

## **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-40	A.R. No.	FG/G/24A0965 60 Tablets 01/07/2024	
Generic Name	Telmisartan Tablets IP 40 mg	Sample Quantity		
Batch No.:	AGT40647A	Sample Received on		
Batch Size:	1.0 Lac	Analysis Date	01/07/2024	
Mfg. Date.	06/2024	Release Date	10/07/2024	
Exp. Date	05/2026	Page No.:	Page 1 of 1	

Sr. No.	Test Parameter		Acceptance Criteria			Result			
1.	Description		White colour, round shaped, biconvex, having both side plain, uncoated tablet.			White colour, round shaped, biconver having both side plain, uncoated table			
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.				Complies			
3.	Average weight	300.00 mg ± 3%			300.058 mg				
4.	Uniformity of weight	± 5.0% of its average weight.			Min: 294.38 mg ; Max: 307.50 mg -1.89% ; +2.48%				
5.	Disintegration	Not more than 15 minutes.			02 minutes 46 seconds.				
6.	Hardness	Not less than 4.0 Kg/cm <sup>2</sup>			6.25 Kg/cm <sup>2</sup>				
7.	Friability	Not more than 1.0% w/w			0.24 %w/w				
8.	Dissolution	Not less than 75.0% (Q)			Minimum = 85.80% Maximum = 90.22% Average = 87.47%				
9.	Assay:								
	Each uncoated tablet contains:		Claim		Limit		mg	%	
	Telmisartan IP 4		40 m	ıg	Between 90.0 % to 110.0 % of labeled amount. (Between 36.0 mg to 44.0 mg)		39.893 mg	99.73 %	
10.	<b>Microbial Limit Tests:</b>								
i.	Total aerobic microbial count			NMT 1000 cfu/g		45 cfu/g			
ii.	Total yeast and mould count			NMT 100 cfu/g			Less than 10 cfu/g		
iii.	Pathogens: Escherichia	nia coli Should be absent/g			ould 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	Braveen Kumar	DURGESH KUMAR	Chautgan singh
Designation	Executive	BG Heerd	Hoad-8A
Signature	A	AL.	4
Date	10/07/224	10/07/2024	10/07/2024

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