



Solvipuritý

ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00285

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

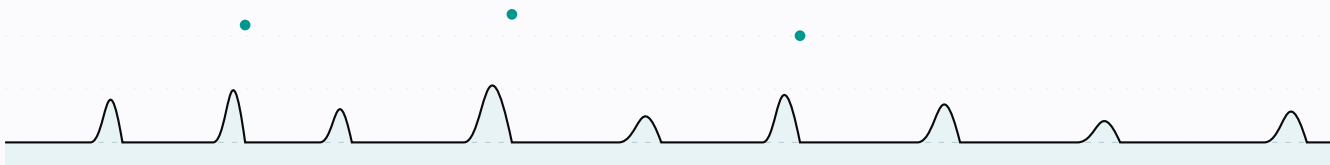
CERTIFICATE OF ANALYSIS

AUTHENTIC

BPC-157 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-202SMVK

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

2026-02-19

EXPIRY

2027-11-19

RECEIVED

2026-03-16

RELEASE

2026-03-16

DECLARED COMPOSITION

BPC-157 10mg — synthetic peptide; sequence:
Gly-Glu-Pro-Pro-Gly-Lys-Pro-Ala-Asp-Asp-Ala-Gly-Leu-Val; CAS 137525-51-0; theoretical MW
1419.53 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 137525-51-0	–	Match theoretical within ±1 Da	LC-ESI-MS
● Molecular weight (measured)	1419.46 Da Δ = -0.07 Da	0.5 Da	1419.53 Da ± 1.0 Da (theoretical)	ESI-MS
● Chromatographic purity (main peak)	98.36 %	0.05 %	≥ 98.0 %	RP-HPLC-UV 220 nm
● Any single impurity (max)	0.24 %	0.05 %	≤ 1.00 %	RP-HPLC-UV 220 nm
● Peptide content (amino acid analysis)	88.8 % w/w	0.5 %	≥ 80.0 % w/w	AAA (6 N HCl, 110 °C, 24 h)
● Trifluoroacetate (TFA counter-ion)	0.25 % w/w	0.05 %	≤ 1.00 % w/w	IC (ion chromatography)
● Water content (Karl Fischer)	1.21 % w/w	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
● Residual acetonitrile	297 ppm	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Residual DMF	33 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)	0.045 ppm	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
● Bacterial endotoxins (LAL)	4.19 EU/mg	0.125 EU/mg	< 10.0 EU/mg	Kinetic chromogenic LAL (Ph. Eur. 2.6.14)
● TAMC (aerobic bacteria, pre-lyophilization bulk)	3 CFU/g	1 CFU/g	≤ 10 ² CFU/g	Ph. Eur. 2.6.12
● TYMC (yeast / molds, pre-lyophilization bulk)	2 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)

Solvipurity

