

**Solvipurity**

ANALYTICAL LABORATORY · REYKJAVÍK, IS

**SVP-2026-00351**ISSUED 2026-03-16 · ACCREDITATION AL-1142  
ISO/IEC 17025 · GMP · GLP

## CERTIFICATE OF ANALYSIS

**AUTHENTIC**

# Pinealon 20mg

Björn Healthcare ehf. · Sterile lyophilizate, 20 mg per 3 ml clear glass vial, rubber s  
topper + aluminium flip-off (white cake)

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



## BATCH NO.

BJRN-20MALZH

## 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

2026-09-27

## EXPIRY

2028-06-27

## RECEIVED

2026-03-16

## RELEASE

2026-03-16

## DECLARED COMPOSITION

Pinealon 20mg — synthetic peptide; sequence: Glu-Asp-Arg tripeptide; CAS n/a; theoretical MW  
388.41 Da

## Analytical results

19 TESTS · ALL METHODS VALIDATED

SUBSTANCE / PARAMETER	RESULT	LOQ	LIMIT	METHOD
● Appearance — sterile lyophilized cake, white to off-white	<b>Conforms</b>	—	homogeneous white cake, no particulates	Visual
● Solubility (water for injection, 2 mg/ml, 25 °C)	<b>Complete within 60 s — clear colourless solution</b>	—	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-2026-00351 +
● Identification — sequence / mass match	<b>Confirmed</b> CAS n/a	—	Match theoretical within ±1 Da	LC-ESI-MS
● Molecular weight (measured)	<b>388.09 Da</b> Δ = -0.32 Da	0.5 Da	388.41 Da ± 1.0 Da (theoretical)	ESI-MS
● Chromatographic purity (main peak)	<b>98.87 %</b>	0.05 %	≥ 98.0 %	RP-HPLC-UV 220 nm
● Any single impurity (max)	<b>0.19 %</b>	0.05 %	≤ 1.00 %	RP-HPLC-UV 220 nm
● Peptide content (amino acid analysis)	<b>86.0 % w/w</b>	0.5 %	≥ 80.0 % w/w	AAA (6 N HCl, 110 °C, 24 h)
● Trifluoroacetate (TFA counter-ion)	<b>0.55 % w/w</b>	0.05 %	≤ 1.00 % w/w	IC (ion chromatography)
● Water content (Karl Fischer)	<b>2.40 % w/w</b>	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
● Residual acetonitrile	<b>182 ppm</b>	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Residual DMF	<b>164 ppm</b>	10 ppm	≤ 880 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Lead (Pb)	<b>0.035 ppm</b>	0.02 ppm	≤ 0.5 ppm (ICH Q3D parenteral)	ICP-MS
● Arsenic + Cadmium + Mercury (total)	<b>0.158 ppm</b>	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
● Bacterial endotoxins (LAL)	<b>0.77 EU/mg</b>	0.125 EU/mg	< 10.0 EU/mg	Kinetic chromogenic LAL (Ph. Eur. 2.6.14)
● TAMC (aerobic bacteria, pre-lyophilization bulk)	<b>5 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)



