Solvipurity
ANALYTICAL LABORATORY · REYKJAVÍK, IS

SVP-2026-00264
ISSUED 2026-03-16 · ACCREDITATION AL-1142
ISO/IEC 17025 · GMP · GLP

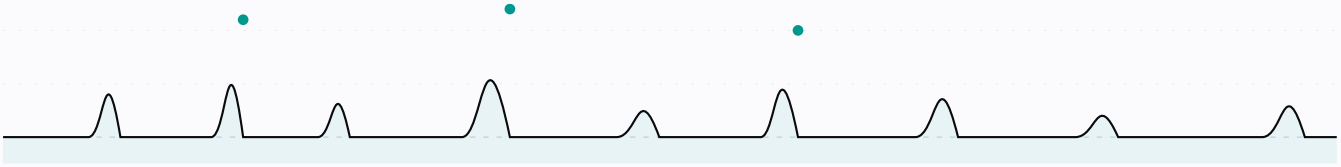
CERTIFICATE OF ANALYSIS

AUTHENTIC

Exemestane 20mg

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

REPRESENTATIVE CHROMATOGRAM · HPLC-UV 205 NM



BATCH NO.
BJRN-20P575X

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
2026-05-01

EXPIRY
2028-09-01

RECEIVED
2026-03-16

RELEASE
2026-03-16

DECLARED COMPOSITION
Exemestane 20 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	**185 mg**	1 mg	176–194 mg	Ph. Eur. 2.9.5
Identification — HPLC retention time	**Matches reference**	—	±2.0 % of ref	HPLC-UV
Exemestane (assay)	**19.91 mg/tab** 99.54 %	0.05 %	95.0–105.0 %	HPLC-UV
Uniformity of dosage units (AV)	**AV = 3.4**	—	AV ≤ 15.0	Ph. Eur. 2.9.40

issolution (Q at 30 min)	**92.6 %**	2 %	Q ≥ 80 % at 30 min	Ph. Eur. 2.9.3 (paddle)
Exemestane 17-β-dihydro (specified impurity)	**0.169 %**	0.03 %	≤ 0.30 %	HPLC-UV
Any unspecified impurity	**< 0.08 %**	0.03 %	≤ 0.20 %	HPLC-UV
Total impurities	**0.382 %**	0.05 %	≤ 1.00 %	HPLC-UV
Water content (Karl Fischer)	**1.67 %**	0.1 %	≤ 5.0 %	Ph. Eur. 2.5.32
Residual methanol	**227 ppm**	10 ppm	≤ 3 000 ppm (ICH Q3C Class 2)	GC-MS
Residual ethanol	**392 ppm**	10 ppm	≤ 5 000 ppm (ICH Q3C Class 3)	GC-MS
Lead (Pb)	**0.094 ppm**	0.02 ppm	≤ 0.5 ppm (ICH Q3D oral)	ICP-MS
Cadmium (Cd)	**0.119 ppm**	0.01 ppm	≤ 0.5 ppm	ICP-MS
Mercury (Hg)	**0.0105 ppm**	0.005 ppm	≤ 0.3 ppm	ICP-MS
Arsenic (As)	**0.089 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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FMCGZW

VERIFICATION CODE

ANALYST
mgr Ingrid Dahl
Senior chemist

INDEPENDENT REVIEWER
dr Helga Thorgeirsdottir
Quality assurance · AL-1142

SHA-256 CHECKSUM
0-x6a147dec925dca386a147dec925dca386a147dec925dca38
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.