

**Solvipurity**

ANALYTICAL LABORATORY · REYKJAVÍK, IS

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ISO/IEC 17025 · GMP · GLP

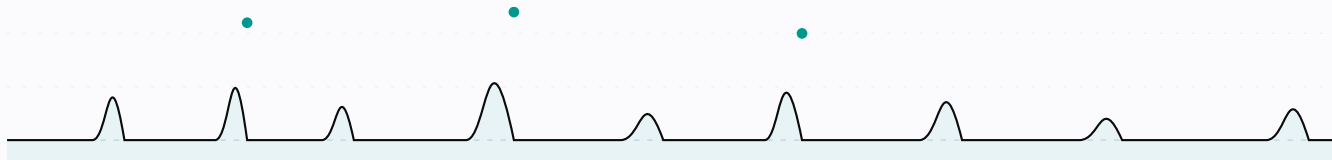
CERTIFICATE OF ANALYSIS

AUTHENTIC

MK-677 Ibutamoren 25mg

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

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



BATCH NO.

BJRN-20T63BP

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

2026-03-14

EXPIRY

2028-07-14

RECEIVED

2026-03-16

RELEASE

2026-03-16

DECLARED COMPOSITION

MK-677 (Ibutamoren) 25 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	218 mg	1 mg	207–229 mg	Ph. Eur. 2.9.5
Identification — HPLC retention time	Matches reference	–	±2.0 % of ref	HPLC-UV
K-677 (Ibutamoren) (assay)	24.67 mg/tab 98.69 %	0.05 %	95.0–105.0 %	HPLC-UV
Uniformity of dosage units (AV)	AV = 4.0	–	AV ≤ 15.0	Ph. Eur. 2.9.40

●	issolution (Q at 30 min)	94.5 %	2 % Q ≥ 80 % at 30 min	Ph. Eur. 2.9.3 (paddle)
●	K-677 sulfoxide (specified impurity)	0.055 %	0.03 % ≤ 0.30 %	HPLC-UV
●	Any unspecified impurity	< 0.08 %	0.03 % ≤ 0.20 %	HPLC-UV
●	Total impurities	0.135 %	0.05 % ≤ 1.00 %	HPLC-UV
●	Water content (Karl Fischer)	3.14 %	0.1 % ≤ 5.0 %	Ph. Eur. 2.5.32
●	Residual methanol	190 ppm	10 ppm ≤ 3 000 ppm (ICH Q3C Class 2)	GC-MS
●	Residual ethanol	375 ppm	10 ppm ≤ 5 000 ppm (ICH Q3C Class 3)	GC-MS
●	Lead (Pb)	0.171 ppm	0.02 ppm ≤ 0.5 ppm (ICH Q3D oral)	ICP-MS
●	Cadmium (Cd)	0.118 ppm	0.01 ppm ≤ 0.5 ppm	ICP-MS
●	Mercury (Hg)	0.0368 ppm	0.005 ppm ≤ 0.3 ppm	ICP-MS
●	Arsenic (As)	0.110 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

