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-AM	**A.R. No.**	FG/G/24A0089
Generic Name	Telmisartan and Amlodipine Tablets IP	**Sample Quantity**	60 Tablets
Batch No.:	AGT40165	**Sample Received on**	02/02/2024
Batch Size:	1.0 Lac	**Analysis Date**	02/02/2024
Mfg. Date.	01/2024	**Release Date**	09/02/2024
Exp. Date	12/2025	**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**	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%	303.480 mg
4.	**Uniformity of weight**	± 5.0% of its average weight.	Min: 298.87 mg ; Max: 306.67 mg -1.52% ; +1.05%
5.	**Disintegration**	Not more than 15 minutes.	03 minutes 42 seconds.
6.	**Hardness**	Not less than 4.0 Kg/cm^2	5.13 Kg/cm^2
7.	**Friability**	Not more than 1.0% w/w	0.15 % 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)	3.95
9.	**Dissolution:**		
	For Telmisartan	Not less than 80.0% (Q)	Minimum = 90.17% Maximum = 101.74% Average = 96.21%
	For Amlodipine Besylate	Not less than 80.0% (Q)	Minimum = 93.42% Maximum = 100.50% Average = 97.23%
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)	38.967 mg	97.42%
Amlodipine Besylate IP eq. to Amlodipine	**5 mg**	Between 90.0% to 110.0% (Between 4.5 mg to 5.5 mg)	4.8919 mg	97.84%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	09/02/2024	09/02/2024	09/02/2024

ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Telmafox-AM	**A.R. No.**	FG/G/24A0089
Generic Name	Telmisartan and Amlodipine Tablets IP	**Sample Quantity**	60 Tablets
Batch No.:	AGT40165	**Sample Received on**	02/02/2024
Batch Size:	1.0 Lac	**Analysis Date**	02/02/2024
Mfg. Date.	01/2024	**Release Date**	09/02/2024
Exp. Date	12/2025	**Page No.:**	Page 2 of 2

11.	**Microbial Limit Tests:**		
i.	**Total aerobic microbial count**	NMT 1000 cfu/g	15 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	Gautam singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	09/02/2024	09/02/2024	09/02/2024