.00 % w/w	IC (ion chromatography)
Water content (Karl Fischer)	**2.35 % w/w**	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
Residual acetonitrile	**283 ppm**	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
Residual DMF	**87 ppm**	10 ppm	≤ 880 ppm (ICH Q3C Class 2)	GC-MS (headspace)
Lead (Pb)	**0.084 ppm**	0.02 ppm	≤ 0.5 ppm (ICH Q3D parenteral)	ICP-MS
Arsenic + Cadmium + Mercury (total)	**0.090 ppm**	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
Bacterial endotoxins (LAL)	**4.75 EU/mg**	0.125 EU/mg	< 10.0 EU/mg	Kinetic chromogenic LAL (Ph. Eur. 2.6.14)
TAMC (aerobic bacteria, pre-lyophilization bulk)	**5 CFU/g**	1 CFU/g	≤ 10^2 CFU/g	Ph. Eur. 2.6.12
TYMC (yeast / molds, pre-lyophilization bulk)	**3 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)

INDEPENDENT VERIFICATION

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VERIFICATION CODE

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Quality assurance · AL-1142

SHA-256 CHECKSUM
0-xb79784661cfaa7beb79784661cfaa7beb79784661cfaa7be
Tamper-evident digest

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SAMPLE RETENTION

Sealed aliquot retained for 24 months from issue date under controlled conditions (Ph. Eur. 5.1, −20 °C).

DISPUTE WINDOW

Requests for re-testing accepted within 30 days of report publication. Contact lab@solvipurity.com quoting the report number.