



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/24A0234
Generic Name	Amlodipine Besilate & Metoprolol Succinate (ER) Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT40337	Sample Received on	30/03/2024
Batch Size:	1.0 Lac	Analysis Date	30/03/2024
Mfg. Date.	03/2024	Release Date	05/04/2024
Exp. Date	02/2026	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%	305.557 mg
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 298.70 mg ; Max: 309.41 mg -2.24% ; + 1.26%
5.	Hardness	Not less than 4.0 Kg/cm ²	10.4 Kg/cm ²
6.	Dissolution (Metoprolol Succinate) :		
	1 st Hour:	Not more than 25.0%	Minimum = 8.29% Maximum = 10.73% Average = 9.49%
	4 th Hours:	Between 15.0% to 40.0%	Minimum = 24.14% Maximum = 39.32% Average = 29.17%
	8 th Hours:	Between 40.0% to 65.0%	Minimum = 49.09% Maximum = 53.02% Average = 51.44%
	20 th Hours:	Not less than 70.0%	Minimum = 82.06% Maximum = 96.34% Average = 86.13%
	For Amlodipine Besilate	Not less than 70.0% (Q)	Minimum = 89.51% Maximum = 99.41% Average = 95.45%

Particulars	Prepared By	Checked By	Approved By
Name	Braveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	05/04/2024	05/04/2024	05/04/2024



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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)	6.32		
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	5.060 mg	101.20%
	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	48.552 mg	97.10%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		35 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	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	05/04/2024	05/04/2024	05/04/2024