

**Solvipurity**

ANALYTICAL LABORATORY · REYKJAVÍK, IS

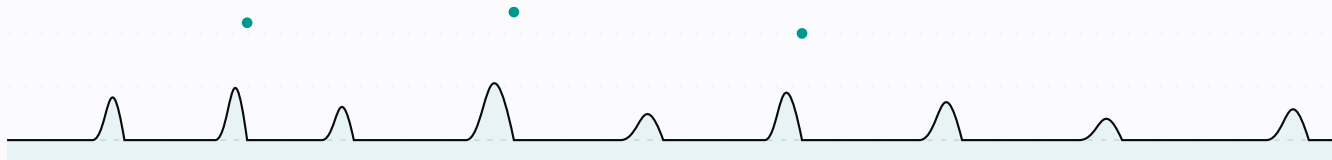
**SVP-2026-00273**ISSUED 2026-03-16 · ACCREDITATION AL-1142  
ISO/IEC 17025 · GMP · GLP

## CERTIFICATE OF ANALYSIS

**AUTHENTIC****S-23 10mg**

Björn Healthcare ehf. · DPE bottle, 60 capsules, induction-sealed, with desiccant

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



## BATCH NO.

BJRN-20TWBTF

## 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

2026-06-12

## EXPIRY

2028-10-12

## RECEIVED

2026-03-16

## RELEASE

2026-03-16

## DECLARED COMPOSITION

S-23 10 mg per capsule

*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>218 mg</b>	1 mg	207–229 mg	Ph. Eur. 2.9.5
● Identification — HPLC retention time	<b>Matches reference</b>	–	±2.0 % of ref	HPLC-UV
● S-23 (assay)	<b>10.15 mg/tab</b> 101.55 %	0.05 %	95.0–105.0 %	HPLC-UV
● Uniformity of dosage units (AV)	<b>AV = 4.8</b>	–	AV ≤ 15.0	Ph. Eur. 2.9.40

●	issolution (Q at 30 min)	93.3 %	2 % Q ≥ 80 % at 30 min	Ph. Eur. 2.9.3 (paddle)
●	S-23 des-cyano (specified impurity)	0.082 %	0.03 % ≤ 0.30 %	HPLC-UV
●	Any unspecified impurity	< 0.08 %	0.03 % ≤ 0.20 %	HPLC-UV
●	Total impurities	0.200 %	0.05 % ≤ 1.00 %	HPLC-UV
●	Water content (Karl Fischer)	2.05 %	0.1 % ≤ 5.0 %	Ph. Eur. 2.5.32
●	Residual methanol	284 ppm	10 ppm ≤ 3 000 ppm (ICH Q3C Class 2)	GC-MS
●	Residual ethanol	267 ppm	10 ppm ≤ 5 000 ppm (ICH Q3C Class 3)	GC-MS
●	Lead (Pb)	0.142 ppm	0.02 ppm ≤ 0.5 ppm (ICH Q3D oral)	ICP-MS
●	Cadmium (Cd)	0.048 ppm	0.01 ppm ≤ 0.5 ppm	ICP-MS
●	Mercury (Hg)	0.0280 ppm	0.005 ppm ≤ 0.3 ppm	ICP-MS
●	Arsenic (As)	0.055 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



