



# ALVENTA PHARMA LIMITED

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

Quality Control Department

## CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Telmafox-AM	A.R. No.	FG/G/24A1032
Generic Name	Telmisartan and Amlodipine Tablets IP	Sample Quantity	60 Tablets
Batch No.:	AGT40653B	Sample Received on	15/07/2024
Batch Size:	1.0 Lac	Analysis Date	15/07/2024
Mfg. Date.	06/2024	Release Date	25/07/2024
Exp. Date	05/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White and sky blue coloured, round shaped biconvex, both side plain, uncoated bilayered tablet.	White and sky blue coloured, round shaped biconvex, both side plain, uncoated bilayered tablet.		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution (c).	Complies		
3.	Average weight	300.0 mg $\pm$ 3%	303.844 mg		
4.	Uniformity of weight	$\pm$ 5.0% of its average weight.	Min: 301.23 mg ; Max: 308.56 mg -0.86% ; +1.55%		
5.	Disintegration	Not more than 15 minutes.	03 minutes 55 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm <sup>2</sup>	5.92 Kg/cm <sup>2</sup>		
7.	Friability	Not more than 1.0% w/w	0.27 % w/w		
8.	Uniformity of content (For Amlodipine Besylate)	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	4.17		
9.	Dissolution:				
	For Telmisartan	Not less than 80.0% (Q)	Minimum = 85.45% Maximum = 95.85% Average = 90.57%		
	For Amlodipine Besylate	Not less than 80.0% (Q)	Minimum = 86.52% Maximum = 105.65% Average = 95.58%		
10.	Assay :				
	Each uncoated bilayered tablet contains:	Claim	Limit	mg	%
	Telmisartan IP	40 mg	Between 90.0% to 110.0% (Between 36.0 mg to 44.0 mg)	39.663 mg	99.16%
	Amlodipine Besylate IP eq. to Amlodipine	5 mg	Between 90.0% to 110.0% (Between 4.5 mg to 5.5 mg)	4.9447 mg	98.89%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	DURGESH KUMAR	Gaunthan Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	25/07/2024	25/07/2024	25/07/2024



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11.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	50 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	Nautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	25/07/2024	25/07/2024	25/07/2024