

**Solvipuritý**

ANALYTICAL LABORATORY · REYKJAVÍK, IS

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ISO/IEC 17025 · GMP · GLP

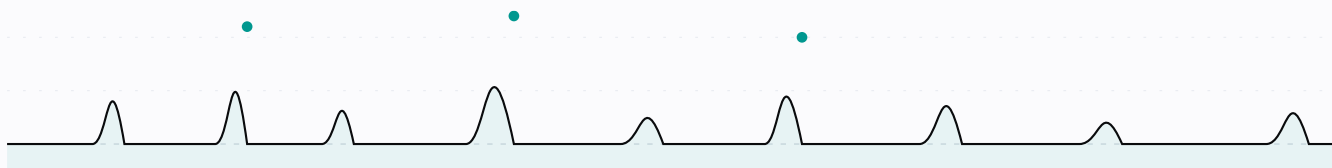
## CERTIFICATE OF ANALYSIS

**AUTHENTIC**

# Leuphasyl (Pentapeptide-18) 200mg

Björn Healthcare ehf. · Sterile lyophilizate, 200 mg per 3 ml clear glass vial, rubber stopper + aluminium flip-off (white cake)

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



## BATCH NO.

BJRN-20HBB62

## 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

2026-09-24

## EXPIRY

2028-06-24

## RECEIVED

2026-03-16

## RELEASE

2026-03-16

## DECLARED COMPOSITION

Leuphasyl (Pentapeptide-18) 200mg — synthetic peptide; sequence: Tyr-D-Ala-Gly-Phe-Leu (Pentapeptide-18); CAS 64963-01-5; theoretical MW 513.65 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)	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 64963-01-5	–	Match theoretical within ±1 Da	LC-ESI-MS
● Molecular weight (measured)	513.75 Da Δ = +0.10 Da	0.5 Da	513.65 Da ± 1.0 Da (theoretical)	ESI-MS
● Chromatographic purity (main peak)	99.28 %	0.05 %	≥ 98.0 %	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)	85.2 % w/w	0.5 %	≥ 80.0 % w/w	AAA (6 N HCl, 110 °C, 24 h)
● Trifluoroacetate (TFA counter-ion)	0.83 % w/w	0.05 %	≤ 1.00 % w/w	IC (ion chromatography)
● Water content (Karl Fischer)	2.42 % w/w	0.1 %	≤ 5.0 % w/w	Ph. Eur. 2.5.32
● Residual acetonitrile	177 ppm	10 ppm	≤ 410 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Residual DMF	64 ppm	10 ppm	≤ 880 ppm (ICH Q3C Class 2)	GC-MS (headspace)
● Lead (Pb)	0.110 ppm	0.02 ppm	≤ 0.5 ppm (ICH Q3D parenteral)	ICP-MS
● Arsenic + Cadmium + Mercury (total)	0.145 ppm	0.02 ppm	≤ 1.5 ppm (ICH Q3D parenteral)	ICP-MS
● Bacterial endotoxins (LAL)	2.01 EU/mg	0.125 EU/mg	< 10.0 EU/mg	Kinetic chromogenic LAL (Ph. Eur. 2.6.14)
● TAMC (aerobic bacteria, pre-lyophilization bulk)	5 CFU/g	1 CFU/g	≤ 10 <sup>2</sup> CFU/g	Ph. Eur. 2.6.12
● TYMC (yeast / molds, pre-lyophilization bulk)	0 CFU/g	1 CFU/g	≤ 10 <sup>1</sup> 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



