

**Solvipur**

ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00276ISSUED 2026-03-16 · ACCREDITATION AL-1142
ISO/IEC 17025 · GMP · GLP

CERTIFICATE OF ANALYSIS

**AUTHENTIC**

ACE-031 1mg

Björn Healthcare ehf. · Sterile lyophilizate, 1 mg per 3 ml clear glass vial, rubber s
topper + aluminium flip-off (white cake)

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



BATCH NO.

BJRN-20UNP96

ANALYTICAL METHODS

RP-HPLC-UV 220 nm · LC-MALDI-TOF · 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

2026-01-20

EXPIRY

2027-10-20

RECEIVED

2026-03-16

RELEASE

2026-03-16

DECLARED COMPOSITION

ACE-031 1mg — recombinant glycoprotein; sequence: ActRIIB-Fc fusion protein; CAS 1105908-67-5;
theoretical MW 44000.00 Da

Analytical results

18 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-2026-00276 +
● Identification — sequence / mass match	Confirmed CAS 1105908-67-5	—	Match theoretical within ±1 Da	LC-MALDI-TOF
● Molecular weight (measured)	44000.25 Da Δ = +0.25 Da	0.5 Da	44000.00 Da ± 1.0 Da (theoretical)	MALDI-TOF
● Chromatographic purity (main peak)	95.72 %	0.05 %	≥ 95.0 %	RP-HPLC-UV 220 nm
● Any single impurity (max)	0.13 %	0.05 %	≤ 1.00 %	RP-HPLC-UV 220 nm
● Peptide content (amino acid analysis)	92.3 % w/w	0.5 %	≥ 80.0 % w/w	AAA (6 N HCl, 110 °C, 24 h)
● Water content (Karl Fischer)	4.00 % w/w	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
● Residual acetonitrile	104 ppm	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Residual DMF	91 ppm	10 ppm	≤ 880 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Lead (Pb)	0.121 ppm	0.02 ppm	≤ 0.5 ppm (ICH Q3D parenteral)	ICP-MS
● Arsenic + Cadmium + Mercury (total)	0.081 ppm	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
● Bacterial endotoxins (LAL)	3.72 EU/mg	0.125 EU/mg	< 5.0 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)	1 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)

