



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 CT 12.5	A.R. No.	FG/G/24A1179
Generic Name	Telmisartan and Chlorthalidone Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT40772	Sample Received on	22/08/2024
Batch Size:	1.50 Lac	Analysis Date	22/08/2024
Mfg. Date.	07/2024	Release Date	27/08/2024
Exp. Date	06/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White and orange coloured, round shaped, biconvex, both side plain, uncoated bilayered tablet.	White and orange 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 standard solution.	Complies		
3.	Average weight	300.0 mg ± 3%	302.45 mg		
4.	Uniformity of weight	± 5.0% of its average weight.	Min: 295.17 mg ; Max: 307.29 mg -2.41% ; +1.60%		
5.	Disintegration	Not more than 15 minutes.	05 minutes 45 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	6.25 Kg/cm ²		
7.	Friability	Not more than 1.0%w/w	0.32 %w/w		
8.	Uniformity of content (For Chlorthalidone)	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	6.23		
9.	Assay :				
	Each uncoated Bilayered tablet contains:	Claim	Limit	mg	%
	Telmisartan IP	40 mg	Between 90.00% to 110.00% (Between 36.00 mg to 44.00 mg)	39.98 mg	99.95%
	Chlorthalidone IP	12.5 mg	Between 90.00% to 110.00% (Between 11.25 mg to 13.75 mg)	12.42 mg	99.40%
10.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		40 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	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-GA
Signature			
Date	22/08/2024	27/08/2024	27/08/2024