Solvipurity
ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00354

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

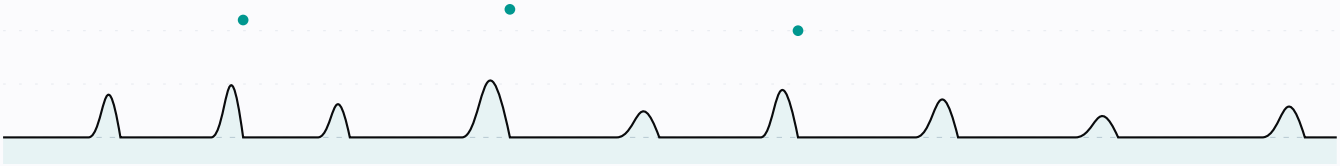
CERTIFICATE OF ANALYSIS

AUTHENTIC

PT-141 (Bremelanotide) 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-20EE6MD

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
2026-10-07

EXPIRY
2028-07-07

RECEIVED
2026-03-16

RELEASE
2026-03-16

DECLARED COMPOSITION
PT-141 (Bremelanotide) 10mg — synthetic peptide; sequence: Ac-Nle-c[Asp-His-D-Phe-Arg-Trp-Lys]-OH; CAS 189691-06-3; theoretical MW 1025.18 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
Identification — sequence / mass match	**Confirmed** CAS 189691-06-3	—	Match theoretical within ±1 Da	LC-ESI-MS
Molecular weight (measured)	**1024.80 Da** Δ = -0.38 Da	0.5 Da	1025.18 Da ± 1.0 Da (theoretical)	ESI-MS
Chromatographic purity (main peak)	**99.59 %**	0.05 %	≥ 98.0 %	RP-HPLC-UV 220 nm
Any single impurity (max)	**0.37 %**	0.05 %	≤ 1.00 %	RP-HPLC-UV 220 nm
Peptide content (amino acid analysis)	**85.6 % 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)	**0.29 % w/w**	0.05 %	≤ 1.00 % w/w	IC (ion chromatography)
Water content (Karl Fischer)	**3.23 % w/w**	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
Residual acetonitrile	**44 ppm**	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
Residual DMF	**49 ppm**	10 ppm	≤ 880 ppm (ICH Q3C Class 2)	GC-MS (headspace)
Lead (Pb)	**0.118 ppm**	0.02 ppm	≤ 0.5 ppm (ICH Q3D parenteral)	ICP-MS
Arsenic + Cadmium + Mercury (total)	**0.091 ppm**	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
Bacterial endotoxins (LAL)	**2.27 EU/mg**	0.125 EU/mg	< 10.0 EU/mg	Kinetic chromogenic LAL (Ph. Eur. 2.6.14)
TAMC (aerobic bacteria, pre-lyophilization bulk)	**4 CFU/g**	1 CFU/g	≤ 10^2 CFU/g	Ph. Eur. 2.6.12
TYMC (yeast / molds, pre-lyophilization bulk)	**5 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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EFG2V6

VERIFICATION CODE

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Quality assurance · AL-1142

SHA-256 CHECKSUM
0-xec960f9e9af11c7aec960f9e9af11c7aec960f9e9af11c7a
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.