



Solvipurity

ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00342

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

CERTIFICATE OF ANALYSIS



AUTHENTIC

Oxytocin 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-20LJRZV

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

2026-08-28

EXPIRY

2028-05-28

RECEIVED

2026-03-16

RELEASE

2026-03-16

DECLARED COMPOSITION

Oxytocin 10mg — synthetic peptide; sequence: Cys-Tyr-Ile-Gln-Asn-Cys-Pro-Leu-Gly-NH₂
(disulfide); CAS 50-56-6; theoretical MW 1007.19 Da

Analytical results

20 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-2026-00342 +				
● Identification — sequence / mass match	Confirmed CAS 50-56-6	—	Match theoretical within ±1 Da	LC-ESI-MS
● Molecular weight (measured)	1006.91 Da Δ = -0.28 Da	0.5 Da	1007.19 Da ± 1.0 Da (theoretical)	ESI-MS
● Chromatographic purity (main peak)	98.14 %	0.05 %	≥ 98.0 %	RP-HPLC-UV 220 nm
● Any single impurity (max)	0.08 %	0.05 %	≤ 1.00 %	RP-HPLC-UV 220 nm
● Peptide content (amino acid analysis)	87.5 % w/w	0.5 %	≥ 80.0 % w/w	AAA (6 N HCl, 110 °C, 24 h)
● Cyclization (disulfide / lactam confirmation)	Confirmed — single cyclic isoform	—	No linear form ≥ 0.5 %	LC-MS (reduction/Ellman)
● Trifluoroacetate (TFA counter-ion)	0.57 % w/w	0.05 %	≤ 1.00 % w/w	IC (ion chromatography)
● Water content (Karl Fischer)	1.35 % w/w	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
● Residual acetonitrile	223 ppm	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Residual DMF	162 ppm	10 ppm	≤ 880 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Lead (Pb)	0.028 ppm	0.02 ppm	≤ 0.5 ppm (ICH Q3D parenteral)	ICP-MS
● Arsenic + Cadmium + Mercury (total)	0.166 ppm	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
● Bacterial endotoxins (LAL)	0.92 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)	0 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)

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