



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Telmaheal-80	A.R. No.	FG/G/24A1576
Generic Name	Telmisartan Tablets IP 80 mg	Sample Quantity	90 Tablets
Batch No.:	AGT41139	Sample Received on	27/11/2024
Batch Size:	1.50 Lac	Analysis Date	27/11/2024
Mfg. Date.	11/2024	Release Date	NA
Exp. Date	10/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Brick red colour, round shaped, biconvex, having both side plain, uncoated tablet.	Brick red 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	300.00 mg $\pm$ 3%	302.44 mg		
4.	Uniformity of weight	$\pm$ 5.0% of its average weight.	Min: 293.48 mg ; Max: 308.74 mg -3.05% ; +2.08%		
5.	Disintegration	Not more than 15 minutes.	04 minutes 24 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	6.75 Kg/cm ²		
7.	Friability	Not more than 1.0%w/w	0.66 %w/w		
8.	Dissolution	Not less than 75.0% (Q) of the labeled amount is dissolved in 30 minutes.	Minimum = 90.40% Maximum = 92.61% Average = 91.54%		
9.	Assay:				
	Each uncoated tablet contains:	Claim	Limit	mg	%
	Telmisartan IP	80 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 72.0 mg to 88.0 mg)	81.808 mg	102.26 %
10.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g			Under test
ii.	Total yeast and mould count	NMT 100 cfu/g			Under test
iii.	Pathogens: Escherichia coli	Should be absent/g			Under test

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	Kuljeet Kaur	Kavita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	27/11/2024	27/11/2024	27/11/2024