



Solvipurity

ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00260

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

## CERTIFICATE OF ANALYSIS

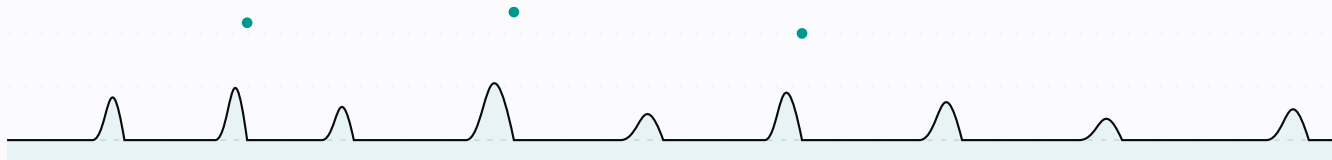


AUTHENTIC

# Metanabol 10mg

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

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



## BATCH NO.

BJRN-20LHHXS

## 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

2026-02-13

## EXPIRY

2028-06-13

## RECEIVED

2026-03-16

## RELEASE

2026-03-16

## DECLARED COMPOSITION

Methandienone 10 mg per tablet

## Analytical results

19 TESTS · ALL METHODS VALIDATED

SUBSTANCE / PARAMETER	RESULT	LOQ	LIMIT	METHOD
● Appearance (shape, colour, engraving)	Conforms	– as specification		Visual
● Average mass	197 mg	1 mg	187–207 mg	Ph. Eur. 2.9.5
● Identification — HPLC retention time	Matches reference	–	±2.0 % of ref	HPLC-UV
● Methandienone (assay)	10.17 mg/tab 101.67 %	0.05 %	95.0–105.0 %	HPLC-UV
● Uniformity of dosage units (AV)	AV = 4.7	–	AV ≤ 15.0	Ph. Eur. 2.9.40

● dissolution (Q at 30 min)		88.4 %	2 % Q ≥ 80 % at 30 min		Ph. Eur. 2.9.3 (paddle)
+ SOLVIPURITY · CERTIFICATE					
SVP-2026-00260 +					
● 17α-Methyl-1-testosterone (specified impurity)	0.175 %	0.03 %	≤ 0.30 %		HPLC-UV
● Any unspecified impurity	< 0.08 %	0.03 %	≤ 0.20 %		HPLC-UV
● Total impurities	0.258 %	0.05 %	≤ 1.00 %		HPLC-UV
● Water content (Karl Fischer)	1.17 %	0.1 %	≤ 5.0 %		Ph. Eur. 2.5.32
● Residual methanol	300 ppm	10 ppm	≤ 3 000 ppm (ICH Q3C Class 2)		GC-MS
● Residual ethanol	266 ppm	10 ppm	≤ 5 000 ppm (ICH Q3C Class 3)		GC-MS
● Lead (Pb)	0.164 ppm	0.02 ppm	≤ 0.5 ppm (ICH Q3D oral)		ICP-MS
● Cadmium (Cd)	0.023 ppm	0.01 ppm	≤ 0.5 ppm		ICP-MS
● Mercury (Hg)	0.0097 ppm	0.005 ppm	≤ 0.3 ppm		ICP-MS
● Arsenic (As)	0.023 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



