



Solvipurity

ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00259

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

## CERTIFICATE OF ANALYSIS

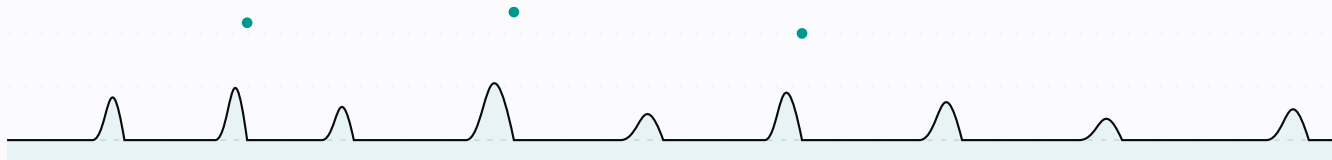


AUTHENTIC

# Anapolon 25mg

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

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



## BATCH NO.

BJRN-20F5DRX

## 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

2026-01-24

## EXPIRY

2028-05-24

## RECEIVED

2026-03-16

## RELEASE

2026-03-16

## DECLARED COMPOSITION

Oxymetholone 25 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	224 mg	1 mg	213–235 mg	Ph. Eur. 2.9.5
● Identification — HPLC retention time	Matches reference	–	±2.0 % of ref	HPLC-UV
● Oxymetholone (assay)	25.14 mg/tab 100.56 %	0.05 %	95.0–105.0 %	HPLC-UV
● Uniformity of dosage units (AV)	AV = 3.4	–	AV ≤ 15.0	Ph. Eur. 2.9.40

+ SOLVIPURITY · CERTIFICATE		2 % Q ≥ 80 % at 30 min		Ph. Eur. 2.9.3 (paddle)
● <b>issolution (Q at 30 min)</b>	<b>93.6 %</b>			
● Mestanolone (specified impurity)	<b>0.094 %</b>	0.03 %	≤ 0.30 %	HPLC-UV
● Any unspecified impurity	<b>&lt; 0.08 %</b>	0.03 %	≤ 0.20 %	HPLC-UV
● Total impurities	<b>0.204 %</b>	0.05 %	≤ 1.00 %	HPLC-UV
● Water content (Karl Fischer)	<b>2.57 %</b>	0.1 %	≤ 5.0 %	Ph. Eur. 2.5.32
● Residual methanol	<b>96 ppm</b>	10 ppm	≤ 3 000 ppm (ICH Q3C Class 2)	GC-MS
● Residual ethanol	<b>118 ppm</b>	10 ppm	≤ 5 000 ppm (ICH Q3C Class 3)	GC-MS
● Lead (Pb)	<b>0.103 ppm</b>	0.02 ppm	≤ 0.5 ppm (ICH Q3D oral)	ICP-MS
● Cadmium (Cd)	<b>0.132 ppm</b>	0.01 ppm	≤ 0.5 ppm	ICP-MS
● Mercury (Hg)	<b>0.0072 ppm</b>	0.005 ppm	≤ 0.3 ppm	ICP-MS
● Arsenic (As)	<b>0.101 ppm</b>	0.01 ppm	≤ 1.5 ppm	ICP-MS
● TAMC (aerobic bacteria)	<b>&lt; 10 CFU/g</b>	10 CFU/g	≤ 10 <sup>3</sup> CFU/g	Ph. Eur. 2.6.12
● TYMC (yeast / molds)	<b>&lt; 10 CFU/g</b>	10 CFU/g	≤ 10 <sup>2</sup> CFU/g	Ph. Eur. 2.6.12
● Absence of E. coli (1 g)	<b>Complies</b>	–	Absence in 1 g	Ph. Eur. 2.6.13



