



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-AM	A.R. No.	FG/G/24A0019
Generic Name	Telmisartan and Amlodipine Tablets IP	Sample Quantity	60 Tablets
Batch No.:	AGT31254	Sample Received on	05/01/2024
Batch Size:	1.50 Lac	Analysis Date	05/01/2024
Mfg. Date.	12/2023	Release Date	12/01/2024
Exp. Date	11/2025	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White and sky blue coloured, round shaped biconvex, both side plain, uncoated bilayered tablet.	White and sky blue coloured, round shaped biconvex, both side plain, uncoated bilayered tablet.		
2.	Identification (By HPLC)	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 (c).	Complies		
3.	Average weight	300.0 mg ± 3%	301.326 mg		
4.	Uniformity of weight	± 5.0% of its average weight.	Min: 297.02 mg ; Max: 305.53 mg -1.42% ; +1.40%		
5.	Disintegration	Not more than 15 minutes.	05 minutes 20 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	7.13 Kg/cm ²		
7.	Friability	Not more than 1.0% w/w	0.48 % w/w		
8.	Uniformity of content (For Amlodipine Besylate)	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	4.73		
9.	Dissolution:				
	For Telmisartan	Not less than 80.0% (Q)	Minimum = 90.16% Maximum = 100.40% Average = 95.06%		
	For Amlodipine Besylate	Not less than 80.0% (Q)	Minimum = 93.27% Maximum = 105.03% Average = 98.82%		
10.	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)	39.5665 mg	98.92%
	Amlodipine Besylate IP eq. to Amlodipine	5 mg	Between 90.0% to 110.0% (Between 4.5 mg to 5.5 mg)	5.0645 mg	101.29%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Tanvej	Gaurav Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	12/01/2024	12/01/2024	12/01/2024



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11.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	30 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	Gaurang Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	12/01/2024	12/01/2024	12/01/2024