



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 Beta-25	A.R. No.	FG/G/24A1610
Generic Name	Telmisartan & Metoprolol Succinate (E.R.) Tablets	Sample Quantity	80 Tablets
Batch No.:	AGT41140	Sample Received on	04/12/2024
Batch Size:	2.0 Lac	Analysis Date	04/12/2024
Mfg. Date.	11/2024	Release Date	10/12/2024
Exp. Date	10/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Brick red and white colour, round shaped, biconvex, having both side plain, uncoated bilayered tablet.	Brick red and white colour, round shaped, biconvex, having both side plain, uncoated bilayered tablet.		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution should be corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	Average weight	340.00 mg ± 5.0%.	338.20 mg		
4.	Uniformity of weight	± 5% of its average weight.	Min: 325.43 mg ; Max: 346.39 mg -3.78% ; +2.42%		
5.	Hardness	Not less than 4.0 Kg/cm ²	8.58 Kg/cm ²		
6.	Friability	NMT 1.0 %w/w	0.11%w/w		
7.	Dissolution				
	1 st Hour	Not more than 25.00 %	Minimum = 10.26% Maximum = 13.59% Average = 12.48%		
	4 th Hours	Between 15.00 % to 60.00 %	Minimum = 34.57% Maximum = 46.54% Average = 41.30%		
	10 th Hours	Not less than 70.00 %	Minimum = 72.58% Maximum = 85.72% Average = 80.69%		
8.	Assay:				
	Each uncoated bilayered tablet contains:	Claim	Limit	mg	%
	Telmisartan IP	40 mg	Between 90.00 % to 110.00 % of labeled amount. (Between 36.00 mg to 44.00 mg)	38.766 mg	96.92%
	Metoprolol Succinate IP 23.75 mg Eq. to Metoprolol Tartrate (As extended Release form)	25 mg	Between 90.00 % to 110.00 % of labeled amount. (Between 22.50 mg to 27.50 mg)	24.312 mg	97.25%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kuljeet Kaur	Kavita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	10/12/2024	10/12/2024	10/12/2024



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Sr. No.	Test Parameter	Acceptance Criteria	Result
9.	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	Kuljeet Kaur	Kavita Nandwani
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Signature			
Date	10/12/2024	10/12/2024	10/12/2024