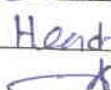


Quality Control Department
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Telmaheal 40-AMH	A.R. No.	FG/G/24A0413
Generic Name	Telmisartan, Amlodipine and Hydrochlorothiazide Tablets	Sample Quantity	90 Tablets
Batch No.:	AGT40503	Sample Received on	22/05/2024
Batch Size:	1.50 Lac	Analysis Date	22/05/2024
Mfg. Date.	05/2024	Release Date	27/05/2024
Exp. Date	04/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	White and blue coloured, round shaped, biconvex, both side plain, uncoated bilayered tablet.	White and 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.	Complies
3.	Average weight	300.00 mg $\pm$ 3%	308.064 mg
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 299.92 mg ; Max: 313.20 mg -2.64% ; +1.67%
5.	Disintegration	Not more than 15 minutes.	04 minutes 42 seconds.
6.	Hardness	Not less than 4.0 Kg/cm ²	6.08 Kg/cm ²
7.	Friability	Not more than 1.0% w/w	0.27 % w/w
8.	Uniformity of content:		
	For Amlodipine	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	5.95
	For Hydrochlorothiazide	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	7.73
9.	Assay :		
	Each uncoated bilayered tablet contains:	Claim	Limit
	Telmisartan IP	40 mg	Between 90.0% to 110.0% (Between 36.0 mg to 44.0 mg)
	Amlodipine Besylate IP Eq. to Amlodipine	5 mg	Between 90.0% to 110.0% (Between 4.5 mg to 5.5 mg)
	Hydrochlorothiazide IP	12.5 mg	Between 90.0% to 110.0% (Between 11.25 mg to 13.75 mg)
			mg
			%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head QA
Signature			
Date	27/05/2024	27/05/2024	27/05/2024



ALVENTA PHARMA LIMITED

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

Quality Control Department

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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	Braveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	27/05/2024	27/05/2024	27/05/2024