ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Telmafox-H	**A.R. No.**	FG/G/24A0144
Generic Name	Telmisartan and Hydrochlorothiazide Tablets IP	**Sample Quantity**	60 Tablets
Batch No.:	AGT40164	**Sample Received on**	24/02/2024
Batch Size:	1.0 Lac	**Analysis Date**	24/02/2024
Mfg. Date.	01/2024	**Release Date**	02/03/2024
Exp. Date	12/2025	**Page No.:**	Page 1 of 2

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 reference solution.	Complies
3.	**Average weight**	265.00 mg ± 3%	264.918 mg
4.	**Uniformity of weight**	± 5.0% of its average weight.	Min: 261.67 mg ; Max: 266.60 mg -1.22% ; + 0.63%
5.	**Disintegration**	Not more than 15 minutes.	05 minutes 06 seconds.
6.	**Hardness**	Not less than 4.0 Kg/cm^2	10.3 Kg/cm^2
7.	**Friability**	Not more than 1.0%w/w	0.30 %w/w
8.	**Dissolution:**		
	For Telmisartan	Not less than 80.00% (Q)	Minimum = 86.38 % Maximum = 100.71 % Average = 93.94 %
	For Hydrochlorothiazide	Not less than 80.00% (Q)	Minimum = 93.93 % Maximum = 105.18 % Average = 99.99 %
9.	**Uniformity of content (Hydrochlorothiazide)**	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	11.04
10.	**Assay :**		

Each uncoated bilayered tablet contains:	**Claim**	**Limit**	**mg**	**%**
Telmisartan IP	**40 mg**	Between 95.00% to 105.00% Between 38.00 mg to 42.00 mg	39.46 mg	98.66%
Hydrochlorothiazide IP	**12.5 mg**	Between 90.00% to 107.50% Between 11.25 mg to 13.44 mg	12.23 mg	97.88%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	02/03/2024	02/03/2024	02/08/2024

Format No.: SOP/QC/029/F02-01

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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	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	02/03/2024	02/03/2024	02/03/2024