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ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00270
ISSUED 2026-03-16 · ACCREDITATION AL-1142
ISO/IEC 17025 · GMP · GLP

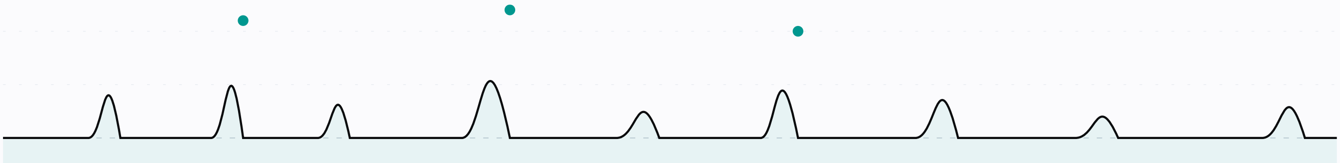
CERTIFICATE OF ANALYSIS

YK-11 Myostine 8mg

AUTHENTIC

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

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



BATCH NO.
BJRN-2059LNQ

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
2026-01-30

EXPIRY
2028-05-30

RECEIVED
2026-03-16

RELEASE
2026-03-16

DECLARED COMPOSITION
YK-11 (Myostine) 8 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	**178 mg**	1 mg	169–187 mg	Ph. Eur. 2.9.5
Identification — HPLC retention time	**Matches reference**	—	±2.0 % of ref	HPLC-UV
K-11 (Myostine) (assay)	**7.96 mg/tab** 99.51 %	0.05 %	95.0–105.0 %	HPLC-UV
Uniformity of dosage units (AV)	**AV = 2.3**	—	AV ≤ 15.0	Ph. Eur. 2.9.40

issolution (Q at 30 min)	**96.5 %**	2 %	Q ≥ 80 % at 30 min	Ph. Eur. 2.9.3 (paddle)
K-11 dihydro (specified impurity)	**0.062 %**	0.03 %	≤ 0.30 %	HPLC-UV
Any unspecified impurity	**< 0.08 %**	0.03 %	≤ 0.20 %	HPLC-UV
Total impurities	**0.222 %**	0.05 %	≤ 1.00 %	HPLC-UV
Water content (Karl Fischer)	**2.40 %**	0.1 %	≤ 5.0 %	Ph. Eur. 2.5.32
Residual methanol	**242 ppm**	10 ppm	≤ 3 000 ppm (ICH Q3C Class 2)	GC-MS
Residual ethanol	**349 ppm**	10 ppm	≤ 5 000 ppm (ICH Q3C Class 3)	GC-MS
Lead (Pb)	**0.160 ppm**	0.02 ppm	≤ 0.5 ppm (ICH Q3D oral)	ICP-MS
Cadmium (Cd)	**0.094 ppm**	0.01 ppm	≤ 0.5 ppm	ICP-MS
Mercury (Hg)	**0.0064 ppm**	0.005 ppm	≤ 0.3 ppm	ICP-MS
Arsenic (As)	**0.039 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

INDEPENDENT VERIFICATION

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VERIFICATION CODE

ANALYST
dr Sigurður Pálsson
Senior chemist

INDEPENDENT REVIEWER
dr Helga Thorgeirsdottir
Quality assurance · AL-1142

SHA-256 CHECKSUM
0-x8e2f10e927a857ef8e2f10e927a857ef8e2f10e927a857ef
Tamper-evident digest

NOTICE · CONDITIONS OF THIS REPORT

This certificate of analysis applies exclusively to the sample received and described above. It does not constitute approval, endorsement or certification of the product or its intended use. Results were obtained under ISO/IEC 17025 accredited methods by Solvipurity ehf. (accreditation AL-1142). Reproduction of this document in part is prohibited — only the full, verified copy may be shared. If the data printed here does not match the online record at solvipurity.com/verify, the document should be considered invalid.

SAMPLE RETENTION
Sealed aliquot retained for 24 months from issue date under controlled conditions (Ph. Eur. 5.1, −20 °C).

DISPUTE WINDOW
Requests for re-testing accepted within 30 days of report publication. Contact lab@solvipurity.com quoting the report number.

SOLVIPURITY EHF. · BORGARTÚN 30, 105 REYKJAVÍK, ICELAND · LAB@SOLVIPURITY.COM · +354 540 3200
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