



Solvipurity

ANALYTICAL LABORATORY · REYKJAVÍK, IS

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ISO/IEC 17025 · GMP · GLP

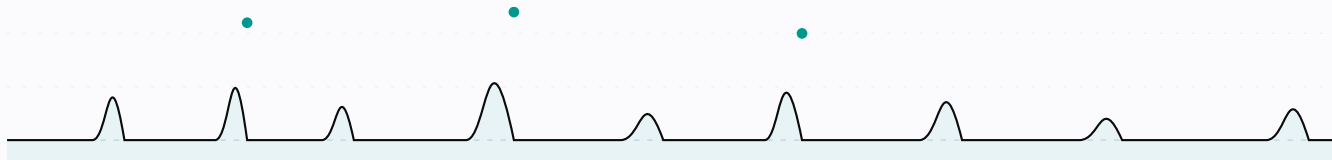
## CERTIFICATE OF ANALYSIS

AUTHENTIC

# Ligandrol LGD-4033 10mg

Björn Healthcare ehf. · Blister, 10 × 10 tablets (100 tabs), PVC/Al

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



## BATCH NO.

BJRN-20T4LCM

## ANALYTICAL METHODS

HPLC-UV · Ph. Eur. 2.9.3 dissolution · Ph. Eur. 2.9.40 uniformity · Karl Fischer 2.5.32 · GC-MS headspace · ICP-MS · Ph. Eur. 2.6.12 / 2.6.13

## MANUFACTURED

2025-06-18

## EXPIRY

2027-10-18

## RECEIVED

2026-03-16

## RELEASE

2026-03-16

## DECLARED COMPOSITION

LGD-4033 (Ligandrol) 10 mg per tablet

## Analytical results

19 TESTS · ALL METHODS VALIDATED

SUBSTANCE / PARAMETER	RESULT	LOQ	LIMIT	METHOD
Appearance (shape, colour, engraving)	<b>Conforms</b>	–	as specification	Visual
Average mass	<b>191 mg</b>	1 mg	181–201 mg	Ph. Eur. 2.9.5
Identification — HPLC retention time	<b>Matches reference</b>	–	±2.0 % of ref	HPLC-UV
D-4033 (Ligandrol) (assay)	<b>10.17 mg/tab</b> 101.74 %	0.05 %	95.0–105.0 %	HPLC-UV
Uniformity of dosage units (AV)	<b>AV = 8.0</b>	–	AV ≤ 15.0	Ph. Eur. 2.9.40

● Dissolution (Q at 30 min)		96.0 %	2 % Q ≥ 80 % at 30 min	Ph. Eur. 2.9.3 (paddle)
● Ligandrol N-oxide (specified impurity)	0.093 %	0.03 %	≤ 0.30 %	HPLC-UV
● Any unspecified impurity	< 0.08 %	0.03 %	≤ 0.20 %	HPLC-UV
● Total impurities	0.271 %	0.05 %	≤ 1.00 %	HPLC-UV
● Water content (Karl Fischer)	1.11 %	0.1 %	≤ 5.0 %	Ph. Eur. 2.5.32
● Residual methanol	253 ppm	10 ppm	≤ 3 000 ppm (ICH Q3C Class 2)	GC-MS
● Residual ethanol	238 ppm	10 ppm	≤ 5 000 ppm (ICH Q3C Class 3)	GC-MS
● Lead (Pb)	0.124 ppm	0.02 ppm	≤ 0.5 ppm (ICH Q3D oral)	ICP-MS
● Cadmium (Cd)	0.059 ppm	0.01 ppm	≤ 0.5 ppm	ICP-MS
● Mercury (Hg)	0.0224 ppm	0.005 ppm	≤ 0.3 ppm	ICP-MS
● Arsenic (As)	0.032 ppm	0.01 ppm	≤ 1.5 ppm	ICP-MS
● TAMC (aerobic bacteria)	< 10 CFU/g	10 CFU/g	≤ 10 <sup>3</sup> CFU/g	Ph. Eur. 2.6.12
● TYMC (yeast / molds)	< 10 CFU/g	10 CFU/g	≤ 10 <sup>2</sup> CFU/g	Ph. Eur. 2.6.12
● Absence of E. coli (1 g)	Complies	–	Absence in 1 g	Ph. Eur. 2.6.13



