



CERTIFICATE OF ANALYSIS

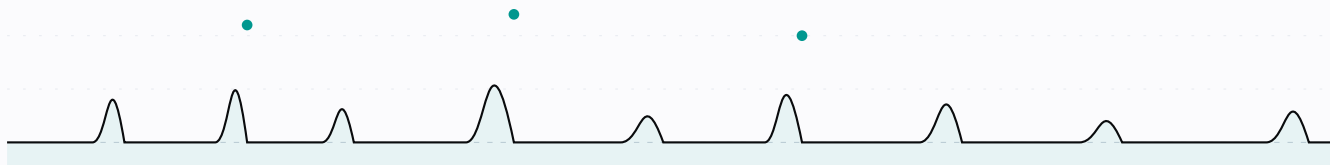


AUTHENTIC

ARA-290 16mg

Björn Healthcare ehf. · Sterile lyophilizate, 16 mg per 3 ml clear glass vial, rubber s
topper + aluminium flip-off (white cake)

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



BATCH NO.

BJRN-20M4YVK

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

2026-02-09

EXPIRY

2027-11-09

RECEIVED

2026-03-16

RELEASE

2026-03-16

DECLARED COMPOSITION

ARA-290 16mg — synthetic peptide; sequence: Cibinetide
(Pyr-Glu-Gln-Leu-Glu-Arg-Ala-Leu-Asn-Ser-Ser); CAS 1152113-32-4; theoretical MW 1257.44 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 SVP-2026-00282 +
Identification — sequence / mass match CAS 1152113-32-4	Confirmed	—	Match theoretical within ±1 Da	LC-ESI-MS
Molecular weight (measured)	1257.57 Da Δ = +0.13 Da	0.5 Da	1257.44 Da ± 1.0 Da (theoretical)	ESI-MS
Chromatographic purity (main peak)	98.28 %	0.05 %	≥ 98.0 %	RP-HPLC-UV 220 nm
Any single impurity (max)	0.10 %	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)
Trifluoroacetate (TFA counter-ion)	0.84 % w/w	0.05 %	≤ 1.00 % w/w	IC (ion chromatography)
Water content (Karl Fischer)	3.92 % w/w	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
Residual acetonitrile	149 ppm	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
Residual DMF	100 ppm	10 ppm	≤ 880 ppm (ICH Q3C Class 2)	GC-MS (headspace)
Lead (Pb)	0.094 ppm	0.02 ppm	≤ 0.5 ppm (ICH Q3D parenteral)	ICP-MS
Arsenic + Cadmium + Mercury (total)	0.107 ppm	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
Bacterial endotoxins (LAL)	3.82 EU/mg	0.125 EU/mg	< 10.0 EU/mg	Kinetic chromogenic LAL (Ph. Eur. 2.6.14)
TAMC (aerobic bacteria, pre-lyophilization bulk)	6 CFU/g	1 CFU/g	≤ 10 ² CFU/g	Ph. Eur. 2.6.12
TYMC (yeast / molds, pre-lyophilization bulk)	4 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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PGP7VJ

VERIFICATION CODE

ANALYST

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Senior chemist

INDEPENDENT REVIEWER

dr Helga Thorgeirsdottir
Quality assurance · AL-1142

SHA-256 CHECKSUM

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xace34388b817a630ace34388b817a630ace34388b817a630
Tamper-evident digest

NOTICE · CONDITIONS OF THIS REPORT

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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.

