



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/24A0058
Generic Name	Telmisartan Tablets IP 40 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40127	Sample Received on	20/01/2024
Batch Size:	1.0 Lac	Analysis Date	20/01/2024
Mfg. Date.	01/2024	Release Date	25/01/2024
Exp. Date	12/2025	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, biconvex, having both side plain, uncoated 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.	Complies		
3.	Average weight	300 mg \pm 3%	302.999 mg		
4.	Uniformity of weight	\pm 5.0% of its average weight.	Min: 293.88 mg ; Max: 309.14 mg -3.01% ; +2.03%		
5.	Disintegration	Not more than 15 minutes.	02 minutes 20 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	6.17 Kg/cm ²		
7.	Friability	Not more than 1.0%w/w	0.42 %w/w		
8.	Dissolution	Not less than 75.0% (Q)	Minimum = 82.76% Maximum = 91.71% Average = 86.59%		
9.	Assay:				
	Each uncoated tablet contains:	Claim	Limit	mg	%
	Telmisartan IP	40 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 36.0 mg to 44.0 mg)	41.139 mg	102.85 %
10.	Microbial Limit Tests:				
i.	Total aerobic microbial count		NMT 1000 cfu/g	20 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	Braveen Kumar	Tanvej	Shashi Kumar
Designation	Executive	Sr. Executive	Manager-QA
Signature			
Date	25/01/2024	25/01/2024	25/01/2024