



Solvipurity

ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00304

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

## CERTIFICATE OF ANALYSIS

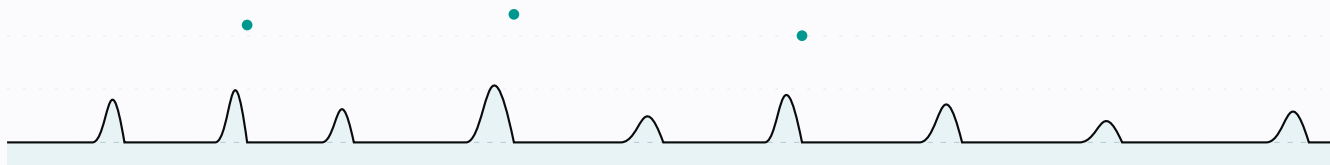


AUTHENTIC

# Follistatin-344 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-20FECZH

## 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

2026-04-22

## EXPIRY

2028-01-22

## RECEIVED

2026-03-16

## RELEASE

2026-03-16

## DECLARED COMPOSITION

Follistatin-344 1mg — recombinant glycoprotein; sequence: Follistatin-344 (344 aa glycoprotein);  
CAS 80449-31-6; theoretical MW 38100.00 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-2026-00304 +
● Identification — sequence / mass match	<b>Confirmed</b> CAS 80449-31-6	—	Match theoretical within ±1 Da	LC-MALDI-TOF
● Molecular weight (measured)	<b>38100.22 Da</b> Δ = +0.22 Da	0.5 Da	38100.00 Da ± 1.0 Da (theoretical)	MALDI-TOF
● Chromatographic purity (main peak)	<b>97.84 %</b>	0.05 %	≥ 95.0 %	RP-HPLC-UV 220 nm
● Any single impurity (max)	<b>0.18 %</b>	0.05 %	≤ 1.00 %	RP-HPLC-UV 220 nm
● Peptide content (amino acid analysis)	<b>85.6 % w/w</b>	0.5 %	≥ 80.0 % w/w	AAA (6 N HCl, 110 °C, 24 h)
● Water content (Karl Fischer)	<b>4.13 % w/w</b>	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
● Residual acetonitrile	<b>216 ppm</b>	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Residual DMF	<b>78 ppm</b>	10 ppm	≤ 880 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Lead (Pb)	<b>0.120 ppm</b>	0.02 ppm	≤ 0.5 ppm (ICH Q3D parenteral)	ICP-MS
● Arsenic + Cadmium + Mercury (total)	<b>0.041 ppm</b>	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
● Bacterial endotoxins (LAL)	<b>1.24 EU/mg</b>	0.125 EU/mg	< 5.0 EU/mg	Kinetic chromogenic LAL (Ph. Eur. 2.6.14)
● TAMC (aerobic bacteria, pre-lyophilization bulk)	<b>2 CFU/g</b>	1 CFU/g	≤ 10 <sup>2</sup> CFU/g	Ph. Eur. 2.6.12
● TYMC (yeast / molds, pre-lyophilization bulk)	<b>4 CFU/g</b>	1 CFU/g	≤ 10 <sup>1</sup> CFU/g	Ph. Eur. 2.6.12
● Sterility (final lyophilized vial)	<b>Complies – no growth</b>	—	No growth, 14 d incubation	Ph. Eur. 2.6.1 (direct inoculation)
● Container closure integrity	<b>Pass</b>	—	No dye uptake	Dye ingress (0.05 % methylene blue, 2 h vacuum)

INDEPENDENT VERIFICATION

# Verify this certificate

Scan the QR or visit the URL and enter the 6-character code.

Everything on this printed copy must match the online record exactly.

Any discrepancy means the document has been tampered with.



[solvipurity.com/pl/verify/result?id=SVP-2026-00304&code=REUDUL](https://solvipurity.com/pl/verify/result?id=SVP-2026-00304&code=REUDUL)

**REUDUL**

VERIFICATION CODE

ANALYST

**mgr Ingrid Dahl**  
Senior chemist

INDEPENDENT REVIEWER

**dr Helga Thorgeirsdottir**  
Quality assurance · AL-1142

SHA-256 CHECKSUM

0-  
xd6c09e48d6034440d6c09e48d6034440d6c09e48d6034440  
Tamper-evident digest

NOTICE · CONDITIONS OF THIS REPORT

This certificate of analysis applies exclusively to the sample received and described above. It does not constitute approval, endorsement or certification of the product or its intended use. Results were obtained under ISO/IEC 17025 accredited methods by Solvipurity ehf. (accreditation AL-1142). Reproduction of this document in part is prohibited — only the full, verified copy may be shared. If the data printed here does not match the online record at solvipurity.com/verify, the document should be considered invalid.

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.

