



Solvipurity

ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00272

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

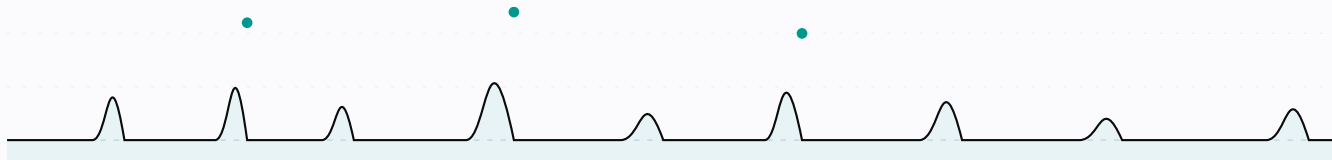
CERTIFICATE OF ANALYSIS

AUTHENTIC

Stenabolic SR-9009 20mg

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

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



BATCH NO.

BJRN-20F3CKQ

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

2026-04-28

EXPIRY

2028-08-28

RECEIVED

2026-03-16

RELEASE

2026-03-16

DECLARED COMPOSITION

Stenabolic (SR-9009) 20 mg per capsule

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
Stenabolic (SR-9009) (assay)	20.09 mg/tab 100.43 %	0.05 %	95.0–105.0 %	HPLC-UV
Uniformity of dosage units (AV)	AV = 7.0	–	AV ≤ 15.0	Ph. Eur. 2.9.40

● dissolution (Q at 30 min)		95.4 %	2 % Q ≥ 80 % at 30 min		Ph. Eur. 2.9.3 (paddle)
+ SOLVIPURITY · CERTIFICATE SVP-2026-00272 +					
● SR-9009 des-chloro (specified impurity)	0.086 %	0.03 %	≤ 0.30 %		HPLC-UV
● Any unspecified impurity	< 0.08 %	0.03 %	≤ 0.20 %		HPLC-UV
● Total impurities	0.278 %	0.05 %	≤ 1.00 %		HPLC-UV
● Water content (Karl Fischer)	2.09 %	0.1 %	≤ 5.0 %		Ph. Eur. 2.5.32
● Residual methanol	119 ppm	10 ppm	≤ 3 000 ppm (ICH Q3C Class 2)		GC-MS
● Residual ethanol	317 ppm	10 ppm	≤ 5 000 ppm (ICH Q3C Class 3)		GC-MS
● Lead (Pb)	0.146 ppm	0.02 ppm	≤ 0.5 ppm (ICH Q3D oral)		ICP-MS
● Cadmium (Cd)	0.115 ppm	0.01 ppm	≤ 0.5 ppm		ICP-MS
● Mercury (Hg)	0.0154 ppm	0.005 ppm	≤ 0.3 ppm		ICP-MS
● Arsenic (As)	0.060 ppm	0.01 ppm	≤ 1.5 ppm		ICP-MS
● TAMC (aerobic bacteria)	< 10 CFU/g	10 CFU/g	≤ 10 ³ CFU/g		Ph. Eur. 2.6.12
● TYMC (yeast / molds)	< 10 CFU/g	10 CFU/g	≤ 10 ² CFU/g		Ph. Eur. 2.6.12
● Absence of E. coli (1 g)	Complies	–	Absence in 1 g		Ph. Eur. 2.6.13

