



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Betablock XL-AM	A.R. No.	FG/G/24A1060
Generic Name	Amlodipine Besilate & Metoprolol Succinate (ER) Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT40706	Sample Received on	24/07/2024
Batch Size:	1.0 Lac	Analysis Date	24/07/2024
Mfg. Date.	07/2024	Release Date	31/07/2024
Exp. Date	06/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	White and yellow colour, round shaped, biconvex, having both side plain, film coated bilayered tablet.	White and yellow colour, round shaped, biconvex, having both side plain, film coated bilayered tablet.
2.	Identification	In the assay, the retention time of the principal peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with the reference solution.	Complies
3.	Average weight	305.00 mg $\pm$ 3%	306.255 mg
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 302.78 mg ; Max: 312.10 mg -1.13% ; + 1.91%
5.	Hardness	Not less than 4.0 Kg/cm ²	9.92 Kg/cm ²
6.	Dissolution (Metoprolol Succinate) :		
	1 st Hour:	Not more than 25.0%	Minimum = 10.52% Maximum = 13.47% Average = 12.72%
	4 th Hours:	Between 15.0% to 40.0%	Minimum = 29.38% Maximum = 33.84% Average = 32.77%
	8 th Hours:	Between 40.0% to 65.0%	Minimum = 58.45% Maximum = 62.50% Average = 61.34%
	20 th Hours:	Not less than 70.0%	Minimum = 90.51% Maximum = 94.46% Average = 92.12%
	For Amlodipine Besilate	Not less than 70.0% (Q)	Minimum = 84.98% Maximum = 95.19% Average = 90.96%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	31/07/2024	31/07/2024	31/07/2024



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Betablock XL-AM	A.R. No.	FG/G/24A1060
Generic Name	Amlodipine Besilate & Metoprolol Succinate (ER) Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT40706	Sample Received on	24/07/2024
Batch Size:	1.0 Lac	Analysis Date	24/07/2024
Mfg. Date.	07/2024	Release Date	31/07/2024
Exp. Date	06/2026	Page No.:	Page 2 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
7.	Uniformity of content :				
	Amlodipine Besilate	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	6.02		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Amlodipine Besilate IP Eq. to Amlodipine	5 mg	Between 90.0 % to 110.0 % of stated amount Between 4.5 mg to 5.5 mg	4.871 mg	97.42%
	Metoprolol Succinate IP 47.5 mg Eq. to Metoprolol Tartrate (As E.R. form)	50 mg	Between 90.0 % to 110.0 % of stated amount Between 45.0 mg to 55.0 mg	50.406 mg	100.81%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		30 cfu/g	
ii.	Total yeast and mould count	NMT 100 cfu/g		Less than 10 cfu/g	
iii.	Pathogens: Escherichia coli	Should be absent/g		Absent/g	

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head QA
Signature			
Date	31/07/2024	31/07/2024	31/07/2024