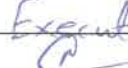


Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Telmaheal 40-AMH	A.R. No.	FG/G/24A1090
Generic Name	Telmisartan, Amlodipine and Hydrochlorothiazide Tablets	Sample Quantity	90 Tablets
Batch No.:	AGT40776	Sample Received on	31/07/2024
Batch Size:	1.50 Lac	Analysis Date	31/07/2024
Mfg. Date.	07/2024	Release Date	08/08/2024
Exp. Date	06/2026	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 ± 3%	298.87 mg		
4.	Uniformity of weight	± 5% of its average weight.	Min: 284.26 mg ; Max: 307.16 mg -4.89% ; +2.77%		
5.	Disintegration	Not more than 15 minutes.	10 minutes 30 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	4.58 Kg/cm ²		
7.	Friability	Not more than 1.0% w/w	0.06 % 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)	2.39		
	For Hydrochlorothiazide	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	3.73		
9.	Assay :				
	Each uncoated bilayered tablet contains:	Claim	Limit	mg	%
	Telmisartan IP	40 mg	Between 90.0% to 110.0% (Between 36.0 mg to 44.0 mg)	39.6177 mg	99.04%
	Amlodipine Besylate IP Eq. to Amlodipine	5 mg	Between 90.0% to 110.0% (Between 4.5 mg to 5.5 mg)	4.9234 mg	98.47%
	Hydrochlorothiazide IP	12.5 mg	Between 90.0% to 110.0% (Between 11.25 mg to 13.75 mg)	12.1373 mg	97.10%

Particulars	Prepared By	Checked By	Approved By
Name	Harveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	08/08/2024	08/08/2024	08/08/2024



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 40-AMH	A.R. No.	FG/G/24A1090
Generic Name	Telmisartan, Amlodipine and Hydrochlorothiazide Tablets	Sample Quantity	90 Tablets
Batch No.:	AGT40776	Sample Received on	31/07/2024
Batch Size:	1.50 Lac	Analysis Date	31/07/2024
Mfg. Date.	07/2024	Release Date	08/08/2024
Exp. Date	06/2026	Page No.:	Page 2 of 2

10.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	50 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	DURGESH KUMAR	Gaurav Singh
Designation	Executive	Q.C. Head	Head-QA
Signature			
Date	08/08/2024	08/08/2024	08/08/2024